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Kathryn Goldberg; Email Received April 6, 2021

Hello,

I would like to make a consideration for the “In Leu of Service “code: S9977: Per Diem. Meals, not otherwise specified.

To read: Per Diem, food prescriptions, not otherwise specified.

This would allow for more flexibility for produce vouchers, CSA boxes etc., then specific prepared meals.

Thank you,

Kathryn Goldberg, RDN

Sent from my iPhone

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UDW The Homecare Providers Union
AFSCME Local 3930 / AFL-CIO

April 8, 2021

Will Lightbourne, Director
California Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

RE: Clarification of CalAIM's In Lieu of Services (ILOS) Benefit

Dear Director Lightbourne,

On behalf of the combined 546,000 In-Home Supportive Services (IHSS) providers we represent and the 641,000 low-income seniors and people with disabilities they care for, SEIU Local 2015 and the UDW/AFSCME Local 3930 is asking DHCS for clarification on CalAIM's optional In Lieu of Services (ILOS) Personal Care and Homemaker Services benefit.

While we support the overarching goals of CalAIM, we have numerous questions about the ILOS personal care and homemaker services benefit and how it will exist alongside and interact with the IHSS program, especially since there seems to be some interdependence on the IHSS program in the provision of the ILOS benefit. Our questions are outlined here:

Consumer choice and access

- Does the ILOS personal care benefit uphold the principle of consumer choice and direction, including the ability for the consumer, i.e., the health plan member, to choose their home care provider and direct their care?
- If a health plan member already has IHSS, would the member be able to select their IHSS provider to deliver the ILOS personal care services should the member want to preserve continuity of care and consumer choice?
- In rural and remote counties, how will the State ensure geographic equity and access to culturally and linguistically competent providers in the delivery of the ILOS personal care and homemaker services benefit?

ILOS provider details

- Are IHSS providers considered allowable providers of ILOS personal care services?
- What is the pathway, if any, for a managed care plan to be able to use IHSS providers to deliver these services?
- Who would pay IHSS providers for these additional hours? Could managed care plans reimburse counties? Would this work be considered part of the IHSS bargaining unit?
- Would the minimum rate of pay for ILOS providers be benchmarked to existing IHSS wages in the county?

- If a member is using an existing IHSS provider to deliver the ILOS services, how would the additional ILOS hours factor into IHSS overtime pay or health insurance eligibility?

ILOS benefit details

- How will DHCS ensure that the ILOS personal care benefit does not duplicate or supplant IHSS services?
- In efforts to improve care delivery and health outcomes, could the ILOS personal care benefit be used to train existing IHSS providers and compensate them for this enhanced level of care?

Managed care plans and IHSS

- Will managed care plans be required to have a Memorandum of Understanding (MOU) in place with the County IHSS Office and Public Authority and what would the MOU cover?
- How will communication, data sharing, and tracking (including referrals and requests for reassessments) between managed care plans and the IHSS program be streamlined, such as between health plan case managers and IHSS social workers? Systematic collaboration and communication between IHSS and managed care plans seems like it would be an important component of administering the ILOS personal care benefit to avoid duplication or replacing of IHSS services.

Tracking and measuring ILOS benefit

- Will DHCS be tracking health plans' uptake of the ILOS personal care benefit and its member utilization?
- Will DHCS be tracking ILOS benefit costs as a whole and each ILOS benefit separately?
- What considerations and metrics will DHCS use to determine their cost effectiveness? Will data on uptake, utilization, and costs be made publicly available?

As the state seeks to give managed care plans the flexibility to fill service gaps and offer services in lieu of more costly substitutes, we have concerns about any adverse or unintended consequences to IHSS, especially given many managed care plans' limited experience working with the program. IHSS consumers and providers have achieved significant gains in the program over the years that could be unintentionally undercut.

Please provide answers to the above questions by close of business on April 22nd, 2021 so that we may have clarity on how the benefit will work in tandem with IHSS and how it will promote consumer choice, access, and quality. Answers to these questions by that date will help to inform our public comments for the upcoming April 26th public comment webinar. Thank you for your time and we look forward to your responses to these questions.

Thank you,

April Verrett
Statewide President
SEIU Local 2015

Doug Moore
Executive Director
UDW/AFSCME 3930

Cc: Michelle Baass, California Health and Human Services Agency
Ana Matosantos, Office of Governor Newsom

Dear sir or madam:

I am commenting on the proposed initiative to transition dual eligibles into mandatory enrollment in Managed care plans.

I speak to you on behalf [redacted] would have wanted me to speak up.

[redacted]

[redacted]

The point I am trying to make by sharing this story is that the dual eligible population is comprised of chronically ill, vulnerable, poor patients needing advocacy. Forcing the chronically ill into Mandatory Managed care will result in:

- Denied Treatment
- Inadequate Treatment
- Lack of choice of quality Hospitals and Providers
- Premature Death

I do not see any upside for the patient and suspect the main reason for this proposal is purely a cost savings initiative. If MA plans have all the power and the beneficiary doesn't have the option to dis-enroll from the assigned Managed care plan, care standards will deteriorate because the MA plans won't have any competition. A retrospective look at the rapid rate of dis-enrollment from these plans after the coordinated care initiative began is telling.

In closing, I strongly oppose mandatory managed care enrollment for dual eligible beneficiaries.

Felicia Viselli

Daughter, caregiver, advocate

Hello, my public comment is that the hope is that with CalAIM, there will be more time for client care and less documentation requirements. Also less concentration on disallowances. Thank you, Angela Rowe, LCSW

I strongly urge that MCOs participants must be required to contract with only high quality long term care providers particularly nursing homes. Our research shows that MCOs in CA often contract with one and two star nursing homes where the quality is unacceptable. I believe that MCOs should only contract with 3-5 star rated nursing homes. The current practice allows disparities in quality for Medi-Cal beneficiaries that is not acceptable. Charlene

To whom it may concern,

As the Vice Chair of the Santa Barbara County Behavioral Wellness Commission, the Santa Barbara County Education Office's mental health liaison, [redacted] urge you to request the IMD Exclusion waiver to address the severe shortage of inpatient beds.

Sincerely,

Valerie

Valerie Cantella
Director, Communications
Santa Barbara County Education Office
805-689-8044 (cell)
www.SBCEO.org

From: John Valencia <john@valencialobby.com>
Sent: Tuesday, April 20, 2021 11:55 AM
To: DHCS Behavioral Health SAC <BehavioralHealthSAC@dhcs.ca.gov>
Subject: [External]Drug Medi-Cal - Organized Delivery Systems (DMC-ODS)

TO: Behavioral health Stakeholder Advisory Committee (BH-SAC)
Department of Health Care Services (DHCS)

RE: "Drug Medi-Cal Organized Delivery System Renewal and Policy Improvement"

On behalf of our client, Alkermes, Inc., we respectfully resubmit comments raised for DHCS in March 2020 on the original CalAIM Proposal and, again, in August 2020 as to the Medi-Cal 2020 1115 Waiver Extension. We joined over 20 patient-centered organizations making similar observations.

We respectfully request a discussion of the issues raised and responsive commentary from the Department.

►Commencing on Page 93 of the now-revised January 2021 CalAIM Proposal, Section 3.10 "Drug Medi-Cal Organized Delivery System Renewal and Policy Improvement," DHCS proposes continuation in its CalAIM relaunch of the position expressed in the one-year 1115 Medi-Cal 2020 Waiver extension request of the same, discriminatory differentiation among FDA-approved Medication Assisted Treatments (MATs) methadone and buprenorphine, and long-acting injectable naltrexone (Vivitrol®).

▪DHCS' proposal is outlined in summary fashion on pages 96 – 97.

The Department refers back to its 12-month extension request "…to keep the additional medication assisted treatment (MAT) services as an optional benefit but clarified the coverage provisions to require that all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to medication assisted treatment." Left unsaid is that the extension request did not require the direct offer or referral mechanisms to demonstrate access to all forms of medication assisted treatment.

DHCS, in net effect, is proposing that DMC-ODS continue only with the "requirement" that "all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to, medication assisted treatment." The Department's proposal omits references to **all** medication assisted treatment. Since Vivitrol® is the only federally-approved MAT not included in the Drug Medi-Cal State Plan, providers need only demonstrate they offer, or refer to, methadone and buprenorphine MATs.

This is, essentially, a statewide policy advanced by the Department. While, currently, DMC-ODS is not a statewide benefit since the program operates only in counties that "opt in" to participate and are approved to do so by both DHCS and CMS, there are 37 counties participating in the DMC-ODS demonstration, providing access to SUD treatment services for 96 percent of the Medi-Cal population.

DHCS has not responded, to date, to input from numerous stakeholders on this unexplained limitation on access to all federally-approved MATs (copies of the previous comments by a wide-ranging coalition of stakeholders are attached for reference).

►Additionally: Section 1006(b) of the SUPPORT Act, signed into law on October 24, 2018, amends section 1902(a)(10)(A) of the Social Security Act (the Act) to require state Medicaid plans to include coverage of MAT for all those eligible to enroll in the state plan or waiver of state plan.

Section 1006(b) of the SUPPORT Act requires states to begin implementing MAT as a mandatory Medicaid state plan benefit for categorically needy populations for the 5-year period beginning October 1, 2020.

Section 2601 of the Continuing Appropriations Act, 2021 and other Extensions Act, Pub. L. No. 116-159, amended the SUPPORT Act to specify that the rebate requirements in section 1927 shall apply to any MAT drug or biological described under the mandatory benefit to the extent that the MAT drug or biological is a covered outpatient drug. (More information on section 2601 is in the section below entitled, "MAT Drug Coverage and Section 1927 Manufacturer Rebates.") Section 1006(b) also adds a new paragraph 1905(a)(29) to the Act to add the new required benefit to the definition of "medical assistance" and to specify that the new required benefit will be in effect for the period beginning October 1, 2020, and ending September 30, 2025.

In addition, section 1006(b) adds section 1905(ee)(1) to the Act to define MAT, for purposes of the new required coverage, as:

. . . all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and[,] . . . with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

CMS interprets section 1905(ee)(1) of the Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the Food and Drug Administration (FDA) has approved or licensed for MAT to treat OUD. Currently, the FDA has approved the following drugs used for MAT to treat OUD: methadone, buprenorphine, and naltrexone.2 Only those formulations of drugs or biologicals that are approved or licensed by the FDA for MAT to treat OUD must be covered under the new mandatory Medicaid benefit.

1 SUPPORT for Patients and Communities Act, Pub. L. No. 115–271 (2018), https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf

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We look forward to a robust discussion of this issue and the Department's written response to the issues raised.

Respectfully submitted,

John R. Valencia

Valencia Government Relations, Inc.

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Valencia Government Relations, Inc.

March 16, 2021

VIA E-MAIL (BehavioralHealthSAC@dhcs.ca.gov)

Will Lightbourne, Director
Department of Health Care Services
1501 Capitol Avenue, Suite 6001, MS 0000
Sacramento, CA 95814

RE: Comment – DHCS (Revised) CalAIM Proposal for 2022 and Beyond -- Recommended Parity for All U.S. FDA-Approved Medication Assisted Treatments (MATs)

Dear Director Lightbourne:

Our client, Alkermes, is a pharmaceutical company committed to developing medicines to help address unmet medical needs and challenges of people living with debilitating diseases, including opioid use disorder (OUD). Alkermes believes all scientific reports should be presented as accurately as possible to further the development of clinical practice and the shaping of public health policy. In an effort to improve accuracy and avoid possible misinformed influence, Alkermes offers these written comments to address the Department's (DHCS) continuing differentiation between Alkermes' once-monthly Vivitrol® (naltrexone for extended-release injectable suspension; XR-NTX) and methadone and buprenorphine as equally effective medication assisted treatments (MATs) for opioid use disorder.

►Commencing on Page 93 of the 2021 Proposal, Section 3.10 "Drug Medi-Cal Organized Delivery System Renewal and Policy Improvement," DHCS proposes continuation in its CalAIM relaunch of its position expressed in the one-year 1115 Medi-Cal 2020 Waiver extension request of the same, discriminatory distinction between methadone and buprenorphine and Vivitrol®.

The Department proposes DMC-ODS continue only with the "requirement" that "*all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to, medication assisted treatment*." The Department's proposal omits references to **all** medication assisted treatment. Since Vivitrol® is the only federally-approved MAT not included in the Drug Medi-Cal State Plan, providers need only demonstrate they offer, or refer to, methadone and buprenorphine MAT.

This is, essentially, a statewide policy advanced by the Department. While, currently, DMC-ODS is not a statewide benefit since the program operates only in counties that "opt in" to participate and are approved to do so by both DHCS and CMS, there are 37 counties participating

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in the DMC-ODS demonstration, providing access to SUD treatment services for 96 percent of the Medi-Cal population.

DHCS has not responded, to date, to input from numerous stakeholders on this unexplained limitation on access to all federally-approved MATs (copies of the previous comments by a wide-ranging coalition of stakeholders are attached for reference).

►As noted, this position is identical to the language contained in the 12-month Medi-Cal 2020 Waiver Extension request on Page 23 of the July 22, 2020, "*DRAFT for PUBLIC COMMENT*, wherein the Department stated:

> *4. Expand access to MAT*
>
> *California proposes to require counties to mandate that all DMC-ODS providers, at all levels of care, demonstrate that they either directly offer, or have effective referral mechanisms to, MAT. The state also seeks to maintain the option for counties to elect to cover additional MAT services, including ordering, prescribing, administering, and monitoring of MAT.*

By relegating Vivitrol® to status as an "optional" or "additional" MAT, the DHCS statement that it "…*proposes to require counties to mandate that all DMC-ODS providers, at all levels of care, demonstrate that they either directly offer, or have effective referral mechanisms to MAT*[,]" translates into a mandate that all DMC-ODS providers either directly offer or have effective referral mechanisms only to methadone or buprenorphine.

This limited mandate does nothing for OUD patients who seek a pathway to recovery utilizing a complete antagonist therapy following medically supervised detoxification, without utilization of a MAT agonist or partial-agonist treatment containing a controlled substance.

There is no clinical or data-based reason for this distinction.

In fact, a 2017 U.S. National Institute on Drug Abuse (NIDA) study "…***comparing the effectiveness of two pharmacologically distinct medications used to treat opioid use disorder – a buprenorphine/naloxone combination and an extended release naltrexone formulation – shows similar outcomes once medication treatment is initiated***." (emphasis added)

"*The good news is we filled the evidentiary void, and also learned that for those who were able to initiate treatment, the outcomes were essentially identical, as were adverse events*," said John Rotrosen, M.D., the study lead investigator. "*This gives patients the freedom to choose a treatment approach that best suits their lifestyle, goals and wishes*."

Patients who take methadone or buprenorphine to treat OUD may experience side effects that are similar to those of opioids, such as nausea, vomiting, constipation, muscle aches, cramps, constipation, fever, cravings, irritability, and inability to sleep (SAMHSA, 2018). People using

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methadone may also experience difficulty breathing, lightheadedness, hives, rash, chest pain, rapid heart rate, and hallucinations (SAMHSA, 2018).

Individuals taking extended-release injectable formulations of buprenorphine or naltrexone or implantable buprenorphine may also experience reactions at the injection site, such as bruising, itching, pain, or swelling (Indivior, 2017; Rosenthal et al., 2016).

There is also a risk that people will misuse methadone or buprenorphine due to their opioid effects (SAMHSA, 2018). This risk is higher with buprenorphine than methadone because people are often prescribed a supply of buprenorphine to take on their own, whereas people receiving methadone are usually required to take their medication under direct supervision at a methadone clinic. There is also less risk of misuse of extended-release injectable formulations of buprenorphine and naltrexone because they are administered in physicians' offices.

Change Recommendation: Alkermes, along with numerous other stakeholders, strongly encourages, and respectfully requests, that DHCS drop the distinction within the CalAIM Proposal, Section 3.10 by eliminating the **option** for counties to elect to provide injectable naltrexone (Vivitrol®), and instead "**require" counties to provide access to all federally-approved MATs, including long-acting injectable naltrexone.**

This approach will enable eligible DMC-ODS providers to demonstrate they directly offer, or have effective referral mechanisms to any or all of the three U.S. FDA-approved medication assisted treatments, including naltrexone for extended-release injectable suspension (Vivitrol®).

In the one-year extension application, the Department noted that "…*California proposes to add naltrexone in the Narcotic Treatment Program setting to align with the pending State Plan Amendment and clarify that this benefit can be utilized for all medication assisted treatment not covered under the State Plan.*"

Alkermes support this change to add naltrexone to the Narcotic Treatment Program and notes the enactment of Assembly Bill 80 (Chapter 12, Statutes of 2020) to expand reimbursable Drug Medi-Cal services to include medication-assisted treatment services, in the form of "Any medication approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and all biological products licensed under Section 351 the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders, along with critically-need psycho-social support services and therapy."

Respectfully submitted,

[redacted]

JOHN R. VALENCIA

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JRV:/
Attachment "1" Assemblymember Blanca Rubio Letter
Attachment "2" Stakeholder Comments Letter

Resource References:

Alkermes Inc. VIVITROL® (Prescribing Information). Waltham, MA:2015.

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Assembly
California Legislature

BLANCA E. RUBIO
ASSEMBLYMEMBER, FORTY-EIGHTH DISTRICT

COMMITTEES
AGING AND LONG-TERM CARE
BUDGET
GOVERNMENTAL ORGANIZATION
WATER, PARKS, AND WILDLIFE

BUDGET SUBCOMMITTEE NO. 1 ON
HEALTH AND HUMAN SERVICES

JOINT LEGISLATIVE AUDIT

Bradley Gilbert
Director
California Department of Health Care Services
CalAIM@DHCS.ca.gov

Dear Director Gilbert:

I am following up on a piece of legislation that I submitted to the department in 2019. I was assured by former Director Jennifer Kent that the issues therein would be resolved in the 2020 Medi-Cal waiver renewal process. As that process has begun under the name Medi-Cal Healthier California For All, I am requesting that the Department of Health Care Services confirm the issues being addressed and respond to a few follow-up questions.

The purpose of my legislation was to ensure that all FDA approved Medication Assisted Treatment (MAT) would be available in all appropriate clinical settings. As identified below while California has removed prior authorizations on all current MAT, there remain significant barriers to access based on the clinical setting from which patient's seek treatment.

While AB 395 authorized NTP/OTPs to utilize long acting naltrexone in their treatment programs, to date DHCS has not provided a pathway to reimbursement for the services that are required to have comprehensive patient care. Both Buprenorphine and Methadone have codes for such services which include urine tests, mouth swabs and counseling services. But the Department has yet to set reimbursement or provide reimbursement codes for the use of these medications.

Since my legislation, significant studies have been published that further stress the need for availability in all settings. In November 2019, the National Academy of Sciences released a consensus study report entitled: *Medications for Opioid Use Disorders Save Lives*, with the following conclusions:

FDA-approved medications to treat opioid use disorder are effective and save lives. FDA-approved medications to treat opioid use disorder—methadone, buprenorphine, and extended-release naltrexone—are effective and save lives. The most appropriate medication varies by individual and may change over time. To stem the opioid crisis, it is critical for all FDA-approved options to be available for all people with opioid use

disorder. At the same time, as with all medical disorders, continued research on new medications, approaches, and formulations that will expand the options for patients is needed.[1]

Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment. Treatment with FDA-approved medications is clearly effective in a broader range of care settings (e.g., office-based care settings, acute care, and criminal justice settings) than is currently the norm. There is no scientific evidence that justifies withholding medications from opioid use disorder patients in any setting or denying social services to individuals on medication for opioid use disorder. Therefore, to withhold treatment or deny services under these circumstances is unethical. [2]

In California, a major barrier to access for thousands of Californians that have been diagnosed with a substance use disorder (SUD) exists within the reimbursement structure of Narcotic (Opioid) Treatment Programs (NTP/OTPs). These programs provide opioid medication assisted treatment to those persons addicted to opiates. NTPs also provide detoxification and/or maintenance treatment services which include medical evaluations and rehabilitative services to help the patient become and/or remain productive members of society.

In the California State Hub & Spoke Medication Assisted Treatment Expansion Project, NTP/OTPs have been designated as the Hub. DHCS defines a "Hub" as a Narcotics (Opioid) Treatment Program (NTP/OTP) that specializes in treating patients with OUD. They have flexibility, within the state guidelines, to choose clinical service providers ("spokes") to build a treatment network that meets community needs.

In 2017, the Legislature passed AB 395 (Bocanegra, Health and Safety Code Section 11839.2) to enhance the medication assisted treatment (MAT) offerings within NTPs.

Prior to the passage of AB 395, Health and Safety Code Section 11839.2 permitted licensed Narcotic (Opioid) Treatment Programs (NTP/OTPs) to provide federally approved controlled substances to patients with an opioid use disorder (OUD) for the purpose of Narcotic Replacement Therapy (NRT).

Once the FDA approved medications which were not controlled substances for the purpose of providing medication assisted treatment (including VIVITROL the long-acting injectable relapse-prevention medication) to patients with SUD, it became necessary to change the language in the statute to specify such medications as "medication-assisted treatment (MAT)." The legislation also specifically added "naltrexone" to the medications authorized for use by NTP/OTPs.

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1 https://www.nap.edu/resource/25310/032019_OUDconclusions.pdf

2 https://www.nap.edu/resource/25310/032019_OUDconclusions.pdf

On January 10, 2018 DHCS circulated "MHSUDS INFORMATION NOTICE NO.: 18-004" "The purpose of this Department of Health Care Services' (DHCS) Information Notice is to summarize and implement the provisions of AB 395, which went into effect on January 1, 2018. AB 395 amends the language in Health and Safety Code Section 11839.2 to state that a licensed NTP/OTP may provide all non-controlled medications approved by the FDA for providing MAT to patients with a SUD (Expanded MAT), in addition to the previously allowable FDA approved NRT medications. However, the information notice provided by DHCS is used when billing Drug Medi-Cal ODS for these services as a bundled fee. Without the ability to reimburse for services, utilizing one of the three FDA approved options for treatment and the only antagonist choice; NTP/OTPs, lack a sustainable business model for offering the medication to patients.

My understanding from testimony by former-Director Kent was that in the process of renewing the 1115 waiver, now known as *Medi-Cal for Healthier California for All*, DHCS would develop a statewide reimbursement code. Reimbursement rates for bundled ancillary long acting injectable naltrexone services would be consistent with the services reimbursed for methadone and buprenorphine and would be used for billing Drug Medi-Cal ODS when a county has opted into SUD services.

In the time since these discussions took place the SUPPORT Act was signed into law. In the SUPPORT Act, Congress mandated that states cover all drugs and biological products (including long acting injectable naltrexone) approved by the FDA for MAT and related counseling services and behavioral therapy beginning on October 1, 2020, and continuing at least through September 31, 2025.

That law also addresses the need for reimbursement reform for all forms of FDA-approved MAT through comprehensive payment models that facilitate the ability to wrap all services into a "bundled payment."

In November, the Centers for Medicare and Medicaid Services (CMS) released the Final Rule for the FY2020 Physician's Fee Schedule (PFS) which includes a bundled-payment model for extended-release naltrexone.[3] Additionally, CMS recently published federal guidance[4] related to primary payer status for the newly announced bundled-payment model.[5]

The purpose of this bulletin is to inform states that starting on January 1, 2020, Medicare will pay Opioid Treatment Programs (OTPs) through bundled payments for opioid use disorder (OUD) treatment services, including medication-assisted treatment (MAT), toxicology testing, and counseling as authorized under Section 2005 of the Substance Use Disorder Prevention that Promotes Opioid Recovery

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3 CMS-1715-P

4 https://www.cms.gov/files/document/letter-otp-program-sponsors-and-state-opioid-treatment-authorities-sotas-pdf.pdf

5 CMS-1715-P

and Treatment (SUPPORT) for Patients and Communities Act and implemented in the final rule CMS-1715-F, "Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and other Revisions to Part B for CY 2020" published in the Federal Register on November 1, 2019 (final rule)[6].

Further complicating the issue, California State Plans currently cover just methadone and oral naltrexone, while the county Drug Medi-Cal Organized Delivery System program requires coverage of methadone and buprenorphine, and allows other medications as an optional benefit.

DHCS states that counties are required to cover opioid treatment program services, also called Narcotic Treatment Programs.[7] DHCS proposes all SUD managed-care providers demonstrate they either offer, or have the ability to refer, all FDA-approved forms of MAT for OUD treatment; *Medi-Cal for Healthier California for All* goal is to have a county-wide delivery system for reimbursement coverage. [8] I

In the Final Rule published by CMS, it's clear that the bundled-payment rate for naltrexone refers to the injectable product, extended-release naltrexone.[9] Therefore by keeping long acting injectable naltrexone as an optional benefit there would be significant discrepancies between what the counties are required to provide and what CMS statute is willing to reimburse.

Based on this information my questions to the Department of Health Care Services are as follows:

1) Does the Department of Health Care Services (DHCS) intend to require all three FDA approved medications for the treatment of opioid use disorder (OUD) which include methadone, buprenorphine and long acting injectable naltrexone, knowing that oral naltrexone is not indicated for the treatment of OUD and only has a clinical indication as a barrier to the effects of exogenously administered opioids, available in counties through the Medi-Cal Healthier for All Californians? If not, can you provide further explanation?

2) Specifically, when referring to "naltrexone services" in the proposal, do those services refer to oral or long acting injectable naltrexone?

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6 Pub L 115-271, the SUPPORT Act

7 Cal Aim Proposal 93

8 Cal Aim Proposal 93

9 CMS FY2020 PFS Pg 62643

3) Does the Department of Health Care Services intend to set a rate for the use of long acting injectable naltrexone (VIVITROL) in Narcotic (Opioid) Treatment Programs?

4) Does the Department foresee any other barriers to the use of long acting injectable naltrexone in Narcotic (Opioid) Treatment Programs?

5) Does the Department of Health Care Services intend to implement guidelines that align with the recently passed SUPPORT Act law that supports a reimbursement pathway for long acting injectable naltrexone in NTPs/ OTPs keeping in mind that the final published CMS rule clearly states: *the naltrexone drug product that is FDA-approved for the treatment of opioid dependence is an extended-release, intramuscular injection. The naltrexone bundled payment category refers to this injectable product.*[10]

Sincerely,

[redacted]

Blanca Rubio
Assemblymember, 48th District

[10] CMS FY2020 PFS Pg. 62643

March 6, 2020

Bradley Gilbert, MD, MPP
Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

RE: ODS Waiver Revision Proposal (CalAIM Behavioral Health Payment Reform Workgroup Comments)

Dear Director Gilbert:

We, the undersigned organizations, would like to express our concern related to recent statements and documents presented at a California Advancing and Innovating Medi-Cal (CalAIM) workgroup regarding medication assisted treatment (MAT). We understand that the California Department of Health Care Services (DHCS) is not requiring counties to provide all forms of FDA-approved MAT in the ODS waiver revision. The proposal discussed in the February 26, 2020 workgroup meeting states that counties may offer additional MAT, which under the current terms and conditions refers to injectable naltrexone.

We do not believe that this proposal is consistent with patient care or the concept of "no wrong door" for patients seeking substance use disorder (SUD) treatment services.

In the CalAIM proposal published on October 28, 2019, DHCS stated the following:

> *"DHCS aims to design a cohesive plan to address beneficiaries' substance use disorder treatment needs across the continuum of care, ensure that all Medi-Cal beneficiaries receive coordinated services, and to promote long-term recovery. This requires developing new approaches to care delivery and system administration that will improve*

> *the beneficiary experience, increase efficiency, ensure cost-effectiveness, and achieve positive health outcomes."*

Under the current terms and conditions of the Drug Medi-Cal Organized Delivery System (DMC-ODS), counties are required to cover opioid treatment including methadone and buprenorphine programs. Currently, counties may elect to cover "additional medication assisted treatment" including the ordering, prescribing, administering, and monitoring of injectable naltrexone.

DHCS proposes keeping the "additional medication assisted treatment" services as an optional benefit but clarifies the coverage provisions to require that all SUD managed care providers demonstrate that they either directly offer, or have referral mechanisms to, medication assisted treatment. The goal is to have a county-wide multi-delivery system of coverage.

While it has been acknowledged that numerous organizations provided input stating all three FDA-approved medications should be included in parity and that there should not be an additional opt-in for medications outside of methadone and buprenorphine, DHCS reiterated its intent to only require two of the three FDA-approved medications for the treatment of opioid use disorder (OUD).

Since the current 1115 waiver was approved in 2015, the medical community and federal agencies have come to agreement that all three FDA-approved medications for the treatment of OUD are effective, underutilized, and should be available to patients in all settings of care. The FDA and the National Institute on Drug Abuse (NIDA) have also continued to distinguish the indications of oral naltrexone (the blockade of the effects of exogenously administered opioids)[1] and long acting injectable naltrexone (the prevention of relapse to opioid dependence following opioid detoxification)[2]. Only extended-release injectable naltrexone is approved for treatment of people with OUD and on November 1, 2019, CMS SUPPORT Act Final Rule stated "the naltrexone drug product that is FDA approved for the treatment of opioid dependence is an extended-release, intramuscular injection. The naltrexone payment category refers only to this product."[3]

FDA notes:

> *All three of medications- methadone, buprenorphine, and long acting injectable naltrexone- have demonstrated to be safe and effective in combination with counseling and psychosocial support and that those seeking treatment for an OUD should be offered access to all three options as this allows providers to work with patients to select the medication best suited to the individual's needs.*[4]

The Substance Abuse and Mental Health Services Administration's (SAMHSA) *TIP 63: Medications for Opioid Use Disorder* publication states:

> *Methadone, extended release injectable naltrexone (XR-NTX) and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for establishing efficacy in clinical medicine.*[5]
>
> *Improving access to treatment with OUD medications is crucial to closing the wide gap*

[1] https://www.ncbi.nlm.nih.gov/books/NBK535266/
[2] https://www.ncbi.nlm.nih.gov/pubmed/29400929
[3] https//s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf See page 237
[4] https//s.3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf See page 196
[5] https://www.cffutures.org/files/fdc/SAMHSA%20TIP%2063%20-%20Medication%20OUD%20-%202018.pdf

> *between treatment need and treatment availability, given the strong evidence of effectiveness for such treatments.*[6]

The National Academy of Sciences released its consensus study report *Medication Assisted Treatment Saves Lives* which came to the following conclusions:

> *FDA-approved medications to treat opioid use disorder- methadone, buprenorphine, and extended release naltrexone- are effective and save lives. The most appropriate medication varies by individual and may change over time. To stem the opioid crisis, it is critical for all FDA-approved options to be available for all people with opioid use disorder.*
>
> *Available evidence suggests that medication-based treatment for opioid use disorder is highly effective across all subgroups of the population, including adolescents and older persons; pregnant women; individuals with co-occurring disorders (e.g., psychiatric, substance use disorders, infectious diseases); and all racial, sex and gender, and socioeconomic groups.*
>
> *Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.*
>
> *Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.*
>
> *The major barriers to the use of medications for opioid use disorder include the fragmented system of care for people with opioid use disorder and current financing and payment policies.*[7]

The National Institute of Drug Abuse states:

> *Effective medications exist to treat opioid use disorder: methadone, buprenorphine, and naltrexone. These medications could help many people recover from opioid use disorder, but they remain highly underutilized.*[8]

Likewise, the Surgeon General's Report, entitled *Facing Addiction in America,* also states:

> *Well-supported scientific evidence shows that medications can be effective in treating serious substance use disorders, but they are under-used. The U.S. Food and Drug Administration (FDA) has approved three medications to treat alcohol use disorders and three others to treat opioid use disorders. However, an insufficient number of existing treatment programs or practicing physicians offer these medications...Key components of care are medications, behavioral therapies, and recovery support services.*[9]

On November 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis Final Report made specific recommendations[10]:

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[6] See note 5, p. ES-3.
[7] National Academy of Sciences "Medication Assisted Treatment Saves Lives" nationalacademies.org/OUDTreatment
[8] https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview
[9] U.S. Department of Health and Human Services, Office of the Surgeon General. (Nov. 2016) Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, p.4-2, Available at: https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf.
[10] President's Commission on Combating Drug Addiction and the Opioid Crisis, Office of National Drug Control Policy, Executive Office of the President. (Nov. 1, 2017). *Final Report*, p. 8.

> *The Commission recommends HHS/CMS, the Indian Health Service (/HS), Tricare, the DEA, and the VA remove reimbursement and policy barriers to SUD treatment, including those, such as patient limits, that limit access to any forms of FDA-approved medication-assisted treatment (MAT), counseling, inpatient/ residential treatment, and other treatment modalities, particularly fail-first protocols and frequent prior authorizations.*[11]
>
> *The Commission recommended several steps to increase the use of and access to all forms of SUD treatment, including MAT [medication assisted treatment} for SUDs [substance use disorders]*[12]
>
> *Access to MAT (e.g., methadone, buprenorphine/naloxone, naltrexone). Choice of medication should be made by a qualified professional in consultation with patient, and based on clinical assessment.* [13]

Given the overwhelming evidence that all three FDA-approved medications for the treatment of OUD are supported by the medical community and federal agencies, we believe that California should rely on the clinical expertise of these entities and follow recommendations to open access to all FDA-approved medications.

We ask that you reconsider your proposal to have separate opt-ins for counties for the different medications and recommend that a single policy should cover all three FDA-approved medications at parity.

Thank you,

[redacted]

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CEO, California Consortium of Addiction Programs and Professionals

[11] President's Commission on Combating Drug Addiction and the Opioid Crisis, Office of National Drug Control Policy, Executive Office of the President. (Nov. 1, 2017). *Final Report*, p. 8. Available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf
[12] Id. At p. 60 [.pdf pagination]
[13] Id. At p. 61 [.pdf pagination]

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
Services 7500 Security Boulevard, Mail
Stop S2-26-12
Baltimore, Maryland21244-1850

SHO# 20-005

RE: Mandatory Medicaid State Plan Coverage of Medication-Assisted Treatment

December 30, 2020

Dear State Health Official:

The Centers for Medicare & Medicaid Services (CMS) is issuing the following guidance about section 1006(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (herein referred to as the SUPPORT Act) (Pub. L. No. 115-271). To increase access to medication-assisted treatment (MAT) for opioid use disorders (OUD), section 1006(b) of the SUPPORT Act requires states to provide Medicaid coverage of certain drugs and biological products, and related counseling services and behavioral therapy.[1] This State Health Official Letter (SHO Letter) also describes available opportunities for increasing treatment options for substance use disorders (SUD) generally. CMS encourages states to consider these opportunities when implementing the mandatory MAT coverage under section 1006(b) of the SUPPORT Act. The new required benefit is limited to the use of MAT for the treatment of OUD, and thus this SHO Letter is generally focused on that topic, not on treatment services for other SUDs, including alcohol use disorders.

Background

Section 1006(b) of the SUPPORT Act, signed into law on October 24, 2018, amends section 1902(a)(10)(A) of the Social Security Act (the Act) to require state Medicaid plans to include coverage of MAT for all eligible to enroll in the state plan or waiver of state plan. Section 2601 of the Continuing Appropriations Act, 2021 and other Extensions Act, Pub. L. No. 116-159, amended the SUPPORT Act to specify that the rebate requirements in section 1927 shall apply to any MAT drug or biological described under the mandatory benefit to the extent that the MAT drug or biological is a covered outpatient drug. (More information on section 2601 is in the section below entitled, "MAT Drug Coverage and Section 1927 Manufacturer Rebates.") Section 1006(b) also adds a new paragraph 1905(a)(29) to the Act to add the new required benefit to the definition of "medical assistance" and to specify that the new required benefit will be in effect for the period beginning October 1, 2020, and ending September 30, 2025.

In addition, section 1006(b) adds section 1905(ee)(1) to the Act to define MAT, for purposes of the new required coverage, as:

> . . . all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section

[1] SUPPORT for Patients and Communities Act, Pub. L. No. 115–271 (2018), https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf.

> 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and[,] . . . with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

CMS interprets section 1905(ee)(1) of the Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the Food and Drug Administration (FDA) has approved or licensed for MAT to treat OUD. Currently, the FDA has approved the following drugs used for MAT to treat OUD: methadone, buprenorphine, and naltrexone.[2] Only those formulations of drugs or biologicals that are approved or licensed by the FDA for MAT to treat OUD must be covered under the new mandatory Medicaid benefit. There are currently no FDA-licensed biological products to treat OUD.[3]

Medication-Assisted Treatment

While states are required to cover all drugs and biologicals approved or licensed by the FDA used for MAT to treat OUD under the new mandatory benefit, various considerations affect which medication should be provided to a particular patient.[4]

- Methadone is a long-acting synthetic opioid agonist medication with a long history of use in treatment of OUD in adults. Methadone is indicated for the detoxification treatment of opioid addiction as well as maintenance treatment of opioid addiction in conjunction with appropriate social and medical services.[5]

  Methadone for treatment of OUD must be administered by an Opioid Treatment Program (OTP). Currently, solid (non-dispersible) and dispersible tablets, as well as the liquid concentrate, are labeled for use in such outpatient OUD therapy. These products cannot be dispensed from a pharmacy for the purpose of treating OUD. OTPs must have a current, valid certification from the Substance Abuse and Mental Health Services Administration (SAMHSA) and be accredited by an independent, SAMHSA-approved accrediting body.[6] Effective January 1, 2020, the Medicare program began covering and reimbursing OUD treatment services furnished by an OTP.[7]

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[2] U.S. Food and Drug Administration (FDA). Information about Medication-Assisted Treatment (MAT). FDA web site. https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat; Substance Abuse and Mental Health Services Administration (SAMHSA). Medication-Assisted Treatment. SAMHSA website. https://www.samhsa.gov/medication-assisted-treatment

[3] "Information about Medication-Assisted Treatment (MAT)," U.S. Food and Drug Administration, last modified February 14, 2019, https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.

[4] SAMHSA. Office of the Surgeon General. Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington (DC). U.S. Department of Health and Human Services. 2016 Nov. Chapter 4, Early Intervention, Treatment, and Management of Substance Use Disorders. Available from: https://www.ncbi.nlm.nih.gov/books/NBK424859/.

[5] FDA. Dolophine Highlights of Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/006134s045lbl.pdf

[6] SAMHSA. Certification of Opioid Treatment Programs. SAMHSA website. https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs.

[7] SUPPORT Act, Section 2005, Medicare Coverage of Certain Services Furnished by Opioid Treatment Programs. See also CMCS Informational Bulletin, "Guidance to State Medicaid Agencies on Dually Eligible Beneficiaries Receiving Medicare Opioid Treatment Services Effective January 1, 2020" (Dec. 17, 2019), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib121719.pdf

- Buprenorphine is a synthetic opioid medication that acts as a partial agonist, blocking and only weakly activating the opioid receptor, thus blunting the euphoric effects of other opioids for the treatment of OUD.[8]

  Buprenorphine is currently available in several dosage forms, including an oral dissolvable film, sublingual tablet, and injection. It is available as a single ingredient or in combination with naloxone, an antagonist (or blocker) of opioid receptors to prevent attempted misuse by injection. For more information on the FDA approved medications for treatment of OUDs, see SAMHSA's Treatment Improvement Protocol 63 as well as the FDA web site: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm.[9]

  Long-acting buprenorphine injections are a route of administration that may help to improve patient adherence, may reduce the risk of accidental exposures, theft, or deliberate misuse, and may reduce risks associated with office visits during the COVID-19 pandemic.[10] Sublocade is a once-monthly injection designed to deliver buprenorphine at sustained levels of medication throughout the month.[11]

- Naltrexone is a synthetic opioid antagonist – it blocks opioids from binding to receptors and is FDA-approved for the prevention of relapse to opioid dependence, following opioid detoxification. Naltrexone is well-tolerated following detoxification. It has no potential for abuse, and it is not addictive.[12] Long-acting injectable naltrexone is FDA-approved with recommended dosing once every four weeks[13] for maintenance of abstinence.[14] Naltrexone can be prescribed by any clinician who is licensed in the state to prescribe medications.[15,16]

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[8] FDA. Subutex Highlights of Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020732s018lbl.pdf

[9] SAMHSA, Treatment Improvement Protocol: Medications for Opioid Use Disorder, May 2020. https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006

[10] Volkow ND. Collision of the COVID-19 and Addiction Epidemics. Ann Intern Med. 2020; 173(1):61-62. doi:10.7326/M20-1212

[11] Crist, Richard C et al. Pharmacogenetics of Opioid Use Disorder Treatment. *CNS drugs*. 2018; vol. 32 (4): 305-320. doi:10.1007/s40263-018-0513-9.

[12] National Institute on Drug Abuse. (2018, January 17). Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition). https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/pharmacotherapies.

[13] FDA. ReVia Highlights of Prescribing Information.https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/018932s017lbl.pdf

[14] Tanum L, Solli KK, Latif ZE, Benth JŠ, Opheim A, Sharma-Haase K, Krajci P, Kunøe N. Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial. JAMA Psychiatry. 2017 Dec 1;74(12):1197-1205. doi: 10.1001/jamapsychiatry.2017.3206. Erratum in: JAMA Psychiatry. 2018 Mar 14;75(5):530. PMID: 29049469; PMCID: PMC6583381.

[15] SAMHSA. Naltrexone. SAMHSA website. https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.

[16] We note that in addition to the MAT drugs listed here that are required to be covered for management of opioid dependency under the new benefit at section 1905(a)(29) of the Act, states that provide optional coverage of prescribed drugs under section 1905(a)(12) must do so consistent with sections 1902(a)(54) and 1927, which require coverage of all drugs and biologicals that satisfy the definition of a covered outpatient drug at sections 1927(k)(2)-(4), if the manufacturer has a national drug rebate agreement in effect. In that some medications not defined as MAT

To address the full scope of patients' treatment needs, section 1905(ee)(1) defines the required MAT benefit as including counseling services and behavioral therapy related to the drugs and biologicals covered under the new mandatory benefit. While states have flexibility to specify which counseling services and behavioral therapy they will include in the new mandatory benefit, states that already cover MAT successfully often cover a range of effective behavioral health services for beneficiaries with OUD receiving MAT, including the following:

- Individual/Group Therapy generally helps patients identify treatment goals and potential solutions to problems that cause emotional stress; seeks to restore communication and coping skills; strengthens self-esteem; and promotes behavior change and optimal mental health. Cognitive behavioral therapy is a type of therapy that has been shown to be successful in treating individuals with OUD.

- Peer Support Services are typically understood to be services in which a qualified peer support provider (also called a recovery coach or peer recovery support specialist) assists individuals with their recovery from substance use disorders, including OUD. Peer support services can also be offered in relation to co-occurring mental disorders and OUD. Services can include counseling on coping with symptoms and navigating early stages of the recovery process; modeling appropriate behavior, skills, and communication; engagement with a supportive community of recovering peers; and helping the person access community resources. CMS has issued guidance that addresses requirements for peer support providers.[17]

- Crisis Intervention Services are typically provided to immediately reduce or eliminate the risk of physical or emotional harm. Services can include evaluation, triage, and access to services; and treatment to effect symptom reduction, harm reduction, and/or safe transition of individuals in acute crisis to the appropriate level of care for stabilization.

MAT Provider Landscape

Section 3502 of the Drug Addiction Treatment Act of 2000[18] amended the Controlled Substances Act (CSA) to permit qualified physicians to receive a waiver of the CSA's separate registration requirements for prescribing and dispensing certain opioid medications, such as buprenorphine, to treat OUD. Because of concerns about the lack of access to OUD treatment, Congress expanded the types of practitioners who are eligible for a waiver to prescribe and dispense buprenorphine to treat OUD. The Comprehensive Addiction and Recovery Act of 2016 allowed nurse practitioners and physician assistants to qualify for a waiver.[19] Additionally,

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may be used to assist in short or long-term treatment success for beneficiaries with OUD, such as medications to treat opioid withdrawal symptoms, CMS would encourage states to focus on optimal patient outcomes in decisions that impact coverage and access.

[17] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD081507A.pdf.

[18] Children's Health Act of 2000, Section 3501, Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000). https://www.govinfo.gov/content/pkg/PLAW-106publ310/pdf/PLAW-106publ310.pdf.

[19] Comprehensive Addiction and Recovery Act of 2016, Section 303, Medication-assisted Treatment for Recovery from Addiction, Pub. L. No. 114–198, 130 Stat. 69, (2016). https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf

section 3201 of the SUPPORT Act[20] extends eligibility for prescribing buprenorphine for the treatment of OUD to clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives until October 1, 2023.

Section 3201 of the SUPPORT Act also expands the eligibility of certain physicians and other qualifying practitioners to treat up to 100 patients in the first year of waiver receipt if they satisfy one of the following two conditions found in regulation:[21]

> 1) The physician holds a board certification in addiction medicine or addiction psychiatry by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology; or
>
> 2) The practitioner provides MAT in a "qualified practice setting." A qualified practice setting is one that:
>
> a. Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
> b. Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
> c. Uses health information technology systems such as electronic health records in accordance with practice setting requirements;
> d. Registers for their state prescription drug monitoring program where operational and in accordance with federal and state law; and
> e. Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or federal health benefits.

After one year at the 100-patient limit, physicians and qualifying other practitioners who meet the above criteria can apply to increase their patient limit to 275.[22]

Current MAT State Plan Coverage

Currently, all state Medicaid programs cover some form of buprenorphine and extended-release naltrexone for treatment of OUD. In addition, most states also cover some form of the counseling and behavioral therapies that are necessary to provide evidence-based MAT. Methadone is indicated for use as part of an MAT protocol for treating OUD, but also for pain management. When used for treating OUD, methadone can only be administered by OTPs, which must be certified by SAMHSA and registered with the Drug Enforcement Administration (DEA).[23] OTPs must be licensed in the state in which they operate and accredited by a

[20] SUPPORT Act, Section 3201, Allowing for More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders.
[21] 21 U.S.C. 823(g)(2)(B)(II)(bb) – (cc); Medication Assisted Treatment for Opioid Use Disorders, 42 C.F.R. 8.610, 42 C.F.R. 8.615.
[22] 21 U.S.C. 823(g)(2)(B)(II)(dd); Medication Assisted Treatment for Opioid Use Disorders, 42 C.F.R. 8.610 – 655.
[23] We note that in contrast, when methadone is used for the treatment of pain, it can be dispensed from pharmacies, which are not able to dispense methadone for OUD unless they are also certified as OTPs.

SAMHSA-approved accrediting body.[24] Additionally, federal regulations at 42 C.F.R. part 8 impose standards governing, for example, required services, staff credentials, patient admission criteria, and patient confidentiality criteria.[25] In a report on the use of medications to treat OUD in the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, SAMHSA found that methadone is covered for MAT to treat OUD by Medicaid in 42 of the 53 states and territories included in the report.[26]

Institution for Mental Diseases (IMD) Exclusion

Frequently, MAT-related counseling and behavioral therapy are provided on-site at clinics and health centers where buprenorphine and/or naltrexone are dispensed. Primary care providers who prescribe MAT drugs often partner with local substance use disorder treatment or mental health care agencies to connect individuals to counseling. Federal regulation requires patients who receive treatment in an OTP to receive access to[27] medical, counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication.[28] Medications for MAT, as well as the counseling and behavioral therapies, can also be furnished in inpatient and residential settings such as psychiatric hospitals, inpatient units, or residential treatment programs, including in IMDs, but Medicaid coverage is generally not available unless the setting is not an IMD or an exception to the IMD exclusion applies, as discussed below.

An IMD is defined in section 1905(i) of the Act as a "hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services." Under section 1905(a) of the Act, there is a general prohibition on Medicaid payment for any services provided to any individual under age 65 who resides in an IMD. This is commonly known as the "IMD exclusion." The IMD exclusion applies to any care or services provided inside or outside of the facility or hospital to a Medicaid beneficiary residing in an IMD, unless an exception to the IMD exclusion applies. As specifically relevant here, MAT and counseling and behavioral therapies provided in an IMD would not be covered by Medicaid unless an exception to the IMD exclusion applies.

Currently, there are several exceptions to the IMD exclusion and other authorities that permit short-term stays in IMDs. First, Medicaid payment is permitted for inpatient hospital services, nursing facility services, and intermediate care facility services provided in IMDs to individuals age 65 and older.[29] Second, Medicaid payment is permitted for inpatient psychiatric hospital services for individuals under age 21, sometimes referred to as the "psych under 21 benefit," furnished by a psychiatric hospital, a general hospital with a psychiatric program that meets the applicable Conditions of Participation, or an accredited psychiatric facility that meets certain requirements, commonly referred to as a "Psychiatric Residential Treatment Facility."[30]

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[24] SAMHSA. Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose. HHS Publication No. SMA-18-5093, page 39.
[25] 42 C.F.R. 8.12.
[26] SAMHSA. HHS Publication No. SMA-18-5093, page 39. Published November, 2018
[27] SAMHSA, Treatment Improvement Protocol: Medications for Opioid Use Disorder, May 2020. https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006
[28] 42 C.F.R 8.12(f)
[29] 42 C.F.R. 440.140
[30] 42 C.F.R. 440.160

Third, section 1012 of the SUPPORT Act, entitled "Help for Moms and Babies," added a new limited exception to the IMD exclusion. For more information, see the CMCS Informational Bulletin, "State Guidance for the New Limited Exception to the IMD Exclusion for Certain Pregnant and Postpartum Women, July 26, 2019."[31] Fourth, section 5052 of the SUPPORT Act, entitled, "State option to provide Medicaid coverage for certain individuals with substance use disorders who are patients in certain institutions for mental diseases," amended the IMD exclusion and established a new section 1915(*l*) of the Act. This provision permits states to cover a state plan option to provide services to Medicaid beneficiaries age 21 through 64 who have at least one SUD diagnosis and reside in an eligible IMD. The period of this state plan option is from October 1, 2019 through September 30, 2023. For more information, see State Medicaid Director Letter (SMDL) # 19-0003, Re: Implementation of Section 5052 of the SUPPORT for Patients and Communities Act – State Plan Option under Section 1915(*l*) of the Social Security Act, November 6, 2019.[32]

Other authorities that permit short-term stays in IMDs include section 1115 demonstrations. CMS announced a section 1115 demonstration initiative where states can receive federal financial participation (FFP) for the continuum of services to treat addictions to opioids or other substances, including services provided to beneficiaries residing in IMDs. For more information, see section 1115 SUD Demonstrations, SMDL # 17-003, Re: Strategies to Address the Opioid Epidemic, November 1, 2017.[33] Finally, states may receive FFP for monthly capitation payments for beneficiaries age 21 through 64 receiving SUD treatment in an IMD for a short-term stay of no more than 15 days during the period of the monthly capitation payment so long as criteria identified in the managed care regulation are met.[34]

SUPPORT Act Section 1006(b) Coverage

Section 1006(b) of the SUPPORT Act requires states to begin implementing MAT as a mandatory Medicaid state plan benefit for categorically needy populations for the 5-year period beginning October 1, 2020. Under the definition of the new mandatory benefit at section 1905(ee)(1) of the Act, states are required to cover all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat OUDs. CMS interprets the statute to require coverage of all forms of the drugs and biologicals that the FDA has approved or licensed for treatment of OUD. States are also required to cover counseling services and behavioral therapies associated with provision of the required drug and biological coverage.

Exception for Provider Shortage

Section 1905(ee)(2) of the Act provides that states may be excused from the mandatory coverage requirement if, before the requirement takes effect on October 1, 2020, the state "certifies to the satisfaction of the Secretary that implementing such provisions statewide for all individuals eligible to enroll in the State plan (or waiver of the State plan) would not be feasible by reason of

[31] https://www.medicaid.gov/federal-policy-guidance/downloads/cib072619-1012.pdf.
[32] https://www.medicaid.gov/federal-policy-guidance/downloads/smd19003.pdf.
[33] https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.
[34] 42 C.F.R. 438.6(e)

a shortage of qualified providers of medication-assisted treatment, or facilities providing such treatment, that will contract with the State or a managed care entity with which the State has a contract under section 1903(m) or under section 1905(t)(3)."

In CMS's view, the purpose of the new requirement is to increase access to MAT to treat OUD for Medicaid beneficiaries, and this can only be accomplished by increasing the enrollment in Medicaid of OTPs and other MAT providers and practitioners. CMS therefore expects states to conduct provider outreach and enrollment as they prepare to meet the new requirements. As discussed above, because methadone for treatment of OUD can only be provided in OTPs, states that do not already enroll OTPs as Medicaid providers will be expected to take action to do so. Additionally, if a state has MAT providers operating in the state that are not currently enrolled in the Medicaid program, states are expected to permit any willing and qualified provider to become a Medicaid provider for the newly required MAT benefit, so that beneficiaries may receive these services from the qualified and willing provider of their choice, consistent with section 1902(a)(23) of the Act and 42 C.F.R. 431.51.

CMS expects a state seeking the exception under section 1905(ee)(2) to document in its exception request that it has made a good faith effort toward enrolling providers of MAT for the Medicaid fee-for-service program, Medicaid managed care organizations (MCOs), and primary care case managers (PCCMs). Such documentation would include information about state review of MCO demonstrations of adequate capacity to furnish services under 42 C.F.R. 438.207; state standards for uniform credentialing policies that MCOs must use in accordance with 42 C.F.R. 438.214(b); and MCO policies and procedures for credentialing and re-credentialing network providers, required under 42 C.F.R. 438.214. A state requesting an exception should conduct a detailed accounting of the current MAT providers in the state, both those that are enrolled in the Medicaid program and those that are not, and should detail in its exception request the process that the state has undertaken to contract with MAT providers (and/or to encourage that MAT providers contract with the state's Medicaid MCOs and/or PCCMs) and the reasons why the providers are not willing to enroll.

We recognize that there may be state-specific administrative challenges with providing CMS with the information necessary for the Secretary to determine that the state has satisfactorily certified to the existence of a shortage of providers, especially in light of the fact that this guidance is being issued after October 1, 2020, the effective date of the new MAT coverage requirement. Therefore, CMS will not require states seeking this exception to have submitted a request for the exception before October 1, 2020. Instead, CMS will accept state requests for this exception on or before January 14, 2021. The request for the exception should be submitted at the same time as a request for flexibility under section 1135 of the Act with respect to state plan amendment (SPA) submission and notice timelines (as described further below). If a state is not granted an exception based on a shortage of providers or facilities, then the state will need to submit a SPA, and requesting flexibility with respect to SPA submission and notice timelines could help the state to safeguard a SPA effective date of October 1, 2020 if the exception request is denied. For further detail, please refer to the "SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines" section below.

CMS remains committed to providing technical assistance to states and other stakeholders in understanding the mandatory MAT benefit and developing implementation approaches that result in the provision of Medicaid services in a manner compliant with program requirements.

States that seek an exception based on a shortage of providers or facilities should submit their request on or before January 14, 2021 to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new "One CMS Portal," the request for the exception based on a shortage of providers or facilities should be submitted via the portal. The information detailed below should be included with the request, which should include the state's certification that it cannot come into compliance with the new requirement due to a shortage of providers. States may, but are not required to, use the following format.

_____ [Insert name of state] certifies that implementing the MAT benefit specified in section 1905(a)(29) of the Act is not feasible due to a shortage of qualified providers or facilities that will enroll in the state Medicaid program or contract with a Medicaid managed care organization (MCO) or Primary Care Case Manager to furnish one or more of the required MAT benefit components, and requests an exception from the requirement to provide this benefit for this reason.

The state's request should include all of the following information:

a. A description of the state's current qualified provider and facility status, including the number, type, and location of qualified providers and facilities that furnish MAT.
b. A brief description of the process that the state has undertaken to contract with all qualified MAT providers and facilities and reasons why the providers did not contract with the state or a managed care organization or Primary Care Case Manager.
c. For all Medicaid MCOs in the state, the written policies and procedures for selection and retention of network providers required by 42 C.F.R. 438.214, and copies of the assurances of adequate capacity and supporting documentation required by 42 C.F.R. 438.207(b), along with the state's certification and supporting documentation required by 438.207(d).
d. A description of the unmet need caused by the shortage of qualified providers or facilities among eligible children and adults whom the state identifies as individuals with OUD who could benefit from MAT.
e. A description of the state's plan to enroll additional qualified providers or facilities to ensure that all individuals eligible for MAT under the state plan (or a waiver of the state plan) are able to access it, and the date when the state thinks it will resolve the qualified provider or facilities shortage.

All exceptions approved under section 1905(ee)(2) will be for the full five-year period that the new MAT benefit is required. However, if a state decides to come into compliance with the MAT benefit requirement after receiving an exception under section 1905(ee)(2), CMS will be available to provide technical assistance to the state.

Extension of Compliance Deadline Due to Legislative Delay

Section 1006(b)(4)(B) of the SUPPORT Act (which was not codified in any provision of the Social Security Act) provides for an "exception" to the October 1, 2020 effective date of the new MAT benefit "for state legislation." Essentially, this provision provides for an extension to the required start date of the new coverage requirement if the only reason the state cannot come into compliance by October 1, 2020 is due to lack of state legislation that is needed to meet the requirement. Not all states will be able to seek this extension, because it depends on the timing of the state's first regular legislative session that began after the date of enactment of the SUPPORT Act (October 24, 2018). If the Secretary of Health and Human Services determines that state legislation is needed to bring the state plan into compliance with the new coverage requirement, the Secretary will not consider the state to be out of compliance with the new coverage requirement solely on the basis of a failure to enact the required state legislation before the first day of the first calendar quarter beginning after the close of the first regular session of the state's legislature that begins after October 24, 2018. If a state's first regular legislative session beginning after October 24, 2018 was the calendar year that began on January 1, 2019 and ended on December 31, 2019, the state would not be able to seek this extension because it would have had only until December 31, 2019 to enact any required legislation, and the first day of the first calendar quarter that begins after that date is January 1, 2020 – well before October 1, 2020.

If, however, a state's first regular legislative session beginning after October 24, 2018 does not end until on or after October 1, 2020, and the Secretary determines that legislation was necessary to meet the new coverage requirement, but the necessary legislative authorization was not obtained, the state could seek to delay compliance with the new coverage requirement until the first day of the first calendar quarter after the legislative session ends. Such a state is expected to come into compliance with the new coverage requirement by the first day of the first calendar quarter after the end of the legislative session, unless the exception in section 1905(ee)(2) applies. If a state has a two-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature for purposes of this extension. This means that a state would not have a longer extension if it has a two-year legislative session; such a state is treated like a state with a one-year legislative session, and any applicable extension ends on the first day of the first calendar quarter following the end of the first year of the two-year session.

CMS will grant an extension based on legislative delay only if a legislative delay is the only reason that a state cannot meet the requirement, and only when the first regular legislative session that began after October 24, 2018 ends on or after October 1, 2020, as discussed above. States should submit requests for the legislative delay extension on or before January 14, 2021 to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new "One CMS Portal," the request for the legislative delay extension should be submitted via the portal. The request should include documentation to support that the state's first regular legislative session that began after October 24, 2018 did not end until on or after October 1, 2020, that state legislation is needed to come into compliance with the new coverage requirement, and that the legislative delay is the only reason the state cannot come into compliance as of October 1, 2020. States are encouraged to submit a request for flexibility under section 1135 of the Act with respect to SPA submission and notice timelines,

as discussed below under "SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines," at the same time as the request for the legislative delay extension, in order to help safeguard a SPA effective date of October 1, 2020 if the state's request for a legislative delay extension is not granted. States may, but are not required to, use the following format for their legislative delay extension submission:

_____ [Insert name of state] requests an exception based on the need for legislative authority to cover the benefit described in section 1905(a)(29) of the Social Security Act, and submits documentation to support that the state's first regular legislative session that began after October 24, 2018 will not end until on or after October 1, 2020. [Describe the documentation that is attached or that accompanies the request and include information about the state's legislative calendar so CMS can determine the state's compliance date.]

States that are granted an extension due to legislative delay will still need to follow the SPA submission requirements below and submit a SPA consistent with the extended compliance deadline.

SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines

SPA effective date requirements outlined at 42 C.F.R. 430.20 provide for an effective date retroactive to the first day of the quarter in which the SPA was submitted. In addition, the public notice requirements at 42 C.F.R. 447.205 require states to publish notice of proposed changes in methods and standards for setting payment rates for services before the proposed effective date of the change. Accordingly, under these rules, states have only until December 31, 2020 to submit a SPA establishing coverage or payment for the new MAT benefit that would take effect October 1, 2020. Additionally, any SPA setting payment rates for the new benefit could take effect only after the state issues public notice of the proposed payment changes. Thus, states would have had to publish notice of their payment rate changes by September 30, 2020, for changes to take effect October 1, 2020.

CMS is aware that most states have been unable to submit a SPA for the new MAT benefit that meets these submission and notice timing requirements because they have had to focus almost exclusively on responding to the COVID-19 pandemic throughout much of 2020. At the same time, the opioid crisis has only been exacerbated by the COVID-19 pandemic. During the COVID-19 public health emergency (PHE), disruptions in treatment have resulted in a resurgence of relapses and fatal overdoses among individuals with OUD.[35]

Consequently, in order to help ensure that beneficiaries can access coverage for the new MAT benefit effective retroactively to October 1, 2020, CMS is giving states the opportunity to request that CMS exercise its section 1135 authority to modify the regulatory deadlines associated with SPA submission and public notice for coverage and payment SPAs for the new MAT benefit while the COVID-19 PHE is still in effect.[36] CMS strongly recommends that states submit these

[35] https://qz.com/1889798/covid-19-is-making-the-opioid-crisis-much-worse/

[36] Section 1135 authority permits the Secretary to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements during a PHE, in order to ensure, to the maximum extent feasible, that sufficient health care items and services are available to meet the needs of individuals enrolled in those programs.

requests on or before January 14, 2021. Specifically, if responding to the COVID-19 pandemic has delayed a state's ability to submit a coverage or payment SPA for the new MAT benefit or provide public notice of payment rate changes related to the new MAT benefit under the time frames set forth at 42 C.F.R. 430.20 and 447.205, the state may request flexibility regarding the timing of the SPA public notice and submission process for these SPAs, so that it can submit SPAs adding coverage and payment for the new mandatory MAT benefit at section 1905(a)(29) of the Act in the first quarter of 2021 that would be effective October 1, 2020. If a state does not submit a request for section 1135 flexibility as described herein and submits a SPA after December 31, 2020 to add the new mandatory MAT benefit, then the SPA's effective date would be on (or sometime after) January 1, 2021, beneficiaries might not be able to access all available MAT coverage before that date, and the state would not be in timely compliance with the new coverage requirement.

CMS will provide states with this flexibility only if they meet the following conditions. First, all state requests for modification of the deadlines for MAT SPA submission and public notice under section 1135 must be submitted and approved during the COVID-19 PHE, and all MAT SPAs must be submitted on or before March 31, 2021. Second, states must solicit and should consider public comments and comments received through tribal consultation before finalizing the SPAs that will take effect. States must conduct tribal consultation if required under section 1902(a)(73)(A) before submission of their MAT SPAs, even if CMS approves a modification under section 1135 of the 42 C.F.R. 447.205 notice timelines. Additionally, CMS strongly recommends that states conduct any public notice required under 42 C.F.R. 447.205 before submitting their MAT SPAs, even if CMS approves a modification under section 1135 of the timeline for that notice. If states have had to put in place interim coverage or rate policies for the new MAT benefit while preparing their SPAs for submission and finalizing them for approval, they would be expected to give effect to the rates and coverage policies that are ultimately approved retroactive to the effective date of October 1, 2020. States seeking these section 1135 flexibilities should submit a letter to Jackie Glaze at Jackie.Glaze@cms.hhs.gov by January 14, 2021. In addition to a statement explaining that the state's response to the COVID-19 pandemic has delayed its ability to submit coverage and/or payment SPAs for the new MAT benefit according to the regulatory SPA submission and notice timelines, the letter should include the following language (as applicable):

Request for Modifications under Section 1135

> Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, the state Medicaid agency requests modification of SPA submission requirements at 42 C.F.R. 430.20, in order to submit a SPA implementing section 1905(a)(29) of the Act by March 31, 2021 that would take effect on October 1, 2020.
>
> Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, the state Medicaid agency requests modification of the public notice time frames set forth at 42 C.F.R. 447.205, in order to obtain an effective date of October 1, 2020 for its SPA implementing statewide methods and standards for setting payment rates for the benefit described at section 1905(a)(29) of the Act. The state will issue public notice as soon as possible, and in no event later than February 28, 2021.

With respect to SPA submissions related to coverage and payment for the new MAT benefit, states should take the following steps.

States should submit an amendment to their Medicaid state plans (including to Alternative Benefit Plans, if applicable), no later than December 31, 2020 (or March 31, 2021, if CMS has approved section 1135 flexibility as discussed above) after having conducted public notice and tribal consultation, as needed, to cover, under the new mandatory benefit at section 1905(a)(29) of the Act, all FDA-approved or licensed drugs and biologicals used for MAT to treat OUD, as well as all forms of the drugs and biologicals approved or licensed by the FDA for MAT to treat OUD, and associated counseling services and behavioral therapies. States should submit their SPAs to the Regional SPA/Waiver mailbox that is currently used for other Medicaid SPA submissions. If a state is participating in the pilot for the new "One CMS Portal," the SPA should be submitted via the portal.

States that already use existing Medicaid authorities to cover items and services that will now be covered under the new mandatory MAT benefit, including FDA-approved or licensed drugs and biologicals used for MAT to treat OUD, and associated counseling services and behavioral therapies, are expected to submit a SPA to move their coverage of these items and services to a new page in their Medicaid state plans for the new mandatory benefit at section 1905(a)(29) of the Act.

In addition to submitting SPAs to add the mandatory MAT benefit to the state plan, states will need to propose associated changes to the payment section of the state plan. States will need to submit a new Attachment 4.19-B page for the mandatory benefit at section 1905(a)(29) that describes the rate-setting methodology used to pay for the services covered under the mandatory MAT benefit. The rate-setting methodology for the new MAT benefit must be consistent with section 1902(a)(30)(A) of the Act, which requires Medicaid payments to be "consistent with efficiency, economy, and quality of care" and to be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." States may include all medical service costs associated with furnishing the MAT benefit services to Medicaid beneficiaries (such as salaries, fringe benefits, supplies, and equipment) in their rate-setting methodology for the new MAT benefit, and the methodology must be a comprehensive description within the state plan consistent with 42 C.F.R. 430.10. As states have a variety of options to choose from in how they pay for MAT services, CMS is available to provide assistance to states as they develop SPA proposals. We encourage states to reach out to their state lead in the Medicaid and CHIP Operations Group for technical assistance.

As with any SPA submission, CMS expects states to comply with all SPA requirements that are not waived or modified, including those found in 42 C.F.R. 440.200, et seq., and to provide information on the source of the non-federal share of the service payments and information on the rate-setting methodology. Specific guidance related to SPA submission procedures may be found on the Medicaid.gov web page.

MAT Drug Coverage and Section 1927 Manufacturer Rebates

CMS interprets section 1905(ee)(1) of the SUPPORT Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the FDA has approved or licensed for MAT to treat OUD. More specifically, under the new mandatory MAT benefit, states are required to cover such FDA approved or licensed drugs and biologicals used for indications for MAT to treat OUD.

Statutory amendments were made to the original language at sections 1905(a)(29) and 1905(ee) by Section 2601 of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. No. 116-159) to specify that the rebate requirements in section 1927 shall apply to any MAT drugs or biologicals described under the mandatory benefit at section 1905(ee)(1)(A), that are furnished as medical assistance under sections 1905(a)(29) and section 1902(a)(10)(A), and are covered outpatient drugs, as that term is defined at section 1927(k)(2). In determining whether such a MAT drug or biological satisfies the definition of a covered outpatient drug, such MAT drugs or biologicals are deemed prescribed drugs for such purposes. More specifically, these amendments ensure that MAT drugs and biologicals can be included in the Medicaid Drug Rebate Program (MDRP). Additionally, for MAT drugs or biologicals that are also covered outpatient drugs, the amendments also ensure a state's ability to seek section 1927 rebates and apply drug utilization management mechanisms (such as preferred drug lists and prior approval), and establish a manufacturer's obligation to pay appropriate rebates and comply with all applicable drug product and drug pricing reporting and payment of rebates. The change in law is effective as if included in the enactment of the SUPPORT Act, which was October 24, 2018.

CMS expects that most manufacturers of MAT drugs and biologicals currently have in effect a rebate agreement with the Secretary and pay rebates to states for all drugs and biologicals that meet the definition of covered outpatient drug (COD) in section 1927(k) of the Act, and if not, that manufacturers of these drugs and biologicals will likely enter into a rebate agreement with the Secretary and pay rebates to states. Should an FDA-approved MAT drug or biological for OUD not meet the definition of a covered outpatient drug, or if the drug is a covered outpatient drug, but the manufacturer does not have a rebate agreement in effect with the Secretary, the state would still be required to cover the drug or biological under the MAT mandatory benefit, and the drug or biological would be eligible for FFP, but not rebates. States could subject MAT drugs or biologicals that are not covered outpatient drugs to prior approval or other utilization management mechanisms under 42 C.F.R. 440.230 as described below, including in order to prioritize coverage of those drugs that are covered outpatient drugs, but the state still must provide coverage for MAT drugs that are not covered outpatient drugs if they are medically indicated for the beneficiary, consistent with 42 C.F.R. 440.230(b).

State Use of Utilization Management Mechanisms

As a reminder, states may use utilization management controls to promote the efficient delivery of care and to control costs.[37] States can use the Section 1927 utilization management mechanisms for MAT drugs used for OUD that are covered outpatient drugs, such as

[37] Medicaid and CHIP Payment and Access Commission's (MACPAC) October 2019, Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid, https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf

encouraging the use of generic products, creating a preferred drug list, or choosing to implement prior authorization to manage drug classes that may require additional monitoring.

For MAT drugs that are covered outside of a rebate agreement, or would be covered outpatient drugs, except that they are subject to the limiting definition at section 1927(k)(3) (e.g. those that are paid as part of a bundle), states may use the utilization management mechanisms authorized under 42 C.F.R. 440.230. In these cases, states may propose limits on the amount, duration, and scope of these drugs under the MAT benefit, including to encourage the use of the most cost-effective MAT drugs and biologicals.

Support to States for Increasing SUD Treatment Options

Well-supported scientific evidence demonstrates that treatment for substance use disorders – including inpatient, residential, and outpatient treatment – is cost-effective compared with no treatment.[38] Existing Medicaid authorities, as well as new opportunities afforded by the SUPPORT Act, are available to help states expand their SUD service continuum, which can include MAT.

Section 1115 demonstration projects – In November 2017, CMS announced a section 1115 initiative that affords states the opportunity to receive federal financial participation (FFP) for expenditures on the continuum of services to treat SUD, including expenditures on treatment while Medicaid enrollees are residing in residential treatment facilities that are IMDs. Such expenditures can generally not be federally matched under Medicaid due to the IMD exclusion. As part of this initiative, states may develop innovative approaches to inpatient and residential care for individuals with SUDs that are expected to supplement and coordinate with community-based care to provide a robust continuum of care in the state. Participating states are required to ensure residential settings included in these demonstrations are either offering beneficiaries access to MAT on-site or facilitating beneficiaries' access to MAT off-site.[39]

Section 1003 of the SUPPORT Act – Section 1003 requires the Secretary to conduct a demonstration project to increase Medicaid SUD provider capacity. In 2019, CMS awarded planning grants to 15 states to conduct an assessment of SUD treatment and recovery needs of the state. The planning grants may also support activities to recruit, train, and provide technical assistance for providers; to improve reimbursement; and to expand the number or treatment capacity of Medicaid providers. Up to five of the states that received planning grants will be selected to implement demonstrations and receive enhanced federal reimbursement for increases in Medicaid SUD treatment and recovery services expenditures. For more information on this demonstration project, and the 15 states that were awarded planning grants, see the Medicaid.gov web page.[40]

Section 1006(a) of the SUPPORT Act – Section 1006(a) of the SUPPORT Act permits CMS to extend, at state request, the period of 90% federal match from eight to 10 fiscal year quarters for

[38] Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*. Washington, DC: HHS, November 2016. Chapter 4, Early Intervention, Treatment, and Management of Substance Use Disorders. https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf.
[39] SMDL # 17-003, Re: Strategies to Address the Opioid Epidemic, November 1, 2017, https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.
[40] https://www.medicaid.gov/medicaid/benefits/bhs/support-act-provider-capacity-demos/index.html

health home services provided to SUD-eligible individuals under a SUD-focused Medicaid health home SPA approved on or after October 1, 2018. The Medicaid health home state plan option (authorized under section 1945 of the Act) promotes coordination of primary and acute physical and behavioral health services and long-term services and supports. Specific guidance related to the health home Medicaid state plan option, including guidance on health home services, health home providers, state reporting, and developing payment methodologies, can be found on the Medicaid.gov web page.[41] Information on section 1006(a) of the SUPPORT Act is also available in the policy guidance tab on the Medicaid.gov web page.[42]

Section 7181 of the SUPPORT Act – Section 7181 of the SUPPORT Act reauthorized and modified the "State and Tribal Response to the Opioid Crisis" grants established under section 1003 of the 21st Century Cures Act. Section 7181 requires the grants to be awarded to Indian tribes in addition to states and territories. This provision also expands the types of activities that grants may support to include the establishment of prescription drug monitoring programs and training for health care practitioners in preventing diversion of controlled substances. It also emphasizes flexibility with use of funds by permitting resources to be directed "in accordance with local needs related to substance use disorders."[43]

Section 7181 authorizes $500 million for each of Fiscal Years 2019-2021, which would remain available until expended. It authorizes a set-aside of up to 15% for states with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of states according to the Centers for Disease Control and Prevention (CDC)[44]. SAMHSA will provide state agencies and Indian tribes with technical assistance on grant application and submission procedures, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing the opioid crisis.

Telehealth – HHS developed materials to help clarify how clinicians can use telemedicine as a tool to expand buprenorphine-based MAT for OUD treatment under current DEA regulations. This information includes a clinical practice example that is consistent with applicable DEA and HHS administered authorities. It is hoped that the materials help expand providers' ability to prescribe MAT to patients, including remote patients under certain circumstances. This information can be found on the HHS.gov web page.[45]

Telehealth could be especially helpful in supporting access to buprenorphine in rural areas, where there may be a smaller number of waivered providers able to prescribe buprenorphine for the treatment of OUD in settings other than federally regulated opioid treatment programs.[46]

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[41] https://www.medicaid.gov/medicaid/ltss/health-homes/index.html.
[42] CMCS Informational Bulletin, Guidance for States on the Availability of an Extension of the Enhanced Federal Medical Assistance Percentage (FMAP) Period for Certain Medicaid Health Homes for Individuals with Substance Use Disorders (SUD), May 7, 2019, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib050719.pdf.
[43] https://www.govinfo.gov/content/pkg/PLAW-115publ271/html/PLAW-115publ271.htm
[44] https://www.cdc.gov/drugoverdose/data/statedeaths.html
[45] https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf.
[46] U.S. Department of Health and Human Services. Telemedicine and Prescribing Buprenorphine for the Treatment of Opioid Use Disorder. DHHS web site. September 2018. https://www.hhs.gov/blog/2018/09/18/using-telemedicine-combat-opioid-epidemic.html.

CMS also released a State Medicaid Director Letter (SMDL) in June 2018, "Leveraging Medicaid Technology to Address the Opioid Crisis,"[47] that includes a section on how states can leverage telehealth technologies to improve access to SUD treatment. This SMDL also discusses the potential availability of enhanced federal funding to support telehealth-enabling technologies. Additionally, consistent with section 1009(b)(1) of the SUPPORT Act, CMS issued guidance on federal Medicaid reimbursement for services to treat SUD furnished via telehealth, including in School-Based Health Centers.[48] Services discussed in this guidance include assessment, MAT, counseling, medication management, and medication adherence with prescribed medication regimes.

Conclusion

MAT is an effective, comprehensive, and evidence-based treatment that is integral to addressing the nation's opioid crisis. Section 1006(b) of the SUPPORT Act amended the Social Security Act to require states to cover MAT for all eligible to enroll in the state plan or waiver of state plan. The new mandatory MAT benefit includes all FDA-approved drugs and licensed biologicals used for MAT to treat OUD, as well as associated counseling and behavioral therapies. CMS interprets the statute to require coverage of all forms of drugs and biologicals approved or licensed by the FDA for use as MAT to treat OUD. CMS is available to provide technical assistance and looks forward to working with states to ensure Medicaid beneficiaries with OUD receive the services they need. If you have any questions, please contact Kirsten Jensen, Director of the Division of Benefits and Coverage, at Kirsten.Jensen@cms.hhs.gov.

Sincerely,

/s/

Anne Marie Costello
Acting Deputy Administrator and Director

cc: State Mental Health Directors
State Substance Use Directors
State Opioid Treatment Authorities
State Budget Officers
State Pharmacy Directors
National Association of Medicaid Directors
National Association of State Mental Health Program Directors
National Association of State Alcohol and Drug Abuse Directors
Association of State and Territorial Health Officials
National Association of State Budget Officers
National Conference of State Legislatures

[47] https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.

[48] CMCS Informational Bulletin, April 2, 2020. Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth. https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib040220.pdf

Disclaimer Language: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

ease repeal of the federal Medicaid IMD Exclusion that prevents Medi-Cal payment for inpatient bed stays in free-standing psychiatric facilities of over 16 beds. [redacted] This is insane and costly.

Dear Angeli Lee and Amanda Font,

Our goal in sending a response regarding the CalAIM project is to open a dialogue with the Department of Health Care Services and our leadership team at ProgenyHealth. ProgenyHealth is a company 100% on NICU care management. We are not writing to sell you on why ProgenyHealth…it is to illustrate why the rising cost of care you are seeing in California deserves a comprehensive NICU care management solution.

By maintaining the status quo, DHCS will continue to see these same variations in care, cost, and process. If these statistics sound familiar, they could be. Many are from the thought leaders in California – your home state and mine:

- The latest CDC statistics confirm Medi-Cal pays for over **15,000 NICU admissions per year**.[1] Medi-Cal is the largest payer for NICU admissions in the country, therefore this spend should be in the top 5 of your high-cost trends.
- A recent study confirmed that NICU length of stays have increase by **8 days** over the course of 14 years. This could equate to **additional $28,000 per baby** for each NICU admission. This also means infants are separated from their family for more than a week longer.[2]
- Schulman et al reported high variability in NICU admission rates for California. And "88% of these admissions **did not meet high illness acuity criteria**". High acuity cases did not explain the variability in admission rates.[3]
- "Hospitals seek to reduce overall length of stay for Medi-Cal covered pregnancies but have limited business incentives to reduce NICU use in particular…because NICU stays receive enhanced Medi-Cal reimbursement and are highly profitable for hospitals." [4]
- Another California study found **wide variation in quality of care** and the NICU designations were not association with quality. "Subcomponent analysis revealed trends for higher performance of Level IV NICUs on several process measures, including antenatal steroids and any human milk feeding at discharge, but lower scores for several outcomes including any health care associated infection, pneumothorax, and growth velocity."[5]
- Socioeconomic factors are also affecting quality of care in NICUs. California data revealed **NICU quality of care is lower in areas of lower socioeconomic status**.[6]

We understand CalAIM is focused on three goals. ProgenyHealth can help address more consistent and seamless system, delivery system transformation and payment reform. Our team recognizes that CCS plays a big role in managing the NICU cases in California. The vast majority of NICU cases are managed via California Children's Services (CCS). Our NICU focused Utilization Management solution could work in conjunction with CCS. The ProgenyHealth team of NICU experts could focus on utilization management of providers across the country, while CCS continues their focus on case management for these babies and their families. Both groups will show up with strengths to have an impact on outcomes in this very fragile population – impacting health outcomes and economic outcomes.

Do not let another year go by of rising trends and variation in care. Acting now, can start reversing these trends and improving the lives of this vulnerable population.

References:

1. CDC - https://wonder.cdc.gov/natality-expanded-current.html
2. Discharge Age and Weight for Very Preterm Infants: 2005–2018" Erika M. Edwards, Lucy T. Greenberg, Danielle E.Y. Ehret, Scott A. Lorch and Jeffrey D. Horbar. Pediatrics February 2021, 147 (2) e2020016006; DOI: https://doi.org/10.1542/peds.2020-016006

3. Schulman, J, et al. Association Between Neonatal Intensive Care Unit Admission Rates and Illness Acuity; JAMA Pediatr. 2018 Jan; 172(1): 17–23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5833518/
4. California Health Care Foundation. 2020 https://www.chcf.org/wp-content/uploads/2020/08/InnovationLandscapeSeriesMaternityCareMediCal.pdf
5. Profit, Jochen, et al. The Association of Level of Care With NICU Quality; Pediatrics. 2016 Mar; 137(3): e20144210. doi: 10.1542/peds.2014-4210
6. Padula, A.M., et al. Multilevel social factors and NICU quality of care in California. *J Perinatol* 41, 404–412 (2021). https://doi.org/10.1038/s41372-020-0647-8

Sincerely,

Mary Villa, MS, RD
Director of Strategic Accounts
ProgenyHealth, LLC | www.progenyhealth.com
Cell: 760.390.6307

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Hello,

Attached is a comment letter that expresses concerns with DHCS's differing treatment of FDA-approved MAT medications contained in the 1115 Medi-Cal Waiver extension request for the CalAIM relaunch. In the comment letter, stakeholder organizations ask that DHCS require coverage of all three MAT medications available on the market, to better allow treatment access to individuals who are struggling to fight addiction.

The comment letter is signed by ten stakeholder organizations who are active in the mental health and addiction spaces. Please consider the concerns and requests outlined in this letter as DHCS moves forward with the CalAIM relaunch.

Sincerely,
Kimaya Gokhale

April 23, 2021

Will Lightbourne, Director
Department of Health Care Services
1501 Capitol Avenue, Suite 6001, MS 0000
Sacramento, CA 95814

RE: Comments in Support of Parity for All U.S. FDA-Approved Medication Assisted Treatments (MATs) – DHCS (Revised) CalAIM Proposal for 2022 and Beyond

Dear Director Lightbourne:

We, the undersigned organizations, would like to reiterate our concern expressed last year in our March 6, 2020, letter regarding the California Department of Health Care Service's (DHCS) differing treatment of FDA-approved medications contained in the 1115 Medi-Cal Waiver extension request for the CalAIM relaunch. DHCS's proposal continues to differentiate between FDA-approved injectable naltrexone and the other FDA-approved medication assisted treatments (MAT) methadone and buprenorphine by requiring that counties only cover methadone and buprenorphine, while allowing coverage of injectable naltrexone to be optional. This policy does not allow those suffering from substance use disorder (SUD) to reliably access all the treatment options available to them, and is not aligned with the concept of "no wrong door" for patients seeking treatment services.

In addition, DHCS's proposal is not in alignment with current federal policy. Services 1006(b) of the SUPPORT Act amended the Social Security Act to require states to cover MAT for all who are eligible to enroll in the state plan and all waivers of the state plan. The new mandatory

benefit includes all FDA-approved drugs and licensed biologicals used for MAT. CMS's new recommendations are in alignment with the recommendations of the medical community and federal agencies, as well as the previous recommendations that we, the undersigned, made to DHCS in our March 6, 2020, letter.

By continuing to only require coverage of two out of the three available MATs, DHCS is restricting patient access to all available treatments for substance use disorder. The FDA, SAMHSA, the National Institute of Drug Abuse, and the National Academy of Sciences have all affirmed the efficacy of all three MAT options and recommended that they all be made available to patients.

Patients seeking treatment should be able to access all effective treatments available. For some patients, the two medications that are currently required to be covered, methadone and buprenorphine, can cause side effects such as nausea, vomiting, constipation, muscle aches, cramps, constipation, fever, cravings, irritability, and inability to sleep. These patients should be afforded the opportunity to try injectable naltrexone as it might be the best option for them to maintain their sobriety and achieve better quality of life.

At the time of this writing, DHCS has yet to respond to the concerns brought forth in our previous letter. We urge the department to take into consideration the recommendations put forth in this letter, the recommendations of highly reputable federal agencies such as the FDA and SAMHSA, as well as the actions of CMS in expanding their coverage requirements to include all three forms of MAT.

We ask that you reconsider your proposal to continue the current policy of separate opt-ins for counties for the different medications and recommend that a single policy should cover all three FDA-approved medications at parity.

Thank you,

[redacted]

Gretchen Bergman
Executive Director, A New PATH (Parents for Addiction Treatment & Healing)

[redacted]

Betty Dahlquist
Executive Director, California Association of Social Rehabilitation Agencies

[redacted]

Heidi Strunk
President & CEO, Mental Health America of California

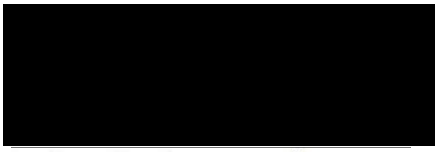
Le Ondra Clark Harvey
Director of Policy &
Legislative Affairs, CBHA

Pete Nielsen
CEO, California
Consortium of Addiction
Programs and
Professionals

Catherina Isidro Executive
Director, Forensic Mental
Health Association of
California

Liz Helms
President & CEO,
California Chronic Care
Coalition

Yvonne Choong
Vice President, Center for
Health Policy, California
Medical Association



Le Ondra Clark Harvey
Executive Director,
California Access Coalition

Al Senella
President, California
Association of Alcohol and
Drug Program Executives

Dear Dr. Pfeiffer:

Thanks for your e-mail of earlier this afternoon.

As you know, it took DHCS quite some time to, first, afford equal access to all FDA-approved MATs without prior authorization in Medi-Cal generally, as well as in Narcotic Treatment Program (NTP) settings, specifically. Thereafter, it took even more time and several efforts. to provide equal NTP setting access – in the form of supportive services coding and reimbursement level specification – to the ancillary services (e.g., psychosocial and counseling support, and other supportive services) critical to afford patients the opportunity for success with all forms of MAT.

Ironically, following the enactment of AB 395 (Ch. 223, Stats. 2017) which statutorily made all MATs available in licensed NTPs at the urging of Treatment Providers, DHCS published "MHSUDS INFORMATION NOTICE NO.: 18-004" which summarized AB 395 as "*not add(ing) funding for Expanded MAT services*." Both the Assembly and Senate Appropriations analyses of the law indicated that costs were expected to be minimal, and therefore the bill was not designated as fiscal legislation. DHCS provided no technical assistance on the matter to the contrary.

Despite possessing broad authority to "*implement, interpret, or make specific the provisions of the legislation by means of plan or provider bulletins, or similar instructions, until regulations were adopted on or before January 1, 2021*," DHCS declined to exercise this broad authority to initiate the development of treatment services coding or reimbursement rates, nor to seek any necessary funding over the course of the next several years.

Fortunately, with the recent enactment of AB 80 (Ch. 12, Stats. 2020), a budget trailer bill, state law now expressly mandates "Drug Medi-Cal reimbursable services" to be all MATs ("*Any medication approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and all biological products licensed under Section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders.*") and the critical psychosocial support and ancillary services for successful recovery (*"Counseling services and behavioral therapy…Case management services, including supportive services to assist a person with substance use disorder diagnoses in gaining access to medical, social, educational, and other needed services* (and) *Aftercare services*.")

In short, particularly with your welcome expression of DHCS support for all forms of MAT, it seems a simple and straightforward clarification - along the lines of that recommended to DHCS over the course of the last year by many patient-centered organizations - that the language in the Drug Medi-Cal Organized Delivery System Renewal and Policy Improvement draft proposed for submission to the federal government clearly and unequivocally reflect the improvements and advances in state law. A constructive option for an update in the language of the request for approval to the federal government could read as follows:

"Additional Medication Assisted Treatment

Counties are required to cover opioid treatment program services, also called Narcotic Treatment Programs. Currently counties may elect to cover additional medication assisted treatment, which includes the ordering, prescribing, administering, and monitoring of all medications for SUD treatment.

DHCS proposed in the 12-month extension request to keep the additional medication assisted treatment (MAT) services as an optional benefit but clarified the coverage provisions to require that all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to medication assisted treatment. For the period of this requested Waiver, DHCS proposes that additional medication assisted treatment (MAT) services be a required benefit and is clarifying that the coverage provisions require that all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to all FDA-approved medication assisted treatments. The goal is to have a county-wide multi-delivery system of coverage."

Simple, consistent changes could be made throughout the Proposal, as necessary for clarity.

We look forward to working with you and the Department in this collaborative effort.

Thank you.

:John

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With its emphasis on addressing social determinants of health and health disparities, CalAIM expands the focus of health care beyond the traditional medical model. Addressing social determinants and heath disparities involves a range of entities that are not primarily health care providers, including community based organizations and governmental agencies ranging from departments of behavioral health and social services as well as public health, but also jails, probation, and schools. Entrusting our efforts to address social determinants to managed care plans puts health plans in charge of key elements of our social service system. This is a big leap of faith.

When the State of California instituted managed care for MediCal, it allowed counties to establish local initiatives as an option to turning over managed MediCal to health plans. We ought to apply the same logic to CalAIM and give local jurisdictions the option of providing CalAIM services before turning to managed care plans to assume this responsibility. Alternatively, managed care plans could be required to offer to contract with local jurisdictions to provide CalAIM services. Local jurisdictions that elect to provide CalAIM services can be held accountable for similar metrics to those for managed care plans. Local jurisdictions should also have access to some of the potential savings associated with CalAIM services such as reduced ER visits or hospitalizations for high risk populations through some type of value-based contract.

There are several potential benefits of requiring local jurisdictions to have right of first refusal for carrying out CalAIM services. First, if there are multiple health plans in a county, there will inevitably be redundant management and infrastructure. Having a single entity responsible will streamline overhead. The other issue is that multiple competing health plans do not have incentives to offer health and wellness services that could benefit the entire neighborhood or community, such as health literacy messages that reach enrollees in all health plans, investments in parks and walking trails to encourage physical activity, or incentives for bringing healthy foods into food deserts. Finally, allowing local jurisdictions to head up CalAIM services is a way to invest in good government and reward and incentivize a more coordinated and responsive governmental structure, rather than sending more tax dollars to for-profit companies.

Just as with managed MediCal, not all local jurisdictions will want to create a CalAIM-oriented local initiative. However, having a CalAIM public option will help raise the bar for managed care plans and could stimulate local jurisdictions to think more broadly about how they can coordinate human and social services and improve the health and well being of their communities.

John Zweifler, MD, MPH
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encompass
COMMUNITY SERVICES

CHANGING LIVES, BUILDING COMMUNITY SINCE 1973

April 26th, 2021

Subject: CalAIM Section 1115 & 1915(b) Waivers

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899−7413

Dear Angeli Lee and Amanda Font,

On behalf of Encompass Community Services of Santa Cruz County, thank you for providing an opportunity to submit public comments in response to the State of California Department of Health Care Services key provisions of the CalAIM Initiative.

Encompass Community Services is the largest human services agency in Santa Cruz County, serving the community since 1973. Encompass Community Services operates approximately 40 programs county-wide that provide counseling for individuals, families, and youth; substance use disorder residential and outpatient treatment; reentry services; housing support; payee services; and Head Start and Pre-K. Our agency served over 2,000 unique individuals in the 2019-2020 fiscal year.

Encompass Community Services strongly supports the following proposed DMC-ODS authorizations:

- **Remove the limitation on the number of residential treatment episodes that can be reimbursed in a one-year period.** Our clients struggle more than they anticipate in residential treatment, and relapse is a common occurrence. Removing the limitation on the number of residential treatment episodes acknowledges that recovery is not a linear journey and allows clients to access treatment when they are ready to do so throughout the year. Removing the limitation also allows clients the flexibility to attend to personal emergencies while in treatment. For example, one of our clients needed to abruptly leave treatment to address a family emergency during the pandemic. The client was not forced to choose between losing a treatment episode and their family; they were able to leave treatment to attend to their emergency and subsequently return to complete treatment.
- **Require counties to mandate that all DMC-ODS providers demonstrate they either directly offer or have effective referral mechanisms for MAT.** Our internal MAT team

ADDRESS 380 Encinal Street Suite 200, Santa Cruz, CA 95060 | PHONE 831.469.1700 | FAX 831.425.1905 | EMAIL info@encompassCS.org | WEB www.encompassCS.org

successfully transitions clients from heroin to suboxone on a regular basis. This is a delicate process that requires rigorous medical oversight. Our MAT services allow clients to safely enter residential treatment services without needing to wait for an open withdrawal management bed, which is extremely limited in our county.

Thank you again for providing the opportunity for stakeholder input. Please do not hesitate to contact me with questions.

Sincerely,

[redacted]

Linda Alves, LCSW, MPP
Director of Compliance & Quality Improvement
Encompass Community Services
380 Encinal Street
Suite 200
Santa Cruz, Santa Cruz County, CA 95060
(831) 261-4866
Linda.alves@encompasscs.org

Hello,
Per instructions on the CalAIM 1115 Demonstration and 1915(b) Waiver website, could we please receive a copy of the 1115 application and 1915(b) overview to assist us in providing public comment?

Many thanks,
Chris

Christine Stoner-Mertz, LCSW (*she/her/hers)*
Chief Executive Officer
California Alliance of Child and Family Services
2201 K Street, Sacramento 95816
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www.catalyst-center.org

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Hello.

I am writing to comment on the improvements to behavioral health medical necessity and "no wrong door" components of CalAIM. I agree strongly with the "no wrong door" approach and believe it is necessary also for adults, as there are many barriers and complicating factors for adults attempting to access behavioral health services. In primary care, we see the result of that: patients who are disconnected/never been connected to care and the challenges of coordinating with the LMHP and the mild-moderate carve-out provider (Beacon). In my experience as a child, adolescent, and TAY therapist through FSP, I saw the barriers families and individuals faced when needing to step down; I also saw the gaps in care and barriers to care at lower levels that would have prevented the individual/family from needing FSP and higher levels of care.

I also see, and hear feedback from our pediatric psychiatrists, the importance of removing obstacles to behavioral health services, including behavioral interventions, medication management, and, where appropriate, therapeutic care for children, adolescents, TAY, and adults of all ages when those individuals have developmental delays/intellectual disability. Often these individuals could benefit from higher levels of behavioral/therapeutic and medication management services than can be handled in primary care or coordinated with Beacon; however, they are barred from entry to specialty MH services due to their developmental delay/intellectual disability diagnoses. These clinicians are skilled and knowledgeable of the specialty delivery system yet find their patients often turned away due to the primary diagnosis that is excluded. I would like to see this addressed in the "no wrong door" policies and requirements in order to ensure they do not fall through the gaps.

Thank you for the opportunity to provide feedback on this very important transformation.

Lucy E. Marrero, MA LMFT CPHQ
Ambulatory Care, Health Care Agency
Quality, Integrated Behavioral Health, Population Health, Clinical Operations
800 S. Victoria
Hall of Administration, L 4615
Ventura, CA 93009
(805) 339-1123
lucy.marrero@ventura.org

VENTURA COUNTY
AMBULATORY CARE

Re: Apply now for the CalAIM 1115 Institution for Mental Diseases (IMD) Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) Exclusion Waiver

Dear Ms. Lee and Ms. Font:

I am writing to request that California apply immediately for the 1115 IMD SMI/SED Exclusion Waiver. Since the availability of this waiver in 2018 we have lost Federal dollars we could now be using to increase our treatment bed capacity not only for IMDs for emergency acute care, but for every level of the continuum of care in our communities. Because we have the SUD waiver, applying for the 1115 SMI/SED waiver will not be as difficult—it is comparable to an amendment. I have been hearing what a "heavy lift" it will be to apply, and that is just not the case. Other big states, such as Utah and Idaho, have applied. Isn't it our jobs to work on behalf of those who are so sick they cannot work or pay for healthcare coverage? The Congressional intent of Medicaid is to provide coverage for people unable to provide for their healthcare and are suffering on the street, in jail cells and in the back bedrooms of families.

Serious mental illnesses are diseases of the brain. Dr. Henry Nasrallah describes psychosis as a "brain attack" that needs immediate treatment, like a stroke, for the best outcome. Imagine your loved one has a stroke or heart attack and you are unable to find a treatment bed at the appropriate level for needed care, or any bed at all. We don't put up with this dismal lack of medical attention for any other organ-based illness. The archaic discriminatory IMD exclusion has limited our bed capacity for our sickest citizens who cannot recognize they are ill, are trapped in their malfunctioning brains in an altered state of reality, and need intense treatment to become stabilized on the right medications with therapy until they can think clearly and then direct their own care. IMD care at this level is not a dirty word and is part of the medical protocol for these progressive diseases. What ARE dirty words when sick people cannot get the medical attention they need: homelessness, incarceration and the morgue.

The 1115 IMD SMI/SED waiver will save California money, but more importantly, save our sickest citizens—sons, daughters, parents, friends, colleagues—lives by getting more people into needed treatment. Brain diseases are treatable, and people can live their best lives when they have access to appropriate, prompt medical care. We owe our sickest citizens this basic human right. We cannot afford to delay lifesaving treatment one more day. Please apply for this waiver immediately.

Thank you.

[redacted]

Serious Mental Illness/Brain Disorders Advocate
Hope Street Coalition
Schizophrenia & Psychosis Action Alliance, Board Member
California Advocates for Treatment

National Shattering Silence Coalition (NSSC)
National Alliance on Mental Illness (NAMI)
[redacted]
http://http//www.linkedin.com/in/lindalmimms

"Every fall deserves a standing up."

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Fong
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

April 28, 2021

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Lee and Ms. Font:

NAMI Santa Barbara County strongly endorses NAMI California's recommendation that California apply for the Institution for Mental Disease's (IMD's) Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) Exclusion waiver without delay.

The federal demonstration project would enable California to receive Medicaid matching funds for short-term stays in psychiatric hospitals or residential treatment settings that are currently considered IMDs and ineligible for Medicaid match.

In our own county, a severe shortage of inpatient, psychiatric beds has resulted in excessively lengthy (and growing) waits in our emergency rooms for bed placement, with some patients on 5150 holds simply being released when their 72-hr. holds expire, and others having holds rescinded with referrals to 24-hr. crisis care insufficient to serve their need for hospitalization.

Our county's Psychiatric Health Facility (PHF) has an artificially constrained capacity of 16 beds due to the IMD exclusion, far less than the need. Placement in an in-county bed fosters a pathway to successful step-down to community-based care, but too few of our seriously ill citizens can secure such beds supporting recovery.

Considering the demonstration requires states to ensure people with mental illness have access to a robust continuum of community-based alternatives to hospitalization, we believe participating in this demonstration does not put individuals at a higher risk of receiving IMD levels of care. Substantial qualitative and quantitative evidence shows that people in crisis in our state simply do not have the equitable access to hospitalization they need and deserve.

Please apply for the IMD Exclusion waiver for SMI/SED without delay.

Respectfully,

Lynne Gibbs, Chair
NAMI SBCO Public Policy Committee

Housing That Heals:
Finding a Place Like Home for Families Like Ours

April 29, 2021

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Lee and Ms. Font:

As the co-authors of the Housing That Heals white paper issued in May 2020, we write to share our support for the overall CalAIM concept. We recognize the intent to build off the success of the previous 1115 and 1915 b Waivers and understand the benefits to many county health systems, including our own of Contra Costa. However, we strongly disagree with the decision to postpone the inclusion of the SMI/SED IMD Exclusion Waiver until July 2022. A placeholder without promise is unacceptable.

At a time when equity and anti-discrimination are a local, state, and national priority, California must move to implement the demonstration waiver that will help to reduce the discrimination and suffering caused by the lack of appropriate treatment beds at all levels of care for our loved ones living with SMI and SED. Our Housing That Heals paper defined the drivers of despair and disparity with both system data and what we call "data of the soul," which is [redacted] carved-out cliff in California's continuum of care. We also defined a system of solutions. Our focus was not only on our families but on all California communities that have human beings waiting for access to a bed instead of a tent, trauma, torture, and tragedy. Our families and communities simply cannot continue to wait for the state to fix every social, economic, and bureaucratic barrier to care.

The state has had years to innovate, integrate and investigate the finance and delivery arms of the behavioral health systems. We see the good intentions of this effort. As former Mental Health Commissioners, MHSA Stakeholders, state and national activists, we have been part of that journey and have partnered with patience with anyone who will help families like ours. We intend to continue collaborative conversations with all local and state partners who have authentically welcomed us to their tables to consider shared agendas, visions, and priorities. We were proud to co-sign the attached letter of support for the Governor's proposed $750 million infrastructure budget item that will signal our state's intent to build up our community-based residential infrastructure. However, we don't see the IMD Waiver opportunity and the infrastructure investments as either/or decisions. We need a both/and approach to the current crisis of care in California.

Part of our Housing That Heal's journey was about finding alternatives to IMDs and locked facilities. We wanted to shatter the myth that moms like us just want to lock up their seriously mentally ill adult children and throw away the key. We wanted to show that it is the system that is designed to lock them up either in solitary cells, IMDs, or in their untreated minds on skid rows. We wanted to find the key that would open doors to healing homes. But, many of those homes will not accept people who are too sick and not medically stabilized enough to live in the community.

[redacted], we are concerned about CalAIM's lack of focus on the current SPMH adult population. We acknowledge the spectrum of solutions needed to end suffering in California for those heroically living along the continuum of behavioral health care. We do understand the need to align our Managed Care Plans and Mental Health Plans. However, we don't understand the need to wait any longer for focused attention on the population that has too often been forgotten and "underfunded from the start."

We are still being told that it is just too much of a "heavy lift" to include the SMI/SED IMD Waiver in the current proposal. We were told that in November 2018 when this waiver opportunity first became available. So, we waited. Then the pandemic hit our world and we saw very heavy lifting taking place to save lives. We saw freedoms withheld to protect the safety of our communities. [redacted]. We saw them left in solitary. We saw them locked in State Hospitals or IMDs longer than was medically necessary waiting for a step-down bed. We saw them dumped from hospital beds and returned to inappropriate lower levels of care. We saw them suffering on the streets. Everyone sees them now. There is no place left to hide.

[redacted] We do not want "anyone, anywhere or anytime" to be denied access to the right door. But, without access to both medically necessary and recovery-based services, the human log jam will grow and our loved ones will continuously cycle through the wrong doors.

If we want a California for all, then all must mean all. If we want equity for all, then all must mean all. If we want parity for all, then California cannot wait to apply for the IMD Exclusion Waiver opportunity. If we want a right to shelter and treatment for all, then California must stop waiving the right care at the right time for the stage 4 adult specialty mental health population.

Families like ours and allies across the state strongly support the application for the SMI/SED waiver now (see attached.)

Respectfully,

Teresa Pasquini and Lauren Retagliatta
Housing That Heals
https://hth.ttinet.com/Housing_That_Heals_2020.pdf

Families like ours and allies from over 20 counties across the state strongly support the application for the SMI/SED IMD Demonstration Waiver now:

Alameda County

Dianne Lam
Oakland, Ca.
Alameda County

Patricia Fontana
Family Advocate Alameda County
Voices of Mothers co,-founder
Families Advocating for the Seriously Mental Ill (FASMI)

Candy and Al De Witt
Alameda County

Alison Monroe
Alameda County, CA

Gloria Vasconcellos
Alameda County

Amador County

Samuel David Ferrise
Amador County

Contra Costa County

Kim Mai
contra costa county

Debbie Walsh
Contra Costa

Tamara Hunter
Contra Costa County

Rebekah Sparling Cooke
Danville, CA
Contra Costa County

Laura Fryer
Contra Costa County

Rick Fryer
Contra Costa county

Jack Fryer
Contra Costa County

Mike Cooke
Contra Costa County

Paula Bull
contra Costa county

Laurie Bothwell
Contra Costa county

Jacquie Kunsman
Contra Costa County

Lauren Downes
Contra Costa County

Daniel Wilson
Contra Costa County

El Dorado County

Diane Rabinowitz
El Dorado County

Kern County

Deborah Fabos
Kern County

Fawn Kennedy Dessy
Kern County

Jean Marie Harris
Kern County

Los Angeles County

Anna Penido
Los Angeles, 90066

Mark Gale
Los Angeles County

Barbara B Wilson LCSW EDPNA
Los Angeles County

Shelley Hoffman
Los Angeles County

Susan Levi
Los Angeles, CA

Gail Evanguelidi
TREATMENT PREVENTS STIGMA
LA County

Cheryl Perkins
Mother Advocates for the SMI,LAC
Los Angeles County

Marin County

Denise Spencer
Marin County

Nevada County

Tomi Riley
Nevada County

Orange County

Virginia Garr
Orange County, CA
92647

Plumas County

Denise Pyper
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Kathy Day, Family Member
President, Pro Caregiver Consultants
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Carmichael, CA
Sacramento County

Lynn Whitney
Carmichael, CA
Sacramento County

Mary Ann Bernard
Sacramento, CA

Nancy Brynelson
Sacramento County

Kelli Butler
Sacramento County

San Diego County

Linda L. Mimms, MA Public Policy
Schizophrenia & Psychosis Action Alliance
San Diego County

Dr. Larry T Mimms, CEO Procise Dx, Inc.
San Diego County

Mary Courtney-Sheldon
San Diego County

Katherine Smith-Brooks
San Diego County

San Francisco County

Sheila Ganz, family member
San Francisco

Virginia Lewis, LCSW
San Francisco. 94123,
California

Dale Milfay
San Francisco, CA

San Mateo County

Claire Harrison
San Mateo County

Santa Barbara County

Lynne Gibbs
Santa Barbara

Santa Clara County

Ed and Lisa Baumann
Santa Clara County

Alison Morantz
Santa Clara County

Santa Cruz County

Lynda Kaufmann
Santa Cruz County

Solano County

Susanne Geotz
Solano County CA

Sherrie Byrum Rasmussen
Solano County

Catherine J. Rippee-Hanson (**CJ Hanson**)
Solano County, California

Lynn Root
Solano County

Linda Rippee Privette
Solano County

Judith Baldwin
Solano County

Cathleen Forte
Solano County CA

Pamela Wilcoxson
Solano County CA

Karen Newton
Solano County

Sarah Privette
Solano County, CA

Sonoma County

Margaret Pasquini
Sonoma County

Stanislaus County

Linda Mayo
Stanislaus County
MHSA Stakeholder
California Advocates for SMI
Mother of twins with schizophrenia

Ventura County

Mary Haffner
Ventura

Jeffery Hayden PHD
Ventura County

Serving Multiple Counties

Psynergy Programs, Inc.

CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

Submitted via e-mail at rene.mollow@dhcs.ca.gov

April 7, 2021

Rene Mollow, Deputy Director
Health Care Benefits and Eligibility
Department of Health Care Services
P.O. Box 997413 MS 0000
Sacramento, CA 95899-7413

RE: Follow-up Comments for Tribal Designee Meeting

Dear Ms. Mollow:

On behalf of the California Rural Indian Health Board, Inc. (CRIHB), a network of 19 Tribal Health Programs (THP), controlled and sanctioned by 59 federally recognized Tribes,[1] serving American Indian and Alaska Native (AIAN) people residing in California, I write this letter to provide input and recommendations regarding several critical topics discussed during the Tribal Designee meeting on March 5, 2021.

1) Vaccine Administration Reimbursement: Reimburse the associated COVID-19 vaccine administration fee at the Indian Health Service Memorandum of Agreement (IHS MOA)/ All Inclusive Rate (AIR) for Tribal IHS MOA and Tribal Federally Qualified Health Center (FQHC) providers based on the number of required doses through a modification to published fee schedules.

As previously requested, CRIHB is advocating for an increase in reimbursement rates for COVID-19 vaccine administration to at least match the IHS MOA/AIR fee schedule for Tribal FQHC/IHS MOA providers. Increasing the vaccination administration fee from the current

[1]CRIHB Member Tribes: Agua Caliente Band of Cahuilla Indians, Barona Band of Mission Indians, Bear River Band of Rohnerville Rancheria, Berry Creek Rancheria of Maidu Indians, Big Lagoon Rancheria, Big Pine Paiute Tribe of the Owens Valley, Big Valley Band of Pomo Indians, Bishop Paiute Tribe, Blue Lake Rancheria, Bridgeport Indian Colony, Cahuilla Band of Indians, Campo Band of Mission Indians, Cher-Ae Heights Indian Community of the Trinidad Rancheria, Chicken Ranch Rancheria of Me-Wuk Indians, Cloverdale Rancheria of Pomo Indians, Dry Creek Rancheria Band of Pomo Indians, Elem Indian Colony, Elk Valley Rancheria, Estom Yumeka Maidu Tribe of the Enterprise Rancheria, Ewiiaapaayp Band of Kumeyaay Indians, Federated Indians of Graton Rancheria, Fort Bidwell Indian Community of the Fort Bidwell Reservation, Fort Independence Indian Community of Paiute Indians of the Fort Independence, Greenville Rancheria, Hoopa Valley Tribe, Habematolel Pomo of Upper Lake, Jamul Indian Village of California, Karuk Tribe, Kashia Band of Pomo Indians of the Stewarts Point Rancheria, La Posta Band of Mission Indians, Lone Pine Paiute-Shoshone Tribe, Lytton Rancheria, Manchester Point Arena Band of Pomo Indians, Manzanita Band of the Diegueno Mission Indians, Middletown Rancheria of Pomo Indians, Mooretown Rancheria of Maidu Indians, Morongo Band of Mission Indians, Pechanga Band of Luiseno Indians, Pit River Tribe, Quartz Valley Indian Reservation, Ramona Band of Cahuilla Indians, Redding Rancheria, Robinson Rancheria of Pomo Indians, San Manuel Band of Mission Indians, Santa Rosa Band of Cahuilla Indians, Santa Ynez Band of Chumash Indians, Scotts Valley Band of Pomo Indians, Soboba Band of Luiseno Indians, Table Mountain Rancheria, Timbisha Shoshone Tribe, Tolowa Dee-ni' Nation, Torres Martinez Desert Cahuilla Indians, Tule River Indian Tribe of the Tule River Reservation, United Auburn Indian Community of the Auburn Rancheria, Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation, Viejas Band of Kumeyaay Indians, Wiyot Tribe, and Yurok Tribe.

Medicare administration rate to the IHS MOA/AIR fee schedule recognizes the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients to answer any questions they may have about the vaccine. The enhanced vaccine administration fee will also allow THPs to defray some of the costs related to personal protective equipment, handling, storage, administration, staffing, tracking and follow-up, and coordination required to effectively deliver the multi-dose COVID-19 vaccine to high-risk and vulnerable populations.

2) Telehealth Flexibilities: Allow IHS MOA providers to establish a new patient that is located within its federal designated service area, through synchronous telehealth.

CRIHB recommends that IHS MOA providers also be allowed to register a new patient within their service area, through synchronous telehealth, as is being proposed for Tribal FQHC/FQHC/RHC providers. Currently, 42 CFR 440.90 restricts IHS MOA clinics from providing reimbursable health care services outside of the physical clinic facility. CRIHB strongly urges DHCS to consider alternate options to continue telehealth flexibilities for IHS MOA providers beyond the public health emergency (PHE), including the use of 1115 Tribal Uncompensated Care Waiver. According to the Morbidity and Mortality Weekly Report, age-adjusted COVID-19–associated mortality among AIANs was 1.8 times that among non-Hispanic Whites. Among AIANs, mortality was higher among men than among women, and the disparity in mortality compared with non-Hispanic Whites was highest among persons aged 20–49 years.[2] Ensuring access to health care for the AIAN population is critical now and beyond the PHE. The 1115 Waiver option could allow for IHS MOA providers to continue receiving reimbursement for telehealth services provided to beneficiaries at home and sustain access to health care services beyond the PHE. It could also allow the state to receive 100% *Federal Medical Assistance Percentage* (*FMAP*) reimbursement for AIAN Medi-Cal beneficiaries.

3) Make the removal of the site limitations on IHS MOA clinics permanent. For example, allow clinics to provide services to beneficiaries in the beneficiary's home.

CRIHB urges DHCS to make the removal of site limitations on IHS MOA clinics permanent, just like what is being proposed for Tribal FQHC/FQHC/RHC providers. This could allow IHS MOA clinics to provide services to beneficiaries without site limitations. Currently, 42 CFR 440.90 restricts IHS MOA clinics from being able to provide reimbursable health care services outside of the clinic facility. CRIHB strongly recommends that DHCS consider alternate options to continue services to beneficiaries without site limitations, including the use of 1115 Tribal Uncompensated Care Waiver. This could allow for IHS MOA clinics to continue to provide services to beneficiaries at the beneficiaries' home or at alternate care sites and for the state to receive 100% *FMAP*.

[2] Arrazola J, Masiello MM, Joshi S, et al. COVID-19 Mortality Among American Indian and Alaska Native Persons — 14 States, January–June 2020. MMWR Morb Mortal Wkly Rep 2020;69:1853–1856. DOI: http://dx.doi.org/10.15585/mmwr.mm6949a.

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4) Medi-Cal 2020 Waiver Renewal Update: Drug Medi-Cal Organized Delivery System (DMC-ODS)

Tribes and THPs request an allowance for specific cultural health care practices for Tribal 638 clinics. Tribal partners insist that having culturally appropriate practices reimbursed is important for Tribal providers, regardless of who the administrative entity is. CRIHB supports this request, reimbursement and definitions of scope of practice for the workforce of traditional healers and natural helpers, and culturally specific best-practice and evidence-based services. CRIHB also supports the use of evidence-based practices as defined in the DMC-ODS and/or from a list developed by DHCS in consultation with Tribal partners.

5) Medi-Cal 2020 Waiver Renewal Update: CRIHB Options/Uncompensated Care Pool CRIHB member THPs want to see the 1115 Waiver Uncompensated Care pool included in a future renewal of the 1115 waiver.

CRIHB requests the extension of the uncompensated care payments for certain optional services previously eliminated from the Medi-Cal state plan that are provided by IHS THPs operating under the authority of Indian Self-Determination and Education Assistance Act (ISDEAA) to IHS-eligible Medi-Cal beneficiaries. This program has served as an important lifeline and equalizer for IHS MOA clinics which would otherwise have lost access to reimbursement for optional benefits such as acupuncture, chiropractic, dental, optometry, podiatry, psychological, and speech therapy services. Given the precarious nature of the economy and potential Medi-Cal budget cuts in the future, it is critical to ensure that THPs who chose to remain in the IHS MOA program can continue to be reimbursed for optional benefits that are excluded from the Medi-Cal program.

6) Medi-Cal Rx Update: 340B Supplemental Payment Pool- The supplemental payments for qualifying non-hospital 340B community clinics need to include both licensed and license-exempt THPs that are actively enrolled as Medi-Cal clinic 340B covered entities.

The proposed State Plan Amendment (SPA) 21-0015 excludes license-exempt THPs that fall under Section 1206(c) and are not covered by Section 1204(a) or 1206(b). The exclusion of license-exempt THPs, but not county clinics that are license-exempt under 1206(b), speaks to the continued disenfranchisement and further perpetuates the tremendous health disparities in AIAN communities. This proposed exclusion of license-exempt THPs has been repeatedly discussed with DHCS leadership before SPA 21-0015's formal announcement, giving DHCS the opportunity to include 1206(c) THPs. CRIHB cannot support a SPA that excludes and further disenfranchises over two-thirds of its member THPs. Assembly Bill 80, which authorized the creation of the 340B Supplemental Payment Pool, references the Welfare and Institutions Code Section 14105.467 (f) and DHCS's ability to modify the methodology used for distribution. As stated, "the department may modify any methodology or other requirement specified in this section to the extent it deems necessary to meet the requirements of federal law or regulations, to obtain or maintain federal approval, or to ensure federal financial participation is available or not otherwise jeopardized." Therefore, DHCS has the authority to add license-exempt 1206(c) THPs to its list of participating clinics.

CRIHB urges DHCS to include license-exempt 1206(c) THP clinics, which are an integral part of the Medi-Cal safety net in California's rural and frontier regions. CRIHB member THPs serve approximately 211,000 people, over fifty percent of whom were Medi-Cal patients. These

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patients face challenges that extend beyond drug affordability, including historical trauma and multiple co-morbidities. The 340B Supplemental Payment Pool funds will allow THPs to continue providing pharmacy and patient support services. The 340B program has been an integral part of THPs' ability to treat chronic diseases in medically underserved and underfunded AIAN communities in rural California. The 340B Supplemental Payment Pool will not make clinics whole but will provide a critical lifeline to clinics that have relied on said funds to provide comprehensive patient support services.

7) Federally Qualified Health Center Update: Request for further information on Tribal FQHC benefits for Medi-Cal beneficiaries.

CRIHB is requesting further clarification regarding the Tribal FQHC benefits for Medi-Cal beneficiaries. According to the Tribal FQHC presentation on March 3rd, slide 26 indicates that the approved SPA "requires that Tribal FQHCs may only be reimbursed for the same list of services that are reimbursable to non-Tribal FQHCs." CRIHB also noted that the Supplement 6 Attachment 4.19-B was updated to indicate that "Tribal FQHCs will be reimbursed for up to three visits per day, per beneficiary, in any combination of medical, mental health, dental, and ambulatory visits." CRIHB requests an outline for which services will be covered and which services will not be covered under the approved Tribal FQHC designation.

I look forward to your response to this input and recommendations. If you have any questions, please contact Rosario Arreola Pro, Health Systems Development Department Director, at (916) 929-9761, ext. 1300 or rarreolapro@crihb.org.

Respectfully,

[redacted]

Mark LeBeau, PhD, MS
Chief Executive Officer
California Rural Indian Health Board, Inc.

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Dear Department of Health Care Services,

On behalf of our Board of Directors, staff, and the thousands of children we serve, we thank you for the opportunity to comment on the CalAIM Section 1115 Demonstration and Section 1915(b) Waiver's proposed amendments and renewal.

Attached is our formal written comment on the proposed amendments. Thank you for your thoughtful time and consideration, and for the opportunity to participate in the 30-day public comment period.
If you have any questions, please feel free to reach out to me at 949-636-8532.

Sincerely,

Ria Berger
Chief Executive Officer
Healthy Smiles for Kids of Orange County
Cell: 949-636-8532
17511 Armstrong Ave., 2nd Floor
Irvine, CA 92614
Email: rberger@healthysmilesoc.org
www.healthysmilesoc.org
"It's all about the kids!"

April 30, 2021

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

Dear Department of Health Care Services,

On behalf of Healthy Smiles for Kids of Orange County and the children we serve, thank you for the opportunity to comment on the CalAIM Section 1115 Demonstration and Section 1915(b) Waiver's proposed amendments and renewal. We are strong advocates for the Department of Health Care Services (DHCS) to (1) establish a new statewide dental benefit for children and certain adult enrollees based on the successes observed with the implementation of the Dental Transformation Initiative (DTI) and to (2) consolidate all delivery systems - including dental managed care - under a single authority in order to meet the needs of Medi-Cal beneficiaries in a patient centered and integrated manner.

When Healthy Smiles for Kids of Orange County (Healthy Smiles) was founded, Orange County did not have a "safety net" for children's oral healthcare, especially for young children in need of specialty care, sedation, or general anesthesia. Healthy Smiles began meeting the need for pediatric oral health services and has since grown to become a premier provider of dental care for underserved children, including patients with special needs, serving one million children and families since 2003. Through collaborative programs aimed at prevention, education, treatment and advocacy, Healthy Smiles has been working to reduce oral disease in underserved communities. With the charitable support of DTI, we were able to expand our programs to meet the needs of our Medi-Cal enrollees and remain in operation despite the challenges the Covid-19 pandemic presented us. We encourage the DHCS to prioritize statewide initiatives that seek to increase access to quality dental care.

The on-going dental disease epidemic affecting the people of California poses serious threats to their overall health and well-being. It is estimated that for every 14 seconds, on average, a patient visits the emergency room department for preventable dental conditions, costing California $3.5 million annually. According to the California Dental Association, tooth decay is the number one chronic childhood illness, accounting for 874,000 missed days of school and a loss of $29 million a year. Most hospital emergency rooms do not have dentists on staff to provide dental treatment and therefore, patients are typically prescribed painkillers or antibiotics. This does not treat the underlying cause of the problem, and 39% of these patients return to the emergency room (American Dental Association).

Low-income communities are disproportionately affected by the dental disease epidemic. The California Poverty Measure, which accounts for a range of local factors puts Orange County's poverty rate at 24.3%. Low-income families in Orange County cannot afford the high upfront costs of dental treatment and/or the cost of dental insurance. The disparity in oral health between low-income and higher-income children in California is the worst in the entire nation. In addition to these financial barriers, low-income families can face transportation barriers that prevent them from visiting dental clinics. Combating the dental disease epidemic and increasing the accessibility dental care must remain priorities for the State in order to maintain the overall well-being of California's most vulnerable communities.

The Covid-19 pandemic exacerbated the prevalence of dental emergencies nationwide, illustrating the health system's urgent need to address oral disease and its overall impact on health and well-being. According to recent data from the American Dental Association, dentists have seen an increase of stress-related oral health conditions in patients since the onset of the pandemic, citing a 26.4% rise in cavities and 29.7% rise in gum disease. Also, pre-existing transportation and financial barriers have reached greater heights, further emphasizing the current need for accessible dental services. Healthy Smiles remained among one of the 5% of dental clinics open nationwide during the onset of the pandemic (American Dental Association), providing critical dental services to low-income children and their families. In Orange County, most emergency rooms were not equipped to treat complex dental cases or cases with patients who had special needs, so they referred these patients to Healthy Smiles. **We did not turn away a single patient in need during this time.**

Investment from DTI allowed Healthy Smiles to expand all collaborative programs and remain in operation as a safety net dental clinic for underserved families and children with special healthcare needs, even during the Covid-19 pandemic. The following descriptions briefly highlight the dental services and programs that Healthy Smiles expanded using the generous funding provided from DTI:

Healthy Smiles Clinics: Healthy Smiles increased the number of dental chairs at the Garden Grove clinic from 7 to 11 chairs and expanded its General Anesthesia Suite that now provides restorative and specialty care. We extended our hours of operation to 6am through 6pm for six days a week, and decreased the average wait times for our clinic located at the Children's Hospital of Orange County (CHOC) from 18 months to 3 months, and from 313 patients down to 106 patients.

FY 05/06 – FY 20/21 total encounters: approximately 126,401

Smile Mobiles – Dental Clinic on Wheels**:** The Smile Mobiles are RVs converted into fully licensed clinical mobile units that provide preventative treatment (dental cleaning, fluoride, sealants) and restorative treatment (fillings and cavity treatment) in easily accessible school sites and community settings. With funding from DTI, we expanded our community sites from 2 schools to over 100 schools since 2017 within Orange County. The school sites that we visit with our Smile Mobiles are categorized as Title 1 schools, where over 40% of the students enrolled are low-income. The investment from DTI also helped fund the Smile Mobiles' staff salaries, supplies, and maintenance costs and allowed us to ensure completion of care and continuity of services, even throughout the Covid-19 pandemic. The Smile Mobiles were integral in our efforts to expand our reach within underserved communities.

FY 05/06 – FY 20/21 total encounters: approximately 225,752

Teledentistry/Telehealth: Our Teledentistry program uses remote technology to provide x-rays, cleanings, preventative treatment, and temporary fillings at a primary care clinic or school site. Offsite, a dentist will use electronic dental records and telehealth technology to review x-ray and intra oral photos to create a treatment plan for each patient. Using the funding we obtained from DTI in 2017, we implemented 11 portable units throughout Orange County schools that provided comprehensive exams directly on site. Overall, Healthy Smiles grew its encounters from the Smile Mobiles and Teledentistry programs from 912 in 2017 to 6,590 in 2019, surpassing the encounter goals for these programs by 120% on average. Teledentistry has been critical in our

efforts to eliminate transportation as a barrier to accessing to oral health care. Stories like that of Kimberly, a 9-year-old patient with special healthcare needs, is one of many we hear that illustrates the impact of accessible dental care in our community:

> *9-year-old Kimberly who has paralysis was seen by our dentists on one of our Smile Mobiles. She was diagnosed with ulcers on her gums from not flossing regularly and she was referred to our clinic in Garden Grove. Her father is a single parent who works two jobs and struggled to get her to our clinic. When Healthy Smiles began offering our school-based program - Teledentistry - at Kimberly's school, this allowed for access to the dental care she desperately needed. She currently receives preventative checkups at school which does not impact her school attendance. In addition, her father does not have to miss work for her dental appointments. Today, Kimberly has a dental home at her school and receives continuous care from Healthy Smiles staff.*

FY 05/06 – FY 20/21 total encounters: approximately 16,576

Care Coordination: Healthy Smiles' Care Coordination program aims to ensure continuity of care and compliance with treatment plans. Our follow-up procedures encourage completion of treatment and ensure that each family member is properly integrated into our case management system. The Care Coordination team has expanded its Call Center, where Coordinators transmit referrals to our clinics and other local providers based on geographic proximity, language capabilities, and other referral criteria. This allows Healthy Smiles to ensure that all patients get connected with a Dental Home - the ongoing relationship between a dentist and a patient inclusive of all aspects of oral health care delivered in a comprehensive, continuously accessible, coordinated, and family-centered way (American Academy of Pediatric Dentistry).

FY 20/21 total encounters: approximately 44,216

The generous funding from DTI was critical in helping Healthy Smiles improve accessibility to quality dental care and sustained our growth as a safety net dental provider for underserved children and children with special healthcare needs in Orange County. That is why we are strong advocates for DHCS to establish a new statewide benefit for children encompassing services from DTI Domains 1 through 3. We must ensure that we continue incentivizing and expanding statewide initiatives that seek to increase access to dental care in order to propel the State to achieve its goal of 60% dental usage rate for Medi-Cal eligible children.

Healthy Smiles is also a strong advocate for DHCS to consolidate delivery systems – including dental managed care – under a single authority within the section 1915(b) waiver. We recognize that the fragmentation present in the current Medi-Cal delivery system could increase risks of service gaps, and we encourage initiatives that aim to better meet the oral health needs of our patients in an integrated and whole-person centered manner.

For these reasons, we concur with the proposed CalAIM Section 1115 Demonstration and Section 1915(b) Waiver's amendments. Poor oral health and limited access to oral health care make it difficult for California to achieve the Triple Aim: improved population health, improved patient care, and reduced costs. We therefore urge the DHCS to continue its momentum to prioritize dental care and pursue initiatives that would meet the oral health needs of California's most vulnerable residents. We thank you for your time and consideration.

Sincerely,

Ria Berger
Chief Executive Officer
Healthy Smiles for Kids of Orange County Cell: 949-636-8532
Email: rberger@healthysmilesoc.org

Thank you for the ability to give feedback about CalAim. My biggest hope is that CalAim will help reduce administrative burden and disallowances. It is often discouraging to do wonderful work with clients to then have all our hard work disallowed for a small mistake. Hoping that CalAim will address this.

Thank you,

Angela Rowe, LCSW
Vista Hill ParentCare Family Recovery Centers

I wish to provide public input on the above item via this email.

[redacted] I fully support the proposed enhancements included in CalAIM, **except!**... There is a critical component of serious mental illness care delivery that has been completely overlooked and un-addressed in the current proposal: the glaring inequity caused by the forced exclusion of coverage by Medicare of nearly all of the few private practice Psychiatrists that are actually willing and able to appropriately treat patients with serious mental illness in an out-patient setting.

The 'Medicare Opt-Out Affidavit' requirement must be abolished. It serves only to transfer 100% of the cost of the type of personalized (whole person) quality care that enables individuals with serious mental illness (bipolar disorder and schizophrenia) to stay well and live independently in the community, and stay **OUT** of the hospital. **This should be the goal!** Staying well and out of the hospital.

On its face, this 'Opt-Out' feature is discriminatory.

[redacted]

[redacted] People should not be forced to fall to the depths of needing custodial hospitalization in order to receive reasonable payment support for needed services.

[redacted] I suppose they do this out of fear, or because it can at times be challenging, but it is puzzling to me why such practitioners chose to go into Psychiatry to begin with.

Adding insult to injury, the very few that DO accept to provide appropriate care in this domain are forced to sign 'opt-out' affidavits with Medicare, essentially barring both them and their patients from obtaining even partial reimbursement for their services from Medicare. They must do this in order to be 'allowed' to treat Medicare-eligible patients [redacted] and charge normal prevailing rates for our area (Medicare rates are roughly 40% below our local prevailing Psychiatry billing rates). This is the only way they can financially survive as private clinicians serving our most vulnerable folks, [redacted] in our metro area. [redacted] doctor's rate is neither excessive nor low, it is appropriate for the level of comprehensive care she provides. She bundles: case-management, medication management, CBT, coaching and general therapy all into one easy to access patient-centered package [redacted] **Make it easy for the patient.**

When they are not well, they cannot advocate for their needs, they cannot navigate multiple points of service, endless phone-tag, and piles of paperwork. [redacted] Most of the new CalAIM guidelines do as well. The system of the last 40 years absolutely did not.

[redacted]

The tri-fecta-fact that many recipients of SSDI are disabled by serious mental illness, combined with the sad reality that Psychiatrists are the **most frequently 'opted-out' specialty**, combined with the prevalence of discrimination within the profession against willingly taking on patients with serious mental illness needs to be acknowledged and adjusted for in your review and final proposed changes.

The simplest and most effective immediate remedy would be to **abolish the 'opt-out' feature** of Medicare (in California) and simply provide set rates of reimbursement to ALL Medicare eligible patients, and allow these patients to easily claim these benefits, even if the benefit only provides for a partial reimbursement of their total costs. This would increase flexibility so individuals can access the care they need, and maintain established relationships with clinicians they know and trust, all while more equitably distributing support for care across the full spectrum of needs of those with serious mental illness. Not all folks with serious mental illness are in the MediCal system. And these folks must not be forgotten. Many [redacted] have worked hard throughout their life to contribute to the fabric of our society. They have worked, raised and supported children, and paid their taxes, but they are still amongst our most vulnerable, especially as they age.

You must not skip over the needs of people [redacted]. They too need, and have earned, support from our MediCal/Medicare system, and they deserve the opportunity to live with dignity alongside their hard-earned independence while they continue on their path of supported recovery.

Sincerely,
Leslie Wambach-Pacalin

[redacted]

[redacted]

Dear DHCS,

The goals of CalAIM are ambitious and important. In order for California to be able to advance to a unified system of public financing, our government health care systems must be leading examples of quality, service, access, and efficiency. CalAIM certainly is a major step in this direction.

However, incredibly, one strategic and vital goal was omitted from Cal AIM – efficient operation and interoperability of the information systems architecture for care coordination, billing, administration, etc. Without an effective IT system, CalAIM will stumble and fall right out of the gate. For example, a Los Angeles Times article from a couple of years ago noted that Medi-Cal has 92 (yes, ninety two) software programs for billing, etc. and that CMS cannot have effective oversight over Medi-Cal because state and federal systems are not interoperable. Another ominous sign is the recent scandal involving the IT system of the California Employment Development Department which led to huge fraud. And many have questioned the effectiveness of the DMV's IT.

There is an evidence-basis for great concern that all the great work and potential of CalAIM will be crippled due to a hard-to-believe failure to consider IT as a central goal in the entire proposal. While California may have somewhat better IT information architecture and systems than many other outdated and rickety systems in other states, that is not an excuse to rest and risk the entire CalAIM initiative on a shaky IT foundation.

For Cal AIM to succeed, IT effectiveness, streamlining, decreased complexity, and interoperability must be included as a central goal of CalAIM.

Thank you.

Stephen F. Tarzynski MD MPH FAAP
Board President
California Physicians Alliance (CaPA)

Dear DHCS - Please find attached our letter of support for the 1115 waiver application to immediately include IMD exclusion waiver authority.

Sincerely,
Brittney

Brittney Weissman (she/her)
Chief Executive Officer
NAMI Greater Los Angeles County
3600 Wilshire Blvd., Suite 1804
Los Angeles, CA 90010
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NAMI Greater Los Angeles County
National Alliance on Mental Illness

May 3, 2021

Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Department of Health Care Services:

National Alliance on Mental Illness Greater Los Angeles County (NAMI GLAC) endorses NAMI California's recommendation that California apply for the Institution for Mental Disease's (IMD's) Serious Mental Illness (SMI)/Serious Emotional Disturbance (SED) Exclusion waiver without delay. Our members are disappointed that the current Demonstration Draft does not request Section 1115 authority to provide residential treatment services for adults with serious mental illness and children with serious emotional disturbances in IMDs.

Research shows that people in crisis in California lack equitable access to the hospital beds they need and deserve. This treatment bed shortage increases the likelihood that individuals with serious mental illness, who would otherwise benefit from IMD care, will experience repeat hospitalizations, homelessness, and incarceration. The crisis is compounding on a daily, monthly, and annual basis causing further, preventable suffering in our homes, the streets, and in our communities.

This matter has been under consideration and analysis for years and continually gets punted at the expense of family members and caregivers, and mostly at the expense of people living with serious mental illness who deserve access to a broad continuum of community-based alternatives to the current array of overcrowded hospitals, streets and jails. It is unacceptable to ask us to continue waiting for parity that would allow people with serious mental illness to live and heal in safe therapeutic environments for as long as they need.

Please apply for the IMD Exclusion waiver for SMI/SED without delay.

Sincerely,

[redacted]

Brittney Weissman
CEO

3600 Wilshire Blvd., Suite 1804, Los Angeles, California 90010
(213) 386-3615 www.namiglac.org

Hello,

[redacted]

Obtaining an IMD waiver would go a long way to addressing the systematic problem that caused people [redacted] to be denied the services they need. Please request the IMD waiver.

JIm
[redacted]

To Whom It May Concern,

Please find attached a public comment from Hope Street Coalition regarding the CalAIM Section 1115 & 1915(b) waivers. If there is any difficulty receiving this attachment, please contact me. Thank you for the opportunity to comment on this critical issue.

Sincerely,

Paul C. Webster
Director, Hope Street Coalition
Phone 760-696-2445
paul@hopestreetcoalition.org
www.hopestreetcoalition.org

April, 30, 2021

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

HOPE STREET COALITION
Healing & Housing To End Suffering

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms Lee and Ms Font:

On behalf of Hope Street Coalition, a grass-roots advocacy organization focusing on the intersection of homelessness, mental illness, and addiction, I am writing to express the concern of our members about the Medicaid section 1115 Demonstration draft that was recently released for public comment. Our members are deeply discouraged that the Draft fails to include language requesting Section 1115 demonstration authority to provide residential treatment services in Institutions of Mental Diseases (IMDs) for adults with serious mental illness (SMI) and children with serious emotional disturbances (SEDs).

Hope Street Coalition recognizes that the Draft includes a short paragraph stating the intention of DHCS to request this authority no sooner than July 1, 2022. While there is merit in implementing necessary payment and data collection reforms as pre-cursors to IMD Exclusion waiver for SMI and SED, the lack of language detailing how this authority might increase care and services to those currently suffering from untreated serious mental illness and be integrated in the larger demonstration does not inspire confidence in DHCS' commitment to this important issue. Moreover, every year the demand for treatment of SMI by those experiencing homelessness increases and any delay increases the suffering on the streets.

Hope Street Coalition recommends that the paragraph on Page 17 entitled "Anticipated Future Demonstration Request" be expanded and include details as to how the waiver would serve the unhoused mentally ill in creating additional treatment and housing options, how the waiver will add to psychiatric bed capacity and increase the provision of residential treatment, and the benefits to the State and counties in creating increased psychiatric and recovery capacity in reducing behavioral health costs and other costs associated with untreated serious mental illness, particularly among those experiencing homelessness.

Thank you for the opportunity to provide public comment on this significant reform. Please contact me should you have any questions.

Sincerely,

[redacted]

Paul C. Webster
Director
Hope Street Coalition

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Please help streamline to administrative paperwork required by the current DMC regulations and help bring the documentation in line with that of Medi-Cal funded Mental Health programs.

Currently, DMC requires treatment plans to be updated every 90 days. As most providers in substance use treatment programs know, 90 is not enough time to see progress, especially in when working with populations that live with substance use, mental illness and in neighborhoods where drug use and sales are visible and commonplace.

At a minimum, we need at least 6 months to see change. Having treatment plans align with the ASAM schedule will help reduce unnecessary paperwork, provide the staff with more time to provide the actual treatment, and reduce the tendency of providers to want to cut and paste treatment plans to fulfill a requirement versus what the client actually needs.

In addition, the current intake assessment interview can take over two hours and even over multiple days to complete. Again, the population we serve have been using substances for many years, and have cognitive impairment. We do not receive reimbursement for the assessment process, which, can take away much of our treatment. The assessments have been stretched out even longer due to the COVID-19 restrictions.

Kimberly Gilgenberg-Castillo, LCSW
Associate Director, *UCSF Citywide STOP*
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Phone: (415) 597-8038
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Kimberly.Gilgenberg-Castillo@ucsf.edu
pronouns: (she/her/hers)

We appreciate the inclusion of Community Based Adult Services (CBAS) in the Section 1115 Demonstration Application and have agree with the expectation of increased enrollment into CBAS over the 5-year period as dual eligible beneficiaries are moved into MLTSS and aligned D-SNPs. We believe that the increased capacity requirements will necessitate a streamlining of regulations and obsolete standards and practices. Lessons learned from the pandemic should be incorporated to allow for services to be delivered in ways that meet the need of individual patients in both close and remote settings.

In order to track the efficacy of programs and person-centered care development, it is critical to implement national outcome measurements that can be quantified and tracked to not only judge quality of care but to support research into long term effects of community-based services.

We would like to see an expedited admission based on presumptive eligibility for those discharged from institutionalized settings. The current process does not support the best interest of those persons who might value from services leaving months until they are able to attend the centers after leaving institutional settings.

Federal policy is leading in the direction of prioritizing and expanding access to non-institutional settings in the community. We support seeing CBAS transitioned back to a State Plan Benefit by the end of the next 1115 Waiver demonstration period.

Respectfully submitted,

Beverly Greer
Chief Executive Officer
Neuro Vitality Center
2800 E. Alejo Rd.
Palm Springs, Ca

COMMUNITY BRIDGES
PUENTES DE LA COMUNIDAD

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Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

RE: Comments on the Proposed CalAIM Section 1115 Demonstration Application

Community Bridges appreciates the continued inclusion of Community Based Adult Services (CBAS) in the Section 1115 Demonstration Application so that programs such as Elderday can continue to provide comprehensive and needed support to eligible beneficiaries. There is no doubt that, based on the aging of our target population, we can anticipate increased enrollment into CBAS over the next 5-year period as dual eligible beneficiaries are moved into MLTSS and aligned D-SNPs. We note that there is not enough capacity within the existing center-based structure of CBAS without expansion to underserved and unserved areas as well as an acknowledgment that the current reimbursement rate for services is insufficient for quality services and costs. All across the state, programs are subsidized and supported in many ways from foundations to larger agencies absorbing costs to maintain opening hours. In order for these programs to continue to exist we believe there are solutions within the 1115 Waiver to more quickly increase access to person-center care. As outlined below, we believe these should be included in this next 5-year waiver period to demonstrate innovation and creative use of existing resources, consistent with the goals of the waiver.

In general, we support the California Department of Aging proposal to use the renewal of the 1115 Waiver through CalAIM to modernize the Medi-Cal funded CBAS model, incorporating lessons learned during the Public Health Emergency and aligning those lessons with the goals of the Master Plan for Aging to improve access to Home and Community Based Services throughout the state. We believe that the flexibility granted through a demonstration and research model lends itself to such innovation. However, we would go further. In that spirit of improving access to community based care, we offer the following recommendations for consideration by DHCS:

The foremost requirement and request is that, as an ultimate goal, the 1115 Waiver will no longer be the method by which approval of services be allowed but that the state actively engage in and create the necessary infrastructure to support funding CBAS services through its own defined plan. In lieu of that shift, we recommend the following adaptions as recommended by California Association for Adult Day Services (CAADS).

1. **Adopt TAS modalities as an Ongoing Feature:**
   The Temporary Alternative Services (TAS) model has shown how to fully use the expertise and person-centered approach embedded within CBAS by empowering the CBAS MDT to navigate outside of the four walls of the facility to “meet people where they are” in their home and community. This has deeply enriched the relationship between the center team and participants, and importantly, the unpaid caregiver and others providing support. CalAIM is an opportunity to demonstrate the durability of this PHE model that has enhanced the ability of the center teams to flexibly navigate within and outside of the

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center walls in a way that combines intensive care management with the unique benefit of center-based services delivered by an interdisciplinary team. This aligns perfectly with the Enhanced Care Management model envisioned in CalAIM as a separate billable service but could also be built into a "CBAS Plus" model with an enhanced rate.

2. **Add Research Component for CBAS**:

There has already been published research on the benefits of an ADHC-based Community Based Health Home model designed as a pilot project unique to California.[i]Further research has explored the impact of the COVID emergency on participants and families who lost full access to congregate services during the PHE.[ii] We would like to see a research component built into CalAIM specific to CBAS, building on existing literature and the national movement toward common outcome measures.

3. **Define presumptive eligibility for CBAS to expedite access to needed care:**

We have learned through TAS that many people who are discharged from a hospital or nursing facility could benefit from CBAS right away or may need continued recovery and care management prior to being able to attend the center for required services during a 4-hour service day. Individuals who are within 60 days of a nursing home or hospital stay and who meet medical necessity criteria should be presumed eligible for enrollment in CBAS without delay. Ensuring clients are predetermined eligible will expedite the support services and resources that could help recovery in the best interest of Medi-Cal managed care outcomes and the client, as proper care can help prevent re-admission to institutionalized or acute care.

4. **Encourage Enhanced Care Management as a feature of CBAS and CBAS Plus:**

We would like to see active encouragement of MCOs to contract with CBAS providers for Enhanced Care Management in order to meet the demand for services when individuals with dual eligibility transition to Medi-Cal Managed Care as well as the growing population of Medi-Cal only beneficiaries.

5. **Transition to State Plan:**

Federal policy is leaning towards prioritizing and expanding access to non-institutional settings in the community. We would like to see CBAS transitioned back to a State Plan Benefit by the end of the next 1115 Waiver demonstration period, which would ensure we maintain these services in perpetuity. We hope a serious and concerted effort will allow these critical services the resources needed to ensure we can provide them into the future without dependency on a federal waiver but rather with resources allocated through the State.

Sincerely,

[redacted]

/Raymon Cancino
Chief Executive Officer, Community Bridges
Administrator for Elderday, CBAS program

[i] Sadarangani, T., Missaelides, L., Eilertsen, E., Jaganathan, H., & Wu, B. (2019). A Mixed-Methods Evaluation of a Nurse-Led Community-Based Health Home for Ethnically Diverse Older Adults With Multimorbidity in the Adult Day Health Setting.Policy, politics & nursing practice,20(3), 131–144. https://doi.org/10.1177/1527154419864301

[ii] Vora, P., Missaelides, L., Trinh-Shevrin, C., & Sadarangani, T. (2020). Impact of Adult Day Service Center Closures in the Time of COVID-19.Innovation in Aging,4(Suppl 1), 949. Tina Sadarangani, Jie Zhong, Paayal Vora & Lydia Missaelides(2021)"Advocating Every Single Day" so as Not to be Forgotten: Factors Supporting Resiliency in Adult Day Service Centers Amidst COVID-19-Related Closures,Journal of Gerontological Social Work,64(3),291-302,DOI:10.1080/01634372.2021.1879339. https://doi.org/10.1093/geroni/igaa057.3472

AltaMed

May 6, 2021

Will Lightbourne, Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

Will be submitted via email to CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on California 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne,

AltaMed Health Services appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

As the largest independent Federally Qualified Health Center (FQHC) in California, AltaMed has been providing quality health and human services to individuals and families in Southern California for 50 years through an integrated world-class delivery system. Our services include a full continuum of care including pediatrics, complete primary care, obstetrics and gynecology, senior services with PACE programs, dental care, youth services, and HIV/AIDS services.

We commend the Administration's commitment to implement CalAIM, an initiative that will lead to broad delivery system, program, and payment reforms across Medi-Cal. While we see many positive changes in the proposal, we do have concerns and recommendations, and would like to share them below for your review and consideration. Specifically, in the paragraphs below, we detail the following:

- DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.
- DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).
- DHCS must ensure the public has opportunity to review and comment on all policy changes.

Thank you for your continued work on this important initiative and look forward to working with the Department on CalAIM implementation.

AltaMed

Comments

1. ***DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.***

We appreciate of the time and investment the state committed to the design and vision of Medi-Cal Rx. However, providers and health plans have systems in place today that ensure pharmacy access for Medi-Cal beneficiaries. Delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine already strained delivery systems and further confuse and worry Medi-Cal beneficiaries. To that end, we ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic.

AltaMed began vaccinating our patients and PACE participants, who are among the most impacted communities by COVID-19. Our vaccine distribution includes utilizing our pharmacies to reach our patients, thus this transition would greatly affect our ability to do our part in ending this pandemic. Further, we anticipate some retail pharmacies may have to close because of the transition. Shuttering pharmacies now, which our patients rely on, would come at the worst possible time for our patients and delivery systems as we respond to the pandemic. We urge the Administration to act quickly, acknowledge the gravity of this moment, and delay the transition now.

Recognizing the rapidly evolving pandemic response, as well as the current challenges and unknown resolution to conflict concerns with the project's contractor vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

2. ***DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.***

The CalAIM proposal will ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which often can be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. For that reason, we applaud the Administration proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal that will ensure provider's ability to render necessary medical services to patients. However, questions remain as to how providers can comply with, and bill for, those services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan. Health centers often are the entry into the SMH/SUD system, yet few health centers are contracted providers with their county SMH/SUD health plans. This arrangement

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often leaves health centers in a financially disadvantaged position where they must provide needed services under federal law but cannot bill for those services.

We ask DHCS to provide clarification on how non-contracted providers can provide medically necessary services prior to an assessment.

3. ***DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.***

The Cal AIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although we recognize a statewide need to enhance access to both sets of services in a coordinated manner, we see several issues that need to be addressed to ensure that counties are prepared to adequately meet the demand for services and patients/families can be assured they are receiving the highest quality of care.

Most notably, we are concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs are consolidated. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, 2017/18 External Quality Review Organization (EQRO) reported that several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care. Thus, while AltaMed agrees that the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure access to timely and quality SMH/SUD services.

4. ***DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).***

We are pleased to see the inclusion of Enhanced Care Management and In-lieu-of Services in the Cal AIM proposal as well as the Administration's commitment to ensure adequate funding is allocated for these services in this year's budget. To ensure successful implementation of these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to work together. We are encouraged by the inclusion of the Providing Access and Transforming Health Supports, which is necessary to transition existing services and build up capacity, including payments for new staffing and infrastructure. Supports are also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care.

We are concerned with several program elements that may impact current operation and infrastructure, namely implementation of a new care management system and process, new care referral process or new claim submission process, new patient assignment process and other. Yet

AltaMed

more is needed. Therefore, we respectfully ask DHCS to ensure ample resources and support available to ECM and ILOS providers.

5. ***DHCS must ensure the public has opportunity to review and comment on many policy changes that are described in the waivers but are not included as part of the waiver proposal.***

While we appreciate the opportunities to comment on the 1115 and 1915(b) waivers and expect DHCS will release other policy changes for public comment in the future, we would like to underscore the importance of gathering and incorporating stakeholder input into final policies.

Specifically, we request extensive public comment and engagement on the following items noted in the proposal:

- A standardized screening tool for county Behavioral Health plans and Medi-Cal managed care plans to use to guide beneficiaries toward the delivery system that is most likely to meet their needs.
- A standardized transition tool for MHPs and MCPs to use when a beneficiary's condition changes and they would be better served in the other delivery system.
- A process for facilitated referral and linkage from county correctional institution release to county specialty mental health, Drug Medi-Cal, DMC-ODS, and Medi-Cal MCPS when the inmate was receiving behavioral health services while incarcerated, to allow for continuation of behavioral health treatment in the community.

As providers continue to support the Administration in COVID-19 vaccination effort, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operation.

Again, we appreciate this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Shauna Day, Director of Government Affairs, at shaday@altamed.org.

Sincerely,

[redacted]

Cástulo de la Rocha, J.D.
President & CEO

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AltaMed

Cc: Members, Assembly Business and Professions Committee
Assemblymember Wendy Carrillo, author

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Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

May 03, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding Removal of Pharmacy Services from Medi-Cal Managed Care in Conjunction with CalAIM Section 1915(b) Waiver Proposal

Dear Director Lightbourne:

The Community Health Center Alliance for Patient Access ("CHCAPA"), a non-profit organization composed of 31 federally-qualified health centers ("FQHCs") and support organizations, writes to object to the California Department of Health Care Service ("DHCS") proposal to carve pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of Medi-Cal managed care in connection with implementation of DHCS' California Advancing and Innovating Medi-Cal ("CalAIM"). The proposed removal of pharmacy benefits and services from Medi-Cal managed care is also known as "Medi-Cal Rx."[1]

Medi-Cal Rx is antithetical to the stated goals of CalAIM. Indeed, in the Background and Overview section of the Executive Summary, DHCS touts the benefits of Medi-Cal managed care as follows:

> Medi-Cal has significantly expanded and changed over the last ten years, most predominantly because of changes brought by the Affordable Care Act and various federal regulations as well as state-level statutory and policy changes. During this time, the DHCS has also undertaken many initiatives and embarked on innovative demonstration projects to improve the beneficiary experience. In particular, DHCS has increased the number of beneficiaries receiving the majority of their physical health care through Medi-Cal managed care plans. These plans are able to offer more complete care coordination and care management than is possible through a fee-for-service system. They can also provide a broader array of services aimed at stabilizing and supporting the lives of Medi-Cal beneficiaries. [Emphasis added.]

CHCAPA agrees that Medi-Cal managed care plans are able to offer more complete care coordination and care management than is possible through a fee-for-service ("FFS") system. Carving pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of managed care, and instead reimbursing these benefits or services on a FFS basis, increases,

[1] Specifically, page 18 of the CalAIM Executive Summary and Summary of Changes, Proposal 3.1, identifies as an element of "Managed Care Benefit Standardization" that benefits to be carved out include: "4/1/21: Pharmacy benefits or services by a pharmacy billed on a pharmacy claim." https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-Executive-Summary-02172021.pdf Medi-Cal Rx was not implemented on 4/1/21, and has not been implemented to date, with no implementation date yet announced to the public.

rather than decreases, system fragmentation and renders care coordination and care management more, rather than less, difficult.

Integrating pharmacy and medical services in managed care allows FQHCs to better serve patients. The FQHCs can serve as a one-stop-shop for all of their patients' medical needs, and integration facilitates the FQHCs' ability to assist patients in following their treatment plan, including pharmacy. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for historically underserved patients.

Additionally, providing pharmacy benefits and services in the context of Medi-Cal managed care enables FQHCs to effectively leverage discount drug pricing available through the 340B Drug Pricing Program. The savings available through participation in the 340B program allow FQHCs to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed on a FFS basis. As a result of the current managed care system, FQHC patients have better access to more services, as Congress intended in enacting the 340B program.[2]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[3] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede FQHCs' ability to provide critical services to patients. The proposed FFS reimbursement, compounded with the loss of 340B savings and COVID-19 financial losses, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of the Medi-Cal program and CalAIM, which is to improve access to healthcare and reduce health inequities.

Finally, federal Medicaid law prohibits states from waiving the FQHC reimbursement requirements described in 42 U.S.C. § 1396a(bb) under a 1915b waiver.[4] California's Medi-Cal program does not currently have a compliant manner of reimbursing FQHCs for Medi-Cal's share of the cost of providing pharmacy services outside of the managed care system.

On the dispensary side, DHCS has not implemented the requirements of Welfare & Inst. Code § 14132.01 relating to reimbursement of Medi-Cal drugs provided through a clinic dispensary and has made no attempt to ensure that the dispensing fee for FQHC pharmacies or

[2] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[3] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

[4] 42 U.S.C. § 1396n(b).

dispensaries reimbursed under the fee-for-service alternative payment methodology are not less than the specific FQHC site would receive under the PPS floor. Moreover, the Mercer study that supported the pharmacy fee-for-service dispensing fees completely failed to address the requirements of 42 U.S.C. § 1396a(bb)(6)(B).

In addition, Medi-Cal has failed to adopt a standard for avoiding duplicate discounts on drugs dispensed through contract pharmacies, as required under HRSA's 2010 Contract Pharmacy Guidance, thus the transition would eliminate use of contract pharmacies for fee-for-service claims.

As a result, if Medi-Cal Rx is approved as part of the 1915b waiver, FQHCs will no longer be able to dispense Medi-Cal covered drugs through clinics' dispensaries or contract pharmacies, and will not be reimbursed at their actual cost of providing the mandatory FQHC services benefit, in violation of 42 U.S.C. § 1396n(b),resulting in a backdoor waiver of the FQHC reimbursement and service requirements in violation of federal law

Please see the attached letter from CHCAPA to the Centers for Medicare and Medicaid Services ("CMS"), dated April 16 2021, for a full description of our substantive and procedural concerns regarding Medi-Cal Rx.

In conclusion, CHCAPA agrees with Secretary Becerra that FQHCs and DHCS should "work in partnership to provide individuals access to affordable healthcare, including prescription drugs." Therefore, CHCAPA urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration.

Thank you for your time and consideration. CHCAPA looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Anthony White
President

Encl.

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HansonBridgett

April 16, 2021

VIA OVERNIGHT DELIVERY

Teresa DeCaro, Acting Director
State Demonstrations Group,
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: Community Health Center Alliance for Patient Access Request that CMS Reject California's Removal of Pharmacy Services from Managed Care, as proposed in Attachment N to the State of California's Section 1115 Waiver Extension

Dear Director DeCaro:

As follow-up to my previous letter dated March 18, 2021, please see the enclosed letter from the Community Health Center Alliance for Patient Access ("CHCAPA"). CHCAPA's letter provides a comprehensive description of the serious flaws and consequences of the so-called "Medi-Cal Rx" initiative.

CHCAPA is an organization of 31 California Federally-qualified health centers and support organizations throughout California whose mission is to ensure access to care for underserved communities. The list of CHCAPA's affiliate members includes the following organizations:

Avenal Community Health Center

Clinicas de Salud del Pueblo

Community Health Centers of the Central Coast

Desert AIDS Project

Family Health Centers of San Diego

Gardner Family Health Network

Golden Valley Health Centers

HealthRIGHT 360

Hill Country Health & Wellness Center

Imperial Beach Community Clinic

La Maestra Family Clinic

MCHC Health Centers

Mission Area Health Associates

Omni Family Health

Open Door Community Health Centers

Ravenswood Family Health Network

San Francisco Community Health Center

San Ysidro Health

Shasta Community Health Center

South of Market Health Center

TrueCare

United Health Centers of the San Joaquin Valley

Vista Community Clinic

WellSpace Health

Central California Partnership for Health (Affiliate Support Organization)

Thank you for your consideration. Please direct any questions, follow-up discussion, or responses to me via email or phone.

Thank you,

[redacted]

Kathryn E. Doi
Partner

cc: Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Heather Ross, Project Officer, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Jacey Cooper, Chief Deputy Director, California Department of Health Care Services
Rob Bonta, California Attorney General
Darrel W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

April 16, 2021

VIA FEDERAL EXPRESS

Teresa DeCaro, Acting Director
State Demonstrations Group
Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: California's Removal of Pharmacy Services from Managed Care, as proposed in Attachment N to the State of California's Section 1115 Waiver[1]

Dear Director DeCaro:

The Community Health Center Alliance for Patient Access ("CHCAPA") writes to inform CMS of significant problems with the California Department of Health Care Service's ("DHCS") proposed Attachment N to its 1115(a) Medicaid Waiver, entitled "Medi-Cal 2020" (Project Number 11-W-00193/9). Specifically, CHCAPA has serious concerns about the proposed removal of pharmacy services from managed care, an initiative called "Medi-Cal Rx."

CHCAPA urges CMS to reject the Medi-Cal Rx proposal for four reasons. First, California's fee-for-service ("FFS") reimbursement method fails to adequately fund Federally-Qualified Health Centers ("FQHCs") at the level that federal law requires. Second, Medi-Cal Rx deprives FQHCs of the 340B Drug Pricing Program ("340B") savings that currently fund numerous whole-person care services for the most vulnerable Medi-Cal beneficiaries. Third, DHCS did not follow the legal process for amending the 1115 Waiver, and misled the public and CMS regarding Medi-Cal Rx's negative effects on providers and patients. Fourth, Medi-Cal Rx undermines Medicaid's central objective of providing health care to low-income patients and does not produce any significant savings.

Despite its implications for health care for over 11 million Medi-Cal beneficiaries, DHCS has not thoroughly considered how Medi-Cal Rx affects the Medi-Cal program, Medi-Cal beneficiaries, or overall Medi-Cal costs. At minimum, CMS should require an additional 30-day public comment period and for DHCS to provide a detailed analysis of how Medi-Cal Rx affects underserved beneficiaries and FQHCs. *See* 42 C.F.R. § 431.412(a)(2), (c)(3).

I. California's fee-for-service reimbursement method for Medi-Cal pharmacy services will not reimburse FQHCs at the level federal law requires.

Federal law requires California to reimburse FQHCs at 100 percent of their costs. *See* 42 U.S.C. § 1396a(bb); *Tulare Pediatric Health Care Ctr. v. Dep't of Health Care Svc's*, 41 Cal. App. 5th 163, 171 (2019).

[1] This letter provides the substantive information for CMS to consider as it evaluates Medi-Cal Rx as promised in the earlier letter from CHCAPA's counsel, dated March 18, 2021 (attached as **Exhibit A).**

Managed care is California's predominate Medi-Cal delivery system. Roughly 83 percent of Medi-Cal beneficiaries – over 11 million people – are enrolled in managed care[2]. About 70 percent of pharmacy services spending occurs in managed care.[3] As CMS knows, managed care plans negotiate directly with FQHCs to establish reimbursement rates for pharmacy services that generally reimburse FQHCS at 100 percent of their costs. Because managed care plans cover the vast majority of pharmacy claims, California and DHCS have not addressed deficiencies in the state's other delivery systems.

California did not design its non-managed care delivery systems to adequately reimburse FQHCs for their costs. First, by statute, California's FFS methodology only pays FQHCs their "actual acquisition cost for the drug," plus either a professional fee or dispensary fee. *See* Cal. Welf. & Inst. Code § 14105.46(d). The professional fee is capped at $10.05, or $13.20, depending on the pharmacy's annual claim volume. *Id.* § 14105.45(b)(1)(B). Similarly, the dispensary fee is set at $12 or $17 for certain take-home drugs. *Id.* § 14132.01(b)(2). However, these fee amounts did not account for FQHCs' costs when the State adopted them[4]. Additionally, DHCS has not created a billing mechanism for dispensing medication through a dispensary license. *See* Francisco Castillon Decl. ¶ 14 (attached as **Exhibit B**).

Second, California's prospective payment system ("PPS") rate is similarly flawed. The PPS method reimburses providers on a "per visit basis," but California excludes a patient's visit to a pharmacist as a reimbursable "visit." *See* Cal. Welf. & Inst. Code § 14132.100(g). Further, if an FQHC experiences a cost increase due to changes in its scope of services, it faces an automatic 20 percent reduction of the total new costs before the new PPS rate is set. *See* Dean Germano Decl. ¶ 19 (attached as **Exhibit C**).

In short, Medi-Cal Rx will replace California's managed care delivery system with undeveloped systems that do not comply with federal law. Therefore, CMS should reject Medi-Cal Rx.

II. Medi-Cal Rx undermines the 340B Program by depriving FQHCs of the savings they use to provide comprehensive care to underserved communities.

The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most.[5] Managed care currently generates necessary savings for FQHCs to do exactly that.

California FQHCs, including CHCAPA affiliates, leverage 340B savings to provide better care to their patients and communities. For example, Family Health Centers of San Diego uses its 340B savings to provide expanded vision services, substance abuse recovery programs, and mobile

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[2] *See* Medi-Cal Monthly Eligible Fast Facts, DHCS, February 2021, at p. 9 available at: https://www.dhcs.ca.gov/dataandstats/statistics/Documents/FastFacts-November2020.pdf

[3] "The 2019-20 Budget: Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care," California Legislative Analyst's Office, April 5, 2019, at p. 6. (hereinafter "LAO Carve-Out Report").

[4] *See* "Professional Dispensing Fee and Actual Acquisition Cost Analysis for Medi-Cal – Pharmacy Survey Report," Mercer Government Human Services Consulting, January 4, 2017, at p. 4.

[5] *See* H.R. Rep. No. 102-384, pt. 2, at 10.

health services to low-income patients. Ricardo Roman Decl. ¶ 13 (attached as **Exhibit D**). Shasta Community Health Center's 340B savings enable it to subsidize prescription costs for the poorest patients, some of whom will pay a maximum of $10 for their medication. Germano Decl. ¶ 2. The Desert AIDS Project uses its 340B savings to employ four infectious disease physicians and provide ongoing HIV and STD testing to combat the spread of HIV. David Brinkman Decl. ¶ 7 (attached as **Exhibit E**). These are just a few examples of how the managed care system enables FQHCs to use 340B savings the way Congress intended.

Nevertheless, DHCS seeks to deprive FQHCs of these 340B savings by moving all pharmacy services into an undeveloped FFS system. California's FFS model will not support the vital whole-person care programs upon which the most vulnerable FQHC patients rely. Instead, FQHCs will experience a "significant loss" in order for the State of California to gain an uncertain amount of savings for its general fund[6]. Without 340B savings, FQHCs will have to cut services to already underserved Medi-Cal patients. *See, e.g.*, Castillon Decl. ¶¶ 12-13.

Thus, Medi-Cal Rx causes a reduction in patient services, which DHCS neither mentioned nor even considered in its Extension Request.

III. CMS should neither excuse nor permit DHCS to obtain approval for Medi-Cal Rx through a flawed and misleading public process.

A. DHCS improperly submitted Medi-Cal Rx as a "technical" change contrary to federal law and the Special Terms and Conditions of California's 1115 Waiver.

Federal law and the Special Terms and Conditions of California's 1115 Waiver ("STCs") require that "substantial" changes to benefits, delivery systems, reimbursement methods, and other "comparable program elements" occur as amendments to the 1115 Waiver. 42 C.F.R. § 431.412(c); STC III, Section 7. Amendments require the State to follow specific public processes and to provide detailed information and analyses on the impact of the proposed change. STC III, Section 8. CMS has the authority to deny or delay approval of any amendment based on California's violation of the STCs. *Id.*

Medi-Cal Rx is undoubtedly a substantial change to the delivery and reimbursement of Medi-Cal pharmacy services. It completely removes the pharmacy benefit from the managed care delivery system, and places it into the FFS delivery system. The FFS system, in turn, has an entirely different reimbursement method that will underfund FQHCs, as discussed.

Moreover, Medi-Cal Rx will "fundamentally alter" how more than 11 million Medi-Cal beneficiaries receive treatment. *See* Kelvin Vu Decl. ¶ 8 (attached as **Exhibit F**). For example, doctors currently are able to access the availability of prescriptions and their patient's adherence to their treatment plan in real-time. *Id*. If a pharmacy does not have a prescription in stock, the doctor will know immediately and can adjust the order. *Id.* ¶ 5. As a result, the patient is more likely to get their medication and adhere to their treatment plan. *Id.* ¶¶ 5-8. But not under Medi-Cal Rx. Instead, Medi-Cal Rx removes the doctor's ability to coordinate with a pharmacy, and creates a new barrier for the patient to access the prescriptions they need. Vu Decl. ¶ 8; Paramvir Sidhu Decl. ¶¶ 5-9 (attached as **Exhibit G**).

[6] LAO Carve-Out Report, at p. 1.

Despite these substantial changes to Medi-Cal, DHCS submitted Medi-Cal Rx as a "technical" amendment. *See* Extension Request at p. 14. The only analysis DHCS provided was that Medi-Cal Rx would "reflect the transition of pharmacy benefits to the fee-for-service delivery system effective January 1, 2021." *Id.* This is a description, not an analysis. DHCS further described Medi-Cal Rx in the two short paragraphs, with no mention of the differences in delivery systems, the shortcomings of non-managed care reimbursement methods, the impact on 340B savings and the patient services they fund, or the real effects on patients and their doctors. *See id.*

CMS should treat Medi-Cal Rx as the substantial amendment that it is. CMS cannot allow DHCS to avoid its obligation to fully describe and understand Medi-Cal Rx. Accordingly, CMS should reject Medi-Cal Rx, or at the very least, require DHCS to provide additional information and more time for public input. *See* 42 C.F.R. § 431.412(a), (c).

B. DHCS has been implementing Medi-Cal Rx without CMS' approval.

Federal law and the STCs prohibit DHCS from implementing major changes to California's Waiver without CMS' approval. *See Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1017-18 (9th Cir. 2013); STCs III, Sections 7-8.

DHCS is not waiting for CMS to move forward with Medi-Cal Rx. For example, it has unilaterally set and changed two different "effective" dates that did not depend on CMS approval. *See* Extension Request at p. 14[7]. DHCS contracted with Magellan Medicaid Administration to create a Medi-Cal Rx customer service center. Providers have already had to register for secure Medi-Cal Rx portals and participated in Medi-Cal Rx trainings. The State of California created a supplemental payment pool in its state budget because of the losses FQHCs will suffer under Medi-Cal Rx. Germano Decl. ¶¶ 4-15. DHCS has begun to implement Medi-Cal Rx without CMS approval and without understanding its consequences.

DHCS' unapproved implementation of Medi-Cal Rx is already affecting providers. For example, Family Health Centers of San Diego has had to undergo a complete budget review anticipating the loss of 340B savings, and has dedicated significant staff time to enroll in Medi-Cal Rx provider portals and to track Medi-Cal Rx updates. Fran Butler-Cohen Decl. ¶ 9 (attached as **Exhibit H**). Providers have also had to register for and participate in several different trainings, answer readiness surveys, and provide claims information for calculating their professional dispending fee under FFS. *See, e.g.,* DHCS Medi-Cal Rx Monthly Bulletin (attached as **Exhibit I).** These efforts distract FQHCs from patient service, such as providing free testing and vaccines to combat the spread of COVID-19. *See id.* ¶¶ 6-8.

In sum, DHCS is violating federal law and the STCs by implementing Medi-Cal Rx without CMS' approval. CMS should not allow DHCS to do so, and should accordingly reject Medi-Cal Rx.

[7] *See also* Medi-Cal Rx Transition home page, available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx

C. DHCS prevented meaningful public input regarding Medi-Cal Rx through misleading public notices and a rushed public comment process.

States must allow for "meaningful public input" when submitting 1115 Waiver amendments or extension requests. 42 C.F.R. §§ 431.408(a)(1)(i), 431.412 (c)(2)(ii). This requires states to provide a "comprehensive description" discussing who will be impacted by the proposals, changes to the existing demonstration, and how the state received and considered public comments. *See* 42 C.F.R. §§ 431.408(a), 431.412(a), (c).

DHCS hindered "meaningful" public input regarding Medi-Cal Rx. Specifically, DHCS claimed that there was "no impact" to FQHCs in its Tribal Notice[8]. However, the state's Legislative Analyst's office explicitly stated that Medi-Cal Rx would directly affect FQHC funding and patient care coordination[9]. Also, DHCS held only two public hearings within 20 days of announcing the proposed Extension.

Although CMS waived some of the technical notice requirements, it certainly did not allow DHCS to falsely downplay the impact of the Extension Request and Medi-Cal Rx[10]. As the public was denied meaningful input into Medi-Cal Rx, CMS should not allow DHCS to implement it.

D. DHCS' Waiver Extension Request misled CMS by unfairly minimizing CHCAPA's legitimate and detailed objections to Medi-Cal Rx.

DHCS was obligated to provide CMS with a "report of the issues" raised in public comments and how it addressed them. 42 C.F.R. § 431.412(a)(viii), (c)(vii).

Yet DHCS did not provide an honest report of the public comments to CMS. In its Extension Request, DHCS misrepresented CHCAPA's extensive concerns in one sentence: "one commenter objected to the state's plan to carve-out the pharmacy benefit." Extension Request at p. 45. The "one commenter" was a collection of nearly 20 health centers across California that signed onto a CHCAPA-led comment letter. The "objection" was a detailed letter describing numerous problems with the FFS and PPS reimbursement methods and the overall disruption Medi-Cal Rx will cause. DHCS' characterization hid serious public concerns from CMS.

DHCS' response to CHCAPA's concerns was similarly sparse. In a single paragraph, DHCS claimed that it "must" move the pharmacy benefit out of managed care in order for pharmacy services to move from managed care. *See* Extension Request at p. 49. By contrast, DHCS provided detailed summaries and responses for comments that were generally or strongly supportive of its Extension proposals. *See* Extension Request at 44-49. DHCS cannot provide one-sided information in order to obtain CMS' approval of a flawed initiative.

[8] DHCS Tribal Notice of Proposed Change to Medi-Cal Program, July 22, 2020 at p. 2, available at: https://www.dhcs.ca.gov/Documents/1115-1915bWaiverTribalNotice7-22-20.pdf

[9] LAO Carve-Out Report, at pp. 1, 13-14

[10] *See* CMS Completeness Letter, dated Oct. 1, 2020

CMS cannot adequately evaluate Medi-Cal Rx based on the scant information DHCS provided regarding its scope and costs. At best, DHCS failed to provide accurate and sufficient information to CMS. Therefore, CMS should decline to approve Attachment N and Medi-Cal Rx until these important issues have been addressed.

IV. Medi-Cal Rx impedes Medicaid's primary objective by depriving beneficiaries of high-quality care, and is not likely produce the savings DHCS claims.

Any change to California's Medicaid Waiver must promote the objectives of Medicaid. *See* 42 U.S.C. § 1315(a). Medicaid's most fundamental objective is to provide comprehensive, high-quality medical care to people who would not have access to it otherwise. *See id.* § 1396-1.

Medi-Cal Rx directly undermines Medicaid's purpose in two ways. First, it will eliminate vital patient services for beneficiaries. Because of the COVID-19 pandemic, FQHCs in California are facing an estimated loss of $530 million dollars[11]. Medi-Cal Rx will exacerbate FQHCs' financial strain by shifting 340B savings to the state while underpaying FQHCs through FFS. These cuts will force FQHCs to eliminate key services for their patients, including transportation assistance, mobile health initiatives, and prescription subsidies. *See, e.g.*, Castillon Decl. ¶¶ 12-13; Germano Decl. ¶¶ 2, 16; Brinkman Decl. ¶ 9.

Second, Medi-Cal Rx will diminish the quality of care for the remaining FQHC services. It will disrupt Medi-Cal care coordination, severely undermining the whole-person care model that DHCS expects FQHCs to follow. *See* Vu Decl. ¶ 8; Sidhu Decl. ¶¶ 5-9. It will also disrupt important medical intervention programs that combat substance abuse and opioid addiction. *See* Vu Decl. ¶ 10. Medi-Cal Rx will therefore lead to fewer services and worse health outcomes during a pandemic that has claimed the lives of over 60,000 Californians.

Medi-Cal Rx will cause significant disruption without any real financial benefit to California. DHCS has not provided any thorough analysis to support its claim of savings, and actually excluded such claims from its final submission to CMS. *See* Extension Request at pp. 37, 49. In fact, an internal DHCS analysis shows that while Medi-Cal Rx would yield a net savings of $5.8 billion, the fee-for-service pharmacy costs would grow to about $5.65 billion[12]. By its own analysis, DHCS knows that Medi-Cal Rx *might* save the state a maximum of $400 million over an unknown period of time.

Studies by reputable entities also cast doubt on whether Medi-Cal Rx will yield significant state savings, if any. The Legislative Analyst's Office noted that even if there is some net savings, the amount is "highly uncertain"[13]. Further, an independent analysis found that moving pharmacy benefits into fee-for-service would actually result in a net *increase* of as much as $757 million to

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[11] *See* "Financial Impact of COVID-19 on California Federally Qualified Health Centers," California Health Care Foundation, available at: https://www.chcf.org/wp-content/uploads/2021/03/FinancialImpactCOVID19CaliforniaFQHCInfographic.pdf

[12] May 2020 Medi-Cal Local Assistance Estimate, DHCS, at PC page 107, available at: https://www.dhcs.ca.gov/dataandstats/reports/mcestimates/Documents/2020_May_Estimate/M2099-Medi-Cal-Local-Assistance-and-Appropriation-Estimate.pdf

[13] LAO Carve-Out Report, at pp. 1, 11-12

California's General Fund over five years[14]. Thus, any benefits of Medi-Cal Rx are limited and uncertain.

In sum, Medi-Cal Rx subverts – not promotes – Medicaid's core objective of providing low-income people with access to health care. CMS should therefore reject the proposal, especially during an ongoing pandemic when the health care system needs stability.

V. Conclusion

Medi-Cal Rx is an undeveloped proposal that directly undermines the purpose of Medicaid. Medi-Cal Rx will significantly disrupt patient care and create new barriers to access for the sake of speculative state savings. DHCS cannot upend an entire delivery system affecting over 11 million Medi-Cal beneficiaries under the label of a "technical" change to its Waiver. By providing insufficient and misleading information to the public and to CMS, DHCS violated federal law and its contract with CMS.

Accordingly, CHCAPA urges CMS to reject the Medi-Cal Rx proposal. At minimum, CMS should use its authority to treat Medi-Cal Rx as a substantive amendment and require DHCS to follow the formal amendment process specified in the Code of Federal Regulations and the Special Terms and Conditions of the Waiver.

Thank you for your time and consideration.

Sincerely,

[redacted]

Anthony White
President, CHCAPA

CC: Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Heather Ross, Project Officer, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Jacey Cooper, Chief Deputy Director, California Department of Health Care Services
Rob Bonta, California Attorney General
Darrel W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General

[14] Assessment of Medi-Cal Pharmacy Benefits Policy Options, The Menges Group, May 15, 2019 at p. 3, available at: https://www.themengesgroup.com/upload_file/assessment_of_medi-cal_pharmacy_benefits_policy_options.pdf.

Exhibit A
to letter dated 4/16/2021

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March 18, 2021

VIA FEDERAL EXPRESS

Judith Cash, Director
State Demonstrations Group
Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: Community Health Center Alliance for Patient Access ("CHCAPA") Request that CMS Pause Its Consideration to Proposed Attachment N to the State of California's Medi-Cal 2020 Section 1115 Waiver Demonstration to Allow for Comment

Dear Ms. Cash:

We represent the Community Health Center Alliance for Patient Access ("CHCAPA") and individual Federally-qualified health centers in federal court litigation challenging the State of California's implementation of the Medi-Cal Rx program to transition the pharmacy benefit from Medi-Cal managed care to fee-for-service reimbursement. (*Community Health Center Alliance for Patient Access, et al. v. Lightbourne, et al.*, United States District Court for the Eastern District of California, Case No. 2:30-cv-02171-JAM-KJN.)

On Tuesday, March 9, 2021, a hearing was held on the Defendants' (the California Department of Health Care Services and its Director Will Lightbourne) motion to dismiss and the Plaintiffs' motion for a preliminary injunction. At the hearing, Judge Mendez indicated on the record that he was granting the motion to dismiss with leave to amend the complaint because CMS has not yet acted on Attachment N to the State's 1115 Waiver. Attachment N was submitted to CMS by the State of California on December 24, 2020 and would result in the removal of the pharmacy benefit from the list of covered services under Medi-Cal managed care, thus effectuating the Medi-Cal Rx transition. During the hearing, the judge encouraged the Plaintiffs to raise with CMS the legal challenges to Medi-Cal Rx and Attachment N that Plaintiffs raised in the federal lawsuit. In the minutes of the proceeding, the judge ordered Plaintiffs to "wait to file an amended complaint until after CMS acts on the approval sought by Defendants."[1]

Consistent with the judge's recommendations, we are writing on behalf of the Plaintiffs to request that CMS pause its consideration of Attachment N to give us time to submit a

[1] Copies of the proposed Attachment N, the December 24, 2020 email message from the Department of Health Care Services ("DHCS") transmitting Attachment N to CMS, CMS' December 29, 2020 response to DHCS regarding the status of Attachment N, and the Court's March 9, 2021 minutes of proceeding are attached to this letter for your reference as **Exhibits A, B, C, and D**, respectively.

comprehensive letter outlining the reasons why approval of Attachment N and implementation of Medi-Cal Rx will result in a violation of the federal Medicaid and 340B laws. Since there is currently no Go Live date for the Medi-Cal Rx transition, we request that we be granted a minimum period of 45-days to submit our substantive comments.[2]

We also encourage CMS adopt an open and transparent process for its consideration of Attachment N to allow Plaintiffs and other stakeholders an opportunity to provide public input into CMS' decision-making process. The 1115 Waiver extension request and associated notices did not describe the Medi-Cal Rx transition, did not attach the proposed Attachment N and inaccurately stated there would be no impact on FQHCs, and therefore, there has been no opportunity for the public and stakeholders to weigh in on the impact of Medi-Cal Rx on patient care and the delivery system.

The proposed Attachment N will change the pharmacy delivery system for the roughly 8.8 million Medi-Cal beneficiaries who receive their health care through Medi-Cal managed care, a significant change for the beneficiaries, as well as the providers and health plans that are a part of their health care delivery system. To date, there has been no public examination of the consequences of removing the pharmacy benefit from managed care, including the resulting impact on coordination of care, oversight of pharmacy usage and patient compliance, or Medi-Cal's ability to deliver the whole person integrated care if the pharmacy benefit is carved out of managed care and delivered and administered by the State.

Such a sea change should not occur in a vacuum, but only after a public process that allows for identification of the key issues and allows for a careful review of the public policy and legal ramifications of such a major disruption to the health care delivery system for millions of low income Californians. To this end, because Attachment N substantially changes the original demonstration design and was not submitted as part of the original 1115 Waiver extension request, we request that CMS exercise its discretion to direct an additional 30-day public comment period pursuant to 42 C.F.R. 431.412(a)(2) and (c)(3).

We also request that CMS timely notify us of any action taken with respect to the State of California's request for approval of Attachment N so we might return to court as provided by the judge's order.

Your attention to this matter is greatly appreciated.

Very truly yours,

[redacted]

Kathryn E. Doi
Partner

KED:KQD
Encls.

[2] DHCS' announcement that the April 1, 2021 Go Live date for Medi-Cal Rx was being suspended with no new date announced, is attached as **Exhibit E**.

cc: (VIA U.S. MAIL)
Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Lindy Harrington, Deputy Director, California Department of Health Care Services
Darrell W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General
Anthony White, President, CHCAPA

Exhibit A

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Acupuncture Services	Other Practitioners' Services and Acupuncture Services	Acupuncture services shall be limited to treatment performed to prevent, modify or alleviate the perception of severe, persistent chronic pain resulting from a generally recognized medical condition.	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Acute Administrative Days	Intermediate Care Facility Services	Acute administrative days are covered, when authorized by a Medi-Cal consultant subject to the acute inpatient facility has made appropriate and timely discharge planning, all other coverage has been utilized and the acute inpatient facility meets the requirements contained in the Manual of Criteria for Medi-Cal Authorization.	~~X[5]~~X[3,~~965~~]	~~X[5]~~X[3,~~965~~]	X	~~X[5]~~X[3]	~~X[5]~~X[3]	~~X[5]~~X[3]
Audiological Services	Audiology Services	Audiological services are covered when provided by persons who meet the appropriate requirements	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Behavioral Health Treatment (BHT)	Preventive Services- EPSDT	The provision of medically necessary BHT services to eligible Medi-Cal members under 21 years of age as required by the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) mandate and state plan.-	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~7~~ ~~6~~]
Blood and Blood Derivatives	Blood and Blood Derivatives	A facility that collects, stores, and distributes human blood and blood derivatives. Covers certification of blood ordered by a physician or facility where transfusion is given.	X	X	X	X	X	X
California Children Services (CCS)	~~Service is not covered under the State Plan~~ EPSDT	California Children Services (CCS) means those services authorized by the CCS program for the diagnosis and treatment of the CCS eligible conditions of a specific Member.	~~X~~	~~X~~	X[9] ~~X[6]X[4]~~	~~X~~	~~X~~	~~X~~

Certified Family ~~nurse~~ Nurse ~~practitioner~~Practitioner	Certified Family Nurse Practitioners' Services	A certified family nurse practitioners who provide services within the scope of their practice.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Certified Pediatric Nurse Practitioner Services	Certified Pediatric Nurse Practitioner Services	Covers the care of mothers and newborns through the maternity cycle of pregnancy, labor, birth, and the immediate postpartum period, not to exceed six weeks; can also include primary care services.	X	X	X	X	X	X
Child Health and Disability Prevention (CHDP) Program	EPSDT	A preventive program that delivers periodic health assessments and provides care coordination to assist with medical appointment scheduling, transportation, and access to diagnostic and treatment services.	X	X	X[4]	X	X	X
Childhood Lead Poisoning Case Management (Provided by the Local County Health Departments)	EPSDT	A case of childhood lead poisoning (for purposes of initiating case management) as a child from birth up to 21 years of age with one venous blood lead level (BLL) equal to or greater than 20 µg/dL, or two BLLs equal to or greater than 15 µg/dL that must be at least 30 and no more than 600 calendar days apart, the first specimen is not required to be venous, but the second must be venous.	X	X	X	X	X	X
Chiropractic Services	Chiropractors' Services	Services provided by chiropractors, acting within the scope of their practice as authorized by California law, are covered, except that such services shall be limited to treatment of the spine by means of manual manipulation.	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Chronic Hemodialysis	Chronic Hemodialysis	Procedure used to treat kidney failure - covered only as an outpatient service. Blood is removed from the body through a vein and circulated through a machine that filters the waste products and excess fluids from the blood. The "cleaned" blood is then returned to the body. Chronic means this procedure is performed on a regular basis. Prior authorization required when provided by renal dialysis centers or community hemodialysis units.	X	X	X	X	X	X
Community Based Adult Services (CBAS)		CBAS Bundled services: An outpatient, facility based service program that delivers skilled nursing care, social services, therapies, personal care, family/caregiver training and support, meals and transportation to eligible Medi-Cal beneficiaries. CBAS Unbundled Services: Component parts of CBAS center services delivered outside of centers, under certain conditions, as specified in paragraph 95.	X	X	X	X	X	X
Comprehensive Perinatal Services	Extended Services for Pregnant Women-Pregnancy Related and Postpartum Services	Comprehensive perinatal services means obstetrical, psychosocial, nutrition, and health education services, and related case coordination provided by or under the personal supervision of a physician during pregnancy and 60 days following delivery.	X	X	X	X	X	X

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Dental Services (Covered under ~~Denti~~Medi-Cal)		Professional services performed or provided by dentists including diagnosis and treatment of malposed human teeth, of disease or defects of the alveolar process, gums, jaws and associated structures; the use of drugs administered in-office, anesthetics and physical evaluation; consultations; home, office and institutional calls.						
Drug Medi-Cal Substance Abuse Services	Substance Abuse Treatment Services	Medically necessary substance abuse treatment to eligible beneficiaries.						
Durable Medical Equipment	DME	Assistive medical devices and supplies. Covered with a prescription; prior authorization is required.	X	X	X	X	X	X
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services ~~and EPSDT Supplemental Services~~	EPSDT	EPSDT is the Medicaid program's benefit for children and adolescents, providing a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act. ~~Preliminary evaluation to help identify potential health issues.~~	X~~76~~	X~~67~~	X~~67~~	X~~67~~	X~~67~~	X~~67~~
~~Erectile~~ Sexual Dysfunction Drugs		FDA-approved drugs that are~~may~~ be prescribed for~~if a~~ male or female sexual dysfunction are non-benefits of the program.~~patient experiences an inability or difficulty getting or keeping an erection as a result of a physical problem.~~						

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Expanded Alpha-Fetoprotein Testing (Administered by the Genetic Disease Branch of DHCS)		A simple blood test recommended for all pregnant women to detect if they are carrying a fetus with certain genetic abnormalities such as open neural tube defects, Down Syndrome, chromosomal abnormalities, and defects in the abdominal wall of the fetus.						
Eyeglasses, Contact Lenses, Low Vision Aids, Prosthetic Eyes and Other Eye Appliances	Eyeglasses, Contact Lenses, Low Vision Aids, Prosthetic Eyes, and Other Eye Appliances	Eye appliances are covered on the written prescription of a physician or optometrist.	X[8]	X[8]	X[8]	X[8]	X[8]	X[8]
Federally Qualified Health Centers (FQHC) (Medi-Cal covered services only)	FQHC	Services described in 42 U.S.C. Section 1396d(a)(2)(C) furnished by ~~An~~ an entity defined in ~~Section 1905 of the Social Security Act (~~42 ~~United States Code~~ U.S.C. Section 1396d(l)(2)(B)).	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Health Home Program Services	Health Home Program Services	The community based care management entity assigns care managers, such as nurses or other trained professionals, to help members who have chronic conditions find the right health care or other services in their communities. Health Home Program services: Comprehensive Care Management; Care Coordination; Health Promotion; Comprehensive Transitional Care; Individual and Family Supports; and Referral to Community/Social Supports; are defined in the CMS- approved Health Home Program SPAs, and include any subsequent amendments to the CMS-approved Health Home Program SPAs.	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]
Hearing Aids	Hearing Aids	Hearing aids are covered only when supplied by a hearing aid dispenser on prescription of an otolaryngologist, or the attending physician where there is no otolaryngologist available in the community, plus an audiological evaluation including a hearing aid evaluation which must be performed by or under the supervision of the above physician or by a licensed audiologist.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Home and Community-Based Waiver Services (Does not include EPSDT Services)		Home and community-based waiver services shall be provided and reimbursed as Medi-Cal covered benefits only: (1) For the duration of the applicable federally approved waiver, (2) To the extent the services are set forth in the applicable waiver approved by the HHS; and (3) To the extent the Department can claim and be reimbursed federal funds for these services.						
Home Health Agency Services	Home Health Services-Home Health Agency	Home health agency services are covered as specified below when prescribed by a physician and provided at the home of the beneficiary in accordance with a written treatment plan which the physician reviews every 60 days.	X	X	X	X	X	X
Home Health Aide Services	Home Health Services-Home Health Aide	Covers skilled nursing or other professional services in the residence including part-time and intermittent skilled nursing services, home health aide services, physical therapy, occupational therapy, or speech therapy and audiology services, and medical social services by a social worker.	X	X	X	X	X	X
Hospice Care	Hospice Care	Covers services limited to individuals who have been certified as terminally ill in accordance with Title 42, CFR Part 418, Subpart B, and who directly or through their representative volunteer to receive such benefits in lieu of other care as specified.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Hospital Outpatient Department Services and Organized Outpatient Clinic Services	Clinic Services and Hospital Outpatient Department Services and Organized Outpatient Clinic Services	A scheduled administrative arrangement enabling outpatients to receive the attention of a healthcare provider. Provides the opportunity for consultation, investigation and minor treatment.	X	X	X	X	X	X
Human Immunodeficiency Virus and AIDS drugs ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021		Human Immunodeficiency Virus and AIDS drugs that are listed in the Medi-Cal Provider Manual			X[5]			

Hysterectomy	Inpatient Hospital Services	Except for previously sterile women, a nonemergency hysterectomy may be covered only if: (1) The person who secures the authorization to perform the hysterectomy has informed the individual and the individual's representatives, if any, orally and in writing, that the hysterectomy will render the individual permanently sterile, (2) The individual and the individual's representative, if any, has signed a written acknowledgment of the receipt of the information in and (3) The individual has been informed of the rights to consultation by a second physician. An emergency hysterectomy may be covered only if the physician certifies on the claim form or an attachment that the hysterectomy was performed because of a life-threatening emergency situation in which the physician determined that prior acknowledgement was not possible and includes a description of the nature of the emergency.	X	X	X	X	X	X
Service	**State Plan Service Category**	**Definition**	**Covered in GMC**	**Covered in 2-Plan**	**COHS**	**Regional**	**Imperial**	**San Benito**
Indian Health Services (Medi-Cal covered services only)		Indian means any person who is eligible under federal law and regulations (25 U.S.C. Sections 1603c, 1679b, and 1680c) and covers health services provided directly by the United States Department of Health and Human Services, Indian Health Service, or by a tribal or an urban Indian health program funded by the Indian Health Service to provide health services to eligible individuals either directly or by contract.	X	X	X	X	X	X

~~In-Home Medical Care Waiver Services and Nursing Facility Waiver Services~~	-	~~In-home medical care waiver services and nursing facility waiver services are covered when prescribed by a physician and provided at the beneficiary's place of residence in accordance with a written treatment plan indicating the need for in- home medical care waiver services or nursing facility waiver services and in accordance with a written agreement between the Department and the provider of service.~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~
Inpatient Hospital Services	Inpatient Hospital Services	Covers delivery services and hospitalization for newborns; emergency services without prior authorization; and any hospitalization deemed medically necessary with prior authorization.	X	X	X	X	X	X
Intermediate Care Facility Services for the Developmentally Disabled	Intermediate Care Facility Services for the Developmentally Disabled	Intermediate care facility services for the developmentally disabled are covered subject to prior authorization by the Department. Authorizations may be granted for up to six months. The authorization request shall be initiated by the facility. The attending physician shall sign the authorization request and shall certify to the Department that the beneficiary requires this level of care.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Intermediate Care Facility Services for the Developmentally Disabled Habilitative	Intermediate Care Facility Services for the Developmentally Disabled Habilitative	Intermediate care facility services for the developmentally disabled habilitative (ICF-DDH) are covered subject to prior authorization by the Department of Health Services for the ICF-DDH level of care. Authorizations may be granted for up to six months. Requests for prior authorization of admission to an ICF-DDH or for continuation of services shall be initiated by the facility on forms designated by the Department. Certification documentation required by the Department of Developmental Services must be completed by regional center personnel and submitted with the Treatment Authorization Request form. The attending physician shall sign the Treatment Authorization Request form and shall certify to the Department that the beneficiary requires this level of care.	X[5] X[3]	X[5] X[3]	X	X[5] X[3]	X[5] X[3]	X[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Intermediate Care Facility Services for the Developmentally Disabled-Nursing.		Intermediate care facility services for the developmentally disabled-nursing (ICF/ID-N) are covered subject to prior authorization by the Department for the ICF/ ID-N level of care. Authorizations may be granted for up to six months. Requests for prior authorization of admission to an ICF/ID-N or for continuation of services shall be initiated by the facility on Certification for Special Treatment Program Services forms (HS 231). Certification documentation required by the Department of Developmental Services shall be completed by regional center personnel and submitted with the Treatment Authorization Request form. The attending physician shall sign the Treatment Authorization Request form and shall certify to the Department that the beneficiary requires this level of care.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
Intermediate Care Services	Intermediate Care Facility Services	Intermediate care services are covered only after prior authorization has been obtained from the designated Medi-Cal consultant for the district where the facility is located. The authorization request shall be initiated by the facility. The attending physician shall sign the authorization request and shall certify to the Department that the beneficiary requires this level of care.	~~X~~[5] X[3,~~965~~]	~~X~~[5] X[3,~~965~~]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
Laboratory, Radiological and Radioisotope Services	Laboratory, X- Ray and Laboratory, Radiological and Radioisotope Services	Covers exams, tests, and therapeutic services ordered by a licensed practitioner.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Licensed Midwife Services	Other Practitioners' Services and Licensed Midwife Services	The following services shall be covered as licensed midwife services under the Medi-Cal Program when provided by a licensed midwife supervised by a licensed physician and surgeon: (1) Attendance at cases of normal childbirth and (2) The provision of prenatal, intrapartum, and postpartum care, including family planning care, for the mother, and immediate care for the newborn.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Local Educational Agency (LEA) Services	Local Education Agency Medi- Cal Billing Option Program Services	LEA health and mental health evaluation and health and mental health education services, which include any or all of the following: (A) Nutritional assessment and nutrition education, consisting of assessments and non-classroom nutrition education delivered to the LEA eligible beneficiary based on the outcome of the nutritional health assessment (diet, feeding, laboratory values, and growth), (B) Vision assessment, consisting of examination of visual acuity at the far point conducted by means of the Snellen Test, (C) Hearing assessment, consisting of testing for auditory impairment using at-risk criteria and appropriate screening techniques as defined in Title 17, California Code of Regulations, Sections 2951(c), (D) Developmental assessment, consisting of examination of the developmental level by review of developmental achievement in comparison with expected norms for age and background, (E) Assessment of psychosocial status, consisting of appraisal of cognitive, emotional, social, and behavioral functioning and self-concept through tests, interviews, and behavioral evaluations and (F) Health education and anticipatory guidance appropriate to age and health status, consisting of non- classroom health education and anticipatory guidance based on age and developmentally appropriate health education.						

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Long Term Care (LTC)		Care in a facility for longer than the month of admission plus one month. Medically necessary care in a facility covered under managed care health plan contracts	~~X~~[5]~~X~~[3,~~9~~65]	~~X~~[5]~~X~~[3,~~596~~]	X[53]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]
Medical Supplies ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. ~~Does not include incontinence creams and washes~~	X	X	X	X	X	X
Medical Supplies (effective April 1, 2021 onward)	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. Does not include medical supplies carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including medical supplies described in the Medi-Cal Rx All Plan Letter (APL 20-020). [1] ~~Medically necessary supplies when prescribed by a licensed practitioner.~~	X	X	X	X	X	X
Medical & Non-Medical (NMT) Transportation Services	Transportation-Medical & Non-Medical ~~(NMT)~~Transportation (NMT) Services	Covers ambulance, litter van and wheelchair van medical transportation services are covered when the beneficiary's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically contraindicated, and transportation is required for the purpose of obtaining needed medical care. NMT is transportation by private or public vehicle for	X	X	X	X	X	X

[1] https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2020/APL20-020.pdf

		beneficiary~~'s~~sies ~~people~~ who do not have another way to get to their appointment.						
Multipurpose Senior Services Program (MSSP)		MSSP sites provide social and health care management for frail elderly clients who are certifiable for placement in a nursing facility but who wish to remain in the community.	X[9]X[65]	X[9]X[65]	X[9]X[65]			
Nurse Anesthetist Services	Other Practitioners' Services and Nurse Anesthetist Services	Covers anesthesiology services performed by a nurse anesthetist within the scope of his or her licensure.	X	X	X	X	X	X
Nurse Midwife Services	Nurse-Midwife Services	An advanced practice registered nurse who has specialized education and training in both Nursing and Midwifery, is trained in obstetrics, works under the supervision of an obstetrician, and provides care for mothers and newborns through the maternity cycle of pregnancy, labor, birth, and the immediate postpartum period, not to exceed six weeks.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Optometry Services	Optometrists' Services	Covers eye examinations and prescriptions for corrective lenses. ~~Further services are not covered.~~	X	X	X	X	X	X
Outpatient Mental Health	Outpatient Mental Health	Services provided by licensed health care professionals acting within the scope of their license for adults and children diagnosed with a mental condition as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) resulting in mild to moderate distress or impairment of mental, emotional, or behavioral functioning. Services include: • Individual and group mental health evaluation and treatment (psychotherapy) • Psychological testing when clinically indicated to evaluate a mental health condition • Outpatient Services for the purpose of monitoring drug therapy • Outpatient laboratory, ~~drugs,~~ supplies and supplements • Screening and Brief Intervention (SBI) • Psychiatric consultation for medication management	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Organized Outpatient Clinic Services	Clinic Services and Organized Outpatient Clinic Services	In-home medical care waiver services and nursing facility waiver services are covered when prescribed by a physician and provided at the beneficiary's place of residence in accordance with a written treatment plan indicating the need for in- home medical care waiver services or nursing facility waiver services and in accordance with a written agreement between the Department and the provider of service.	X	X	X	X	X	X
Outpatient Heroin Detoxification Services	Outpatient Heroin Detoxification Services	Can cover of a number of medications and treatments, allowing for day-to-day functionality for a person choosing to not admit as an inpatient. Routine elective heroin detoxification services are covered, subject to prior authorization, only as an outpatient service. Outpatient services are limited to a maximum period of 21 days. Inpatient hospital services shall be limited to patients with serious medical complications of addiction or to patients with associated medical problems which require inpatient treatment.						
Part D Drugs		Drug benefits for full-benefit dual eligible beneficiaries who are eligible for drug benefits under Part D of Title XVIII of the Social Security Act.						
Pediatric Subacute Care Services	Nursing Facility Services and Pediatric Subacute Services (NF)	Pediatric Subacute care services are a type of skilled nursing facility service which is provided by a subacute care unit.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Personal Care Services	Personal Care Services	Covers services which may be provided only to a categorically needy beneficiary who has a chronic, disabling condition that causes functional impairment that is expected to last at least 12 consecutive months or that is expected to result in death within 12 months and who is unable to remain safely at home without the services.	~~X~~[9] ~~X~~[65, 14]	~~X~~[9] ~~X~~[65, 14]	~~X~~[9] ~~X~~[65, 14]			
Pharmaceutical Services and Prescribed Drugs ~~(effective Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Pharmaceutical Services and Prescribed Drugs	Covers medications including prescription and nonprescription and total parenteral and enteral nutrition supplied by licensed physician.	X	X	X	X	X	X
Pharmaceutical Services and Prescribed Drugs (effective Apr 1, 2021 onward)	Pharmaceutical Services and Prescribed Drugs	Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and enteral nutrition supplied by licensed physician. Does not include pharmacy benefits carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including covered outpatient drugs, physician administered drugs (PADs), medical supplies, and enteral/parenteral nutritional products as described in the Medi-Cal Rx All Plan Letter (APL 20-020). ~~Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and~~	X	X	X	X	X	X

		~~enteral nutrition supplied by licensed physician.~~						
Physician Services	Physician Services	Covers primary care, outpatient services, and services rendered during a stay in a hospital or nursing facility for medically necessary services. Can cover limited mental health services when rendered by a physician, and limited allergy treatments.	X	X	X	X	X	X
Podiatry Services	Other Practitioners' Services and Podiatrists' Services	Office visits are covered if medically necessary. All other outpatient services are subject to the same prior authorization procedures that govern physicians, and are limited to medical and surgical services necessary to treat disorders of the feet, ankles, or tendons that insert into the foot, secondary to or complicating chronic medical diseases, or which significantly impair the ability to walk. Services rendered on an emergency basis are exempt from prior authorization.	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]
Preventive Services	Preventive Services	All preventive services articulated in the state plan.	X	X	X	X	X	X

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Prosthetic and Orthotic Appliances	Prosthetic and ~~Orthodic~~ Orthotic Appliances	All prosthetic and orthotic appliances necessary for the restoration of function or replacement of body parts as prescribed by a licensed physician, podiatrist or dentist, within the scope of their license, are covered when provided by a prosthetist, orthotist or the licensed practitioner, respectively	X	X	X	X	X	X
~~Psychology,~~ Physical Therapy and ~~,~~ Occupational Therapy~~,~~ ~~Speech Pathology and Audiological Services~~	~~Psychology Listed as Other Practitioners' Services and Psychology,~~ Physical Therapy and~~,~~ Occupational Therapy~~, Speech Pathology, and Audiology Services~~	~~Psychology, P~~physical therapy and~~,~~ occupational therapy~~, speech pathology and audiological services~~ are covered when provided by persons who meet the appropriate requirements	X[1,1,2*]	X[1,1,2]	X[1,1,2*]	X[1,1,2]	X[1,1,2]	X[1,1,2]
~~Psychotherapeutic drugs~~	~~Services not covered under the State Plan~~	~~Psychotherapeutic drugs that are listed in the Medi-Cal Provider Manual~~	X	X	X[8]	X	X	X
Rehabilitation Center Outpatient Services	Rehabilitative Services	A facility providing therapy and training for rehabilitation on an outpatient basis. The center may offer occupational therapy, physical therapy, vocational training, and special training.	X	X	X	X	X	X
Rehabilitation Center Services	Rehabilitative Services	A facility which provides an integrated multidisciplinary program of restorative services designed to upgrade or maintain the physical functioning of patients.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Renal Homotransplantation	Organ Transplant Services	Renal homotransplantation is covered only when performed in a hospital which meets the standards established by the Department for renal homotransplantation centers.	X	X	X	X	X	X
~~Requirements Applicable to EPSDT Supplemental Services.~~	~~EPSDT~~	~~Early and Periodic Screening, Diagnosis and Treatment: for beneficiaries under 21 years of age; includes case management and supplemental nursing services; also covered by CCS for CCS services, and Mental Health services.~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~
Respiratory Care Services	Respiratory Care Services	A provider trained and licensed for respiratory care to provide therapy, management, rehabilitation, diagnostic evaluation, and care of patients with deficiencies and abnormalities affecting the pulmonary system and aspects of cardiopulmonary and other systems.	X	X	X	X	X	X
Rural Health Clinic Services	Rural Health Clinic Services	Services described in 42 U.S.C. Section 1396d(a)(2)(B) furnished by a rural health clinic as defined in 42 U.S.C. Section 1396d(l)(1)~~Covers primary care services by a physician or a non-physician medical practitioner, as well as any supplies incident to these services; home nursing services; and any other outpatient services, supplies, and e~~Equipment and drugs~~~~.	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~
Scope of Sign Language Interpreter Services	Sign Language Interpreter Services	Sign language interpreter services may be utilized for medically necessary health care services	X	X	X	X	X	X
Services provided in a State or Federal Hospital		California state hospitals provide inpatient treatment services for Californians with serious mental illnesses. Federal hospitals provide services for certain populations, such as the military, for which the federal government is responsible.						

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Short-Doyle Mental Health Medi-Cal Program Services	Short-Doyle Program	Community mental health services provided by Short-Doyle Medi-Cal providers to Medi-Cal beneficiaries are covered by the Medi-Cal program.						
Skilled Nursing Facility Services~~,~~	Nursing Facility Services and Skilled Nursing Facility Services	A skilled nursing facility is any institution, place, building, or agency which is licensed as a SNF by DHCS or is a distinct part or unit of a hospital, (except that the distinct part of a hospital does not need to be licensed as a SNF) and has been certified by DHCS for participation as a SNF in the Medi-Cal program.	~~X~~[5] X[3,~~965~~]	~~X~~[5] X[3,~~965~~]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
~~Special~~ Private Duty Nursing	~~Private Duty Nursing Services~~EPSDT	Private duty nursing is the planning of care and care of clients by nurses, whether a registered nurse or licensed practical nurse.	X[~~67~~]	X[~~67~~]	X[~~67~~]	X[~~67~~]	X[~~67~~]	X ~~X[76]~~
Specialty Mental H~~h~~ealth S~~s~~ervices		Rehabilitative services, which includes mental health services, medication support services, day treatment intensive, day rehabilitation, crisis intervention, crisis stabilization, adult residential treatment services, crisis residential services, and psychiatric health facility services.						
Specialized Rehabilitative Services in Skilled Nursing Facilities and Intermediate Care Facilities	Special Rehabilitative Services	Specialized rehabilitative services shall be covered. Such service shall include the medically necessary continuation of treatment services initiated in the hospital or short term intensive therapy expected to produce recovery of function leading to either (1) a sustained higher level of self care and discharge to home or (2) a lower level of care. Specialized rehabilitation service shall be covered.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Speech Pathology	Speech Pathology	Speech pathology services are covered when provided by persons who meet the appropriate requirements	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
State Supported Services		State funded abortion services that are provided through a secondary contract.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Subacute Care Services	Nursing Facility Services and Skilled Subacute Care Services SNF	Subacute care services are a type of skilled nursing facility service, which is provided by a subacute care unit.	~~X~~[5] X[3,~~965~~]	~~X~~[5] X[3,~~965~~]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
Swing Bed Services	Inpatient Hospital Services	Swing bed services is additional inpatient care services for those who qualify and need additional care before returning home.	X	X	X	X	X	X
~~Targeted Case Management Services Program~~	~~Targeted Case Management~~	~~Persons who are eligible to receive targeted case management services shall consist of the following Medi-Cal beneficiary groups: high risk, persons who have language or other comprehension barriers and persons who are 18 years of age and older.~~						
Targeted Case Management and Services~~.~~	Targeted Case Management	Persons who are eligible to receive targeted case management services shall consist of the following Medi-Cal beneficiary groups: high risk, persons who have language or other comprehension barriers and persons who are 18 years of age and older. Targeted case management services shall include at least one of the following service components: A documented assessment identifying the beneficiary's needs, development of a comprehensive, written, individual service plan, implementation of the service plan includes linkage and consultation with and referral to providers of service, assistance with accessing the services identified in the service plan, crisis assistance planning to coordinate and arrange immediate service or treatment needed in those situations that appear to be emergent in nature or which require immediate attention or resolution in order to avoid, eliminate or						

		reduce a crisis situation for a specific beneficiary, periodic review of the beneficiary's progress toward achieving the service outcomes identified in the service plan to determine whether current services should be continued, modified or discontinued.						

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Transitional Inpatient Care Services	Nursing Facility and Transitional Inpatient Care Services	Focus on transition of care from outpatient to inpatient. Inpatient care coordinators, along with providers from varying settings along the care continuum, should provide a safe and quality transition.	X	X	X	X	X	X
Tuberculosis (TB) Related Services	TB Related Services	Covers TB care and treatment in compliance with the guidelines recommended by American Thoracic Society and the Centers for Disease Control and Prevention.						

[1] ~~Chiropractic~~Optional benefits~~-Optional benefits~~ coverage is limited to only beneficiaries in "Exempt Groups": 1) beneficiaries under 21 years of age for services rendered pursuant to EPSDT program; 2) beneficiaries residing in a SNF (Nursing Facilities Level A and Level B, including subacute care facilities; 3) beneficiaries who are pregnant; 4) CCS beneficiaries; 5) beneficiaries enrolled in the PACE; and 6) beneficiaries who receive services at an FQHC (including Tribal) or RHC.~~.~~ Services include: Chiropractic Services, Audiologist and Audiology Services, and Speech Pathology.

[2] Services provided by primary care physicians; psychiatrists; psychologists; licensed clinical social workers; or other specialty mental health provider. Solano County for Partnership Health plan (COHS) covers specialty mental health, and Kaiser GMC covers inpatient, outpatient, and specialty mental health services.

~~[3] Fabrication of optical lenses only covered by CenCal Health.~~

~~[4] Not covered by CenCalCovered by CenCal as of 7/1/2016~~

~~[5]~~ [3] Only covered for the month of admission and the following month.

~~[6]~~ [4] Not covered by Gold Coast Health Plan.

Covered by CenCal Health, Central California Alliance for Health, and Health Plan of San Mateo (effective July 1, 2018). Covered by Partnership HealthPlan of California (effective January 1, 2019) and CalOptima (effective ~~January~~ July 1, 2019).

~~[7] [5] Only covered in Health Plan of San Mateo and CalOptima.~~

~~[8] Only covered in Health Plan of San Mateo~~

~~[9]~~ [6][5] Services covered under managed care only in MLTSS Eligible Beneficiary Authorized Counties: ~~Alameda,~~ Los Angeles, Orange, Riverside, San Bernardino, San Diego, San Mateo, and Santa Clara~~, and Riverside~~. IHSS benefits are not part of this covered service.

~~[10]~~ [7][6] Benefit coverage is limited to only beneficiaries under 21 years of age for services rendered pursuant to EPSDT ~~program~~requirements.

~~[11]~~ [8][7] Health Home Program (HHP) service coverage is limited to only those beneficiaries specified in the HHP State Plan Amendments (SPAs), including any subsequent amendments to the CMS-approved HHP SPAs. HHP services will be provided only through the Medi-Cal managed care delivery system to beneficiaries enrolled in managed care. Individuals receiving benefits through the fee-for-service (FFS) delivery system who meet HHP eligibility criteria, and who wish to receive HHP services, must instead enroll in an MCP to receive all services, including HHP services. HHP services will not be provided through a FFS delivery system. The HHP-specific provisions of the Medi-Cal 2020 demonstration freedom of choice waiver, and managed care delivery system implementation Medicaid authority, are in effect for any CMS-approved HHP SPAs - including SPA requirements specific to eligible populations, geographic limitation approved providers, and any other SPA requirements, including any subsequent amendments to the CMS - approved HHP SPAs ~~–~~for the duration of the Medi-Cal 2020 demonstration.

[8]The fabrication of eyeglasses lenses are carved out statewide to FFS Medi-Cal contracted optical laboratories, **except specialty lenses, including lenses that exceed contract lab ranges.**

[9]California Children Services covered in COHS counties with the exception of Ventura County (Gold Coast Health Plan)

Exhibit B

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FW: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

[redacted]

Attachment N Updates ...
119 KB

Attachment N Updates ...
104 KB

Show all 2 attachments (223 KB) Download all

[redacted]

From: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>
Sent: Thursday, December 24, 2020 10:17 AM
To: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>
Cc: Young, Cheryl (CMS/CMCS) <Cheryl.Young@cms.hhs.gov>; Zolynas, Brian (CMS/CMCS) <Brian.Zolynas@cms.hhs.gov>; Cooper, Jacey@DHCS <Jacey.Cooper@dhcs.ca.gov>; Toyama, Aaron@DHCS <Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good Morning,

DHCS formally submits the attached updated Attachment N as a technical amendment request to the California Medi-Cal 2020 Demonstration Special Terms and Conditions (STCs).

Changes to Capitated Benefits Provided in Managed Care (Attachment N), an attachment to the California Medi-Cal 2020 Demonstration STCs, stem from recent legislative or administrative changes in Medi-Cal benefit policy including but not limited to the California State Auditor's assessment of the efficacy of preventive care services for children, the State's Medi-Cal Rx initiative, and the restoration of optional benefits as a result of SB 78 and AB 678. These changes are proposed to be effective on January 1, 2021, in conjunction with the State's request to extend the Medi-Cal 2020 Demonstration for 12 months, which is currently under CMS review.

Changes to Attachment N include:

- Clarification of capitated benefits categorized under the Early and Periodic Screening, Diagnostic and Treatment entitlement.

Reply all | Delete Junk |

- In-Home Medical Care Waiver Services was removed.
- Other services updated for clarification include: hysterectomy within all managed care model types and non-emergency medical transportation.
- Updates were made to previously optional benefits, such as fabrication of lenses and the provision of podiatry services with prior authorization.
- Alameda county was removed from the list of Coordinated Care Initiative (CCI) counties.
- Updates to service definitions for dental and outpatient mental health and outpatient rehabilitative services, Federally Qualified Health Care Centers (FQHCs), and Rural Health Clinics.
- Footnotes were appropriately updated to reflect all changes.

Please let us know if CMS has any questions on this amendment request. Thank you, and happy holidays!

Amanda Font
California Department of Health Care Services
Director's Office

Exhibit C

Reply all | Delete Junk |

FW: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Reply all | Delete Junk |

[redacted]

From: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>
Sent: Tuesday, December 29, 2020 3:35 AM
To: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>
Cc: Young, Cheryl (CMS/CMCS) <Cheryl.Young@cms.hhs.gov>; Zolynas, Brian (CMS/CMCS) <Brian.Zolynas@cms.hhs.gov>; Cooper, Jacey@DHCS <Jacey.Cooper@dhcs.ca.gov>; Toyama, Aaron@DHCS <Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: RE: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good morning Amanda,
Thank you for the information. CMS will review the attachment. I would like to let the state know that CMS will not be incorporating this attachment into the STCs for the temporary extension request for December 31, 2020, but we are going to review the information to be updated to the STCs with the other updates to the CA STCs within the state's original extension request. CMS understands that the pharmacy update is not to happen until April 1, 2021 and we are working to make sure this attachment will be incorporated before that time.

If you have additional questions, please reach out to Julian Taylor and myself to discuss.
Thank you
Heather Ross

From: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>
Sent: Thursday, December 24, 2020 1:17 PM
To: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>

Reply all | Delete Junk |

<Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
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Changes to Attachment N include:

- Clarification of capitated benefits categorized under the Early and Periodic Screening, Diagnostic and Treatment entitlement.
- Clarification of specific drug and medical supplies categories both prior to, and after, the April 1, 2021 implementation of Medi-Cal Rx, to make necessary updates associated with Medi-Cal Rx initiative.
- In-Home Medical Care Waiver Services was removed.
- Other services updated for clarification include: hysterectomy within all managed care model types and non-emergency medical transportation.
- Updates were made to previously optional benefits, such as fabrication of lenses and the provision of podiatry services with prior authorization.
- Alameda county was removed from the list of Coordinated Care Initiative (CCI) counties.
- Updates to service definitions for dental and outpatient mental health and outpatient rehabilitative services, Federally Qualified Health Care Centers (FQHCs), and Rural Health Clinics.
- Footnotes were appropriately updated to reflect all changes.

Please let us know if CMS has any questions on this amendment request. Thank you, and happy holidays!

Amanda Font
California Department of Health Care Services
Director's Office

Exhibit D

Christopher M. House

From: caed_cmecf_helpdesk@caed.uscourts.gov
Sent: Tuesday, March 9, 2021 4:14 PM
To: CourtMail@caed.uscourts.dcn
Subject: [EXTERNAL] Activity in Case 2:20-cv-02171-JAM-KJN Community Health Center Alliance for Patient Access et al v. Lightbourne et al Order on Motion to Dismiss.

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.
*****NOTE TO PUBLIC ACCESS USERS*** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.**

U.S. District Court

Eastern District of California - Live System

Notice of Electronic Filing

The following transaction was entered on 3/9/2021 at 4:13 PM PST and filed on 3/9/2021
Case Name: Community Health Center Alliance for Patient Access et al v. Lightbourne et al
Case Number: 2:20-cv-02171-JAM-KJN
Filer:
Document Number: 37(No document attached)

Docket Text:
MINUTES for proceedings held via video conference before District Judge John A. Mendez: MOTION HEARING re Plaintiffs' pending [22] Motion for Preliminary Injunction and Defendants' pending [23] Motion to Dismiss held on 3/9/2021. A. Stroud, R. Boyle and K. Doi appeared via video for the plaintiffs. J. Sondheimer appeared via video for the defendants. The Court and Counsel discussed Plaintiffs' pending Motion for Preliminary Injunction and Defendants' pending Motion to Dismiss. After arguments, for the reasons stated on the record, the Court GRANTED Defendants' [23] Motion to Dismiss without prejudice and ORDERED Plaintiffs wait to file an amended complaint until after CMS acts on the approval sought by Defendants. Court Reporter: J. Coulthard. [TEXT ONLY ENTRY] (Michel, G.)

2:20-cv-02171-JAM-KJN Notice has been electronically mailed to:

Andrew W. Stroud astroud@hansonbridgett.com, calendarclerk@hansonbridgett.com, MFrancis@hansonbridgett.com

Anjana N. Gunn anjana.gunn@doj.ca.gov, adayananthan@gmail.com

Darrell Warren Spence darrell.spence@doj.ca.gov

Joshua Sondheimer joshua.sondheimer@doj.ca.gov, nora.lyman@doj.ca.gov, rowena.manalastas@doj.ca.gov

Kathryn Ellen Doi kdoi@hansonbridgett.com, CalendarClerk@hansonbridgett.com, chouse@hansonbridgett.com, mfrancis@hansonbridgett.com

Regina Mary Boyle rboyle@cliniclaw.com

Tara L. Newman tara.newman@doj.ca.gov, tnewman@gmail.com

2:20-cv-02171-JAM-KJN Electronically filed documents must be served conventionally by the filer to:

Exhibit E

From: DHCS Communications <DHCSCommunications@DHCS.CA.GOV>
Sent: Wednesday, February 17, 2021 5:12 PM
To: DHCSSTAKEHOLDERS@MAILLIST.DHS.CA.GOV
Subject: [EXTERNAL] Important Update on Medi-Cal Rx

Dear Stakeholders,

The Department of Health Care Services (DHCS) is delaying the planned Go Live date of April 1, 2021, for Medi-Cal Rx because of the need to review new conflict avoidance protocols submitted by Magellan Health, the project's contracted vendor.

In January 2021, Centene Corporation announced that it plans to acquire Magellan. Centene operates – through subsidiaries – managed care plans and pharmacies that participate in Medi-Cal. This transaction was unexpected and requires additional time for exploration of acceptable conflict avoidance protocols to ensure that there will be acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal beneficiaries, and to protect other proprietary information.

Medi-Cal Rx remains of utmost importance to the State of California as a tool to standardize the Medi-Cal pharmacy benefit statewide under one delivery system. It will improve access to pharmacy services with a network that includes approximately 94 percent of the state's pharmacies. Medi-Cal Rx will also apply statewide utilization management protocols to all outpatient drugs, standardizing the experience for all Medi-Cal beneficiaries and providers. Medi-Cal Rx will also strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers, helping to reduce pharmaceutical costs.

DHCS anticipates providing further information in May.

If you have any questions, please feel free to direct them to the Medi-Cal Rx Project Team at RxCarveOut@dhcs.ca.gov.

Thank you,
DHCS

From: Medi-Cal Rx Education and Outreach Team <postmaster@dhcs.ca.gov>
Sent: Wednesday, February 17, 2021 5:53 PM
To: Kathryn E. Doi
Subject: [EXTERNAL] Medi-Cal Rx News: Important Update on Medi-Cal Rx

MCRxSS Announcement

The Important Update on Medi-Cal Rx alert posted to the Medi-Cal Rx Web Portal on 2/17/2021.

If the above link does not take you to the alert, then simply copy and paste the following link into your browser to access the Bulletins and News page: https://medi-calrx.dhcs.ca.gov/provider/pharmacy-news.

***Please note: Internet Explorer is no longer a supported web browser. Please utilize Chrome, Microsoft Edge, or another supported web browser when clicking on links for the Medi-Cal Rx Web Portal.

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Our Mailing Address is:
P.O. Box 2088 Rancho Cordova, CA 95741-2088, United States

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Important Update on Medi-Cal Rx

February 17, 2021

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DHCS anticipates providing further information in May. Please note that DHCS will be working to update and/or remove, as applicable, provider guidance and associated Medi-Cal Rx provider bulletins/Newsflash articles in the coming weeks to reflect this change.

Exhibit B
to letter dated 4/16/2021

HANSON BRIDGETT LLP
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Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF FRANCISCO CASTILLON IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Francisco Castillon, declare as follows:

1. I am the Chief Executive Officer ("CEO") at Omni Family Health ("OFH") and have held this role since May 2011. As CEO, I am responsible for overseeing the organization of thirty-five (35) health centers and four (4) pharmacies. In addition, I have

oversight of OFH's 340B Program. I have reviewed the data relevant to impact of the Medi-Cal Rx Transition on OFH in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. OFH is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act that meets all requirements in Section 330 of the Public Health Service Act. OFH has been in business since 1978 and operates health centers in Kern, Fresno, Tulare, and Kings Counties.

3. OFH provides pharmaceutical services through four licensed pharmacies and two clinic dispensaries, as well as through eighty (80) 340B contract pharmacies.

4. In order to comply with applicable State and Federal law relating to the 340B program OFH has registered each of our FQHC sites that dispenses drugs to Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B drugs to our Medi-Cal patients.

5. In 2019 our cost of providing pharmacy services, including the cost of pharmaceuticals, through in-house pharmacies, contract pharmacies and our clinic dispensary license was $7,085,757.00

6. Approximately seventy percent of the patients utilizing our pharmacy services were Medi-Cal beneficiaries, thus Medi-Cal's share of the total cost was approximately $4,960,029.90.

7. OFH carved its pharmacy services costs out of our Medi-Cal prospective payment rate as to our in-house and contract pharmacy services, and is currently reimbursed for these services under the fee schedules applicable to California's Alternative Payment Methodology ("APM"). As a practical matter, this means that we are reimbursed by Medi-Cal managed care plans at a negotiated rate under the APM.

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8. OFH does not dispense 340B drugs (or any drugs) to Medi-Cal beneficiaries who are reimbursed by Medi-Cal's fee-for-service system through contract pharmacies.

9. OFH's in-house pharmacies dispense an extremely limited volume of drugs to Medi-Cal fee-for-service beneficiaries since the majority of our Medi-Cal patients are enrolled in managed care plans. Medicaid managed care plans, under non-discrimination provisions of State and Federal law, are prohibited from paying FQHCs less than they pay to other health care providers furnishing similar services.

10. Fee-for-service reimbursement paid to 340B Covered Entities, including OFH, is limited to the "actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee" of either $10.05 or $13.20, depending on the pharmacy's dispensing volume. This has not had a significant negative impact on OFH to-date, since we have had few prescriptions reimbursed under this methodology.

11. Under this fee-for-service reimbursement methodology, however, the cost of the drug must be determined by the FQHC on a claim-by-claim basis, which would eliminate the benefit intended for the 340B program (allowing us to stretch scarce federal resources through the gap between generally applicable reimbursement and the special discount accorded 340B covered entities), but it would significantly increase our administrative and facility costs associated with dispensing these drugs, since we would no longer be able to fill Medi-Cal prescriptions through low-cost contract pharmacies.

12. If the Medi-Cal Rx Transition became effective on April 1, 2021, approximately seventy percent of our prescriptions would be filled through Medi-Cal's 340B-specific fee-for-service reimbursement schedule. This will require changes to our current operations, which may include discontinuing home delivery of drugs to those unable to come to the clinic for health reasons or due to a lack of transportation. Additionally, we would need to discontinue stocking of more expensive medications.

/ / /

13. If the Medi-Cal Rx Transition became effective, there is a risk that we will have to close the two pharmacies that are carved into our PPS rate, since we are not reimbursed for the cost of these drugs except through a historical assessment of costs that has not kept up with the changes in drug prices, and since we are not reimbursed for pharmacy visits on a per-visit basis. These two pharmacies serve agricultural, rural areas, in which many of our patients are undocumented, and for whom filling prescriptions through our health center is the sole available option. Many of our patients have no access to a pharmacy within a 30-minute drive. We are currently able to fill their prescriptions for the uninsured on a sliding fee scale, consistent with the "open door" requirements applicable to health centers. If we are unable to continue providing pharmaceutical services to these patients at our current level, there will be a severe impact on the quality of care we are able to provide. Our most vulnerable patients will not be able to receive required medications from us, and unless they are able to find another source of care, will likely discontinue taking medications. This would particularly impact patients with diabetes, heart conditions, and patients receiving treatment for opioid addiction through our Medication Assistant Therapy ("MAT") program. Many of our migrant farmworker patients are working in the field all day. They cannot just pop into a local pharmacy, particularly if ours is forced to close.

14. California law requires FQHCs that are reimbursed for pharmaceutical services outside of their PPS rate to be reimbursed for drugs dispensed to Medi-Cal beneficiaries through a dispensary in accordance with Welfare & Inst. Code § 14132.01. With the exception of Medi-Cal beneficiaries enrolled in the Family Planning Access Care and Treatment Program ("Family PACT"), there is currently no billing system in place that would permit us to be reimbursed under this statute.

15. Additionally, our reimbursement for Family PACT drugs has at no time been assessed by DHCS to ensure that it fully covers our cost of providing such services.

16. According to the Uniform Data System ("UDS") report that OFH submitted to the federal Health Resources and Services Administration ("HRSA") for 2019, OFH

provided primary care services to 131,449 unduplicated patients, and had 588,936 patient visits (encounters). The distribution of OFH patients as a percentage of poverty guidelines is 62,160 patients (47.29%) at 100 percent and below the federal poverty level; 10,102 patients (7.69%) at 101 to 150 percent of the federal poverty level; 4,009 patients (3.05%) at 151 to 200 percent of the federal poverty level; 2,433 patients (1.85%) at over 200 percent of the federal poverty level; and 52,745 patients (40.13%) whose percent of the federal poverty level is unknown.

17. OFH also reported the following with respect to the special populations served by our clinics: Migrant/Seasonal = 41,735 patients, Homeless patients = 647, and Veterans = 163.

18. The UDS report also captured OFH's demographic makeup, the largest categories consist of the following: Hispanic/Latino = 52,573 and White Non-Hispanic/Latino = 27,644, followed by African American = 5,582.

19. As reported on our UDS report, with respect to OFH visits involving patients with two or more diseases/diagnoses, the most common diseases/diagnoses involved were: Diabetes Mellitus = 37,494 visits, Overweight and Obesity = 48,295, Hypertension = 52,168, and Heart Disease = 4,747. In addition, the most common visits provided for mental health conditions and substance disorders were: anxiety disorder/PTSD = 37,001, depression and mood disorders = 39,324, and other mental disorders (excluding drug or alcohol dependence) = 22,011.

20. OFH's participation in the 340B Drug Pricing Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as OFH's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population. OFH passes the 340B savings on to its patients by providing uninsured patients of OFH making less than 200 percent of the federal poverty limit a sliding scale discount on all services including significant discounts for medication at OFH's in-house pharmacy. In addition to providing access to

affordable medications for low-income uninsured patients through our sliding scale discount and other prescription savings programs, OFH's 340B savings are reinvested into the cost of providing services that the Medi-Cal program does not include in OFH's prospective payment system per-visit rate, such as having in-house outreach staff, case managers, care coordinators, referral staff, call center staff, pharmacy technicians, and other ancillary support that enhance services provided by the primary care team.

21. OFH's current 340B prescription drug program includes five (5) onsite and eighty (80) contract pharmacy sites. From January 1, 2020 through September 30, 2020, OFH's in-house pharmacies filled 228,791 prescriptions, 26,861 of which were prescriptions filled for uninsured patients. OFH's 80 contract pharmacies filled nearly 10,000 prescriptions, of which over 10 percent were dispensed for uninsured patients.

22. OFH's 2019 UDS report also identified two key payer groups who made up over 80 percent of the overall payer mix:

Medi-Cal Managed Care (MCO)	93,214 patients (71%)
Uninsured	13,821 patients (11%)
Total	**107,035 patients (82%)**

23. In 2019, OFH recognized an estimated net 340B income (reimbursement minus drug costs and program overhead) of $4,200,000 (over 70% of total) from filling Medi-Cal managed care (MCO) patient prescriptions. This net 340B benefit was and continues to be used for "stretching scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" not typically covered by Medi-Cal managed care (MCO) including the following. Our fifth pharmacy having opened only recently, the numbers presented represent the totals from 4 pharmacies.

24. Five in-house pharmacies ensure access to affordable prescription drugs through:

- Free home delivery and delivery options for patients residing in rural areas without local pharmacy access.

- Opening new locations to expand access to services and outreach to new patients, including clinic and pharmacy onsite services.
- Ensuring adequate resource funding for clinic programs and onsite pharmacies that have demonstrated nationally having a significant positive impact on emergency room utilization, improved coordination of care, and improved outcomes for such chronic conditions as asthma and diabetes.

25. OFH estimates 340B savings generated from our pharmacies through the 340B Drug Pricing Program account for about 20 percent of our direct patient care staffing expenses.

26. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes the prescriptions affordable for all patients, including the uninsured. In addition, the savings retained by OFH are utilized to serve even more patients and to increase comprehensive services at no cost to the taxpayer. Because of this action taken by California's Governor to eliminate 340B savings, patient services and programs such as having a call center, referral center, case management, onsite pharmacies, pharmacy technicians, care coordinators, and in-house behavioral services, and dental services are at risk of being significantly reduced or eliminated. This, in turn, puts our patients at risk for increased access to care issues, as well as health problems that increase health care costs to the entire primary care medical home health care system. In addition to the loss of services, higher costs, poorer patient outcomes, and loss of employee positions, losing contract pharmacy 340B savings would negatively affect strategic plans for a much needed facility expansion aimed at increasing our ability to serve more of the uninsured is frightening and will be devastating to the health outcomes of our patients.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 19th day of December 2020, in Sacramento, California.

Francisco Castillon

Exhibit C
to letter dated 4/16/2021

HANSON BRIDGETT LLP
KATHRYN E. DOI, SBN 121979
ANDREW W. STROUD, SBN 126475
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Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF C. DEAN GERMANO IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, C. Dean Germano, declare as follows:

1. I am the Chief Executive Officer ("CEO") of Shasta Community Health Center ("SCHC") and have been in this position since 1992. I am a past Board President of the California Primary Care Association ("CPCA") and am currently Board Emeritus

with CPCA. I am also a past Chair of the Shasta County Public Health Advisory Board, and past-Chair and current member of Golden Umbrella and Senior Nutrition Centers (Dignity Health Affiliates) Advisory Board in Redding, California. I am also past Chair and current member of the Health Alliance of Northern California ("HANC"), an organization that represents Federally Qualified Health Centers ("FQHCs") in the Shasta region, working with hospitals and medical groups to create positive community health systems changes in our region. Beginning in 2006, I was selected to the Board of The California Endowment (the "Endowment"), a $3+ billion statewide healthcare foundation dedicated to improving the health and well-being of all Californians. In 2012, I served as Vice-Chair of the Board of the Endowment, and then served as its Chair until my nine-year term ended in 2015. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. As CEO of SCHC, I am responsible for overseeing care to 40,000 unduplicated patients, providing over 130,000 visits a year in a multi-specialty type practice that includes mental health and dental. Over 92% of SCHC's patients live below 200% of the federal poverty line. I also have oversight of our 340B Program. For many years, the savings that SCHC has retained through the discounted drug purchase prices available through the 340B program has been used to benefit our patients through such things as the passing of the 340B price to our uninsured and underinsured patients, allowing us to charge many sliding fee patients no more than $10 for prescriptions at our contract pharmacies, and providing services such as transportation assistance, covering a significant portion of lab costs for sliding fee patients, and covering patient education services and gap funding for departments that are not profitable, such as telemedicine. In 2019, SCHC's 340B Medi-Cal savings totaled $1.79 million. The Medi-Cal transition to managed care would result in a loss of these savings and would force SCHC to make cuts to these programs that will have a negative impact on patient care and service to our community.

3. Following the Governor's announcement of the pharmacy transition in January 7, 2019, , the California Primary Care Association ("CPCA") began to advocate with the Department of Health Care Services (the "Department") to address the revenue impact that FQHCs were going to experience as a result of the pharmacy transition. I was familiar with these efforts through my participation with CPCA as an emeritus board member and through my active participation in various CPCA committees and meetings.

4. The Department ultimately agreed to support legislation that would establish a "supplemental payment pool" ("SPP"), which is intended to compensate community health centers who will lose Medi-Cal managed care 340B savings if the State transitions the pharmaceutical benefit away from managed care plans and into fee for service.

5. In connection with establishing the SPP, in the fall of 2019, the Department and CPCA asked community health centers to report their projected loss of 340B savings to the State. According to CPCA, 109 community health centers submitted data to the State and 91 submitted data to CPCA and the State. The total amount of lost savings reported by the community health centers that responded to the data request was $105 million. CPCA staff and the CPCA board also appointed a "Solutions Team" to work with the Department regarding implementation of the SPP. I was one of the people appointed to the Solutions Team.

6. The Governor's January 2020 budget included the SPP for non-hospital based clinics in the sum of $105 million ($52.5 million in State funds; $52.5 million in presumed federal matching funds). In February 2020, CPCA staff and the Solutions Team met with Department leadership regarding implementation of the SPP.

7. In March, COVID-19 hit and the Department's focus shifted to addressing the pandemic. CPCA and others urged the Newsom Administration to delay the pharmacy transition given the challenges that were already facing FQHCs, which were on the front line of the pandemic serving the low income communities that were

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disproportionately impacted by the pandemic. The Administration did not agree to a delay.

8. In May, analysts predicted a $54 billion state budget deficit due to COVID-19. Dozens of programs and services were proposed to be cut in the Governor's May Revise budget, including the $105 million SPP.

9. Ultimately, the SPP was adopted in the Budget Trailer Bill, and codified as California Welfare & Institutions Code § 14105.467, which became effective on June 29, 2020. This legislation requires the Department to "establish, Implement, and maintain a supplemental payment pool for nonhospital 340B community clinics, subject to an appropriation by the Legislature." Qualifying FQHCs are to receive fee-for-service-based supplemental payments from a fixed-amount payment pool to compensate them for their loss of 340B program revenue.

10. Section 14105.467(b) further provides: "Beginning January 1, 2021, and any subsequent fiscal year to the extent funds are appropriated by the Legislature for the purpose described in this section, the department shall make available fee-for-service-based supplemental payments from a fixed-amount payment pool to qualifying nonhospital 340B community clinics in accordance with this section and any terms of federal approval ...."

11. Section 14105.467 also requires the Department to establish a stakeholder process that "shall be utilized to develop and implement the methodology for distribution of supplemental pool payments to qualifying nonhospital 340B community clinics." Section 14105.467 further requires the Department to conduct at least three meetings with stakeholders and to finalize the methodology for distribution no later than October 1, 2020.

12. Two stakeholder meetings were held in August and September 2020. Some of the Department's articulated goals/requirements for the process included:

(a) The federal government (the Centers for Medicare and Medicaid Services, or CMS) would approve the federal matching funds.

(b) The purpose of the SPP is to mitigate the impact of the pharmacy transition on community health centers.

(c) The SPP would be simple to administer.

(d) The SPP will be renewed annually.

(e) The SPP will be equitably distributed among the FQHCs losing the benefit of the 340B savings as long as the proposed distribution is acceptable to CMS.

13. Unfortunately, accomplishing these goals has been more challenging than anticipated and the October 1, 2020 statutory deadline for finalizing the methodology for distribution is now long past and the methodology for distribution of the SPP is not finalized today, as 2020 comes to a close.

14. In addition, CPCA has been told by the Department that the Department will be submitting a State Plan Amendment ("SPA") to authorize the SPP. To date, based on the information posted on the Department's website relating to proposed or pending SPAs, no proposed SPA has been submitted relating to the SPP, nor has any other federal approval been requested or obtained for the SPP.

15. Some of the challenges with the SPP concept that have surfaced are:

(a) Not all FQHCs who will suffer a loss of 340B savings submitted data in response to the 2019 request of CPCA and the Department, such that the $105 million that was to fund the SPP for the current fiscal year will not fully compensate all FQHCs who are participating in the 340B program for the loss of the 340B revenue.

(b) The allocation methodology under discussion would allow FQHCs that did not submit data regarding the loss in 340B savings in response to the 2019 call for data to participate in the SPP, such that FQHCs that did submit data will not be fully reimbursed in the amount reported and FQHCs that did not submit data will receive a share of the SPP.

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(c) We have been advised that CMS is requiring that all FQHCs be eligible to participate in the SPP, not just FQHCs that submitted survey data in 2019, and not just FQHCs that will be losing 340B savings. In addition, the proposal is for FQHCs to submit claims for supplemental payments based on submission of *medical claims*, not *pharmacy claims*, such that FQHCs that did not even participate in the 340B program will share in the SPP, and resulting in a further reduction of supplemental payments to the FQHCs that will be losing revenue due to the pharmacy transition. Moreover, FQHCs with high average pharmacy costs but fewer visits would receive less than the amount of their loss in 340B savings and FQHCs with relatively low average pharmacy costs but a high visit count would receive more than the amount of their loss in 340B savings. The only way to prevent this result would be for FQHCs to agree to a redistribution of payments they receive from the Medi-Cal program in order to fulfill the purpose of the SPP, which was to compensate FQHCs who participate in the 340B program for lost savings. This would require an enormous administrative burden and the nearly full cooperation of the health centers, including those who would claim a windfall from this methodology at the expense of those who will otherwise incur real losses as a result of these changes.

16. For the foregoing reasons, by all appearances, the SPP will not be a short- or long-term viable solution to address the significant financial impact that the pharmacy transition will have on FQHCs like SCHC.

17. Shasta County, where SCHC is located, has been hard hit by COVID-19. SCHC is at the heart of the battle against the COVID-19 pandemic in Shasta County. As the largest community clinic organization serving the area, SCHCs services are provided in an already disadvantaged community and one hit hardest by the pandemic. As evidenced by the positivity rates seen at SCHC, health center patients carry more COVID-19 burden than the general population. Since the onset of the pandemic in

March 2020, SCHC has performed 1,883 COVID-19 PCR tests with a 6% overall test positivity rate. SCHC has also performed over 3,231 COVID point-of-care tests (same day results) with an overall positivity rate of 11.7%. These results are taken from the start of the pandemic in March 2020 to December 22, 2020. In the last weeks of November and into December 2020, SCHCs test positivity rate fluctuated between 12 and 17.5% for both types of COVID testing. Thus, SCHC, and FQHCs like ours, are at ground zero of the COVID-19 pandemic. Eliminating the savings we realize through the current 340B structure would be devastating to our ability to continue to care for a population with such high test positivity rates. As we near 2021, the drain on SCHC has become even more grave. With high levels of virus in the community, our providers and support staff are becoming positive at higher rates. The staffing shortage that creates along with the dual struggle of increased demand for testing while trying to first vaccinate our own staff and then the high-risk populations we care for put SCHC at particular disadvantage.

18. If the pharmacy transition is allowed to move forward on April 1, 2021, SCHC will need to implement an Immediate reduction of the amount of prescription drugs we could subsidize for our sliding fee patients. In addition, we would likely cut telemedicine services, which would have a large impact on access to specialists in our largely rural area. Patients, some of whom have little or no transportation, would be forced to travel several hours to access these services, and, as a result of the revenue impact, we would also likely have to cut back transportation assistance. Access to affordable medications and to services such as telemedicine sub-specialty care would be a major set-back in our mostly rural underserved region. The loss of patient education services, that is not typically covered by anyone except maybe through grants, would be a major loss. As a major provider of care for the medically underserved in this region, the loss of access capacity would be felt throughout of community. About a third of our county is low income and we care for about 70% of the low income population, what happens to our programs and services is deeply felt.

19. Over the years, SCHC has submitted change-in-scope-of-services requests ("CSOSRs") to DHCS in connection with changes in the scope of SCHC's services that increased costs and constituted grounds for an adjustment to SCHC's prospective payment system rates. In connection with each of these CSOSRs, at the end of the audit process, DHCS applied the 80% adjustment factor to reduce the increase in SCHC's actual and reasonable costs by 20% before adding the adjusted increase to SCHC's PPS rates.

20. In my capacity as CEO of SCHC I am also a member of the Board of Directors of Partnership Health Plan of California ("PHP"), a non-profit community based health care organization that contracts with the State to administer Medi-Cal benefits through local care providers, as the Shasta County Community Health Center Representative. In this role, I am familiar with the contract that the State has with Medi-Cal managed care plans like PHP to manage the care of the Medi-Cal beneficiaries who receive their health care through Medi-Cal managed care. One of the most critical elements of the agreement between the State and a Medi-Cal managed care plan is the range of capitated benefits that will be provided to Medi-Cal beneficiaries under the plan, which is reflected in Attachment N to California's 1115 Waiver. The State pays the managed care plan a capitated rate per patient to manage and coordinate the covered services that are listed on the list of capitated benefits, and the managed care plan is responsible for contracting with downstream providers to provide those services. Thus, a change to the list of capitated benefits provided in managed care is a major substantive change that has a ripple effect from the State to the managed care plans to the providers of health care services to the Medi-Cal beneficiaries who receive those services. Such a change is not a "technical" change because it has a real and substantive impact up and

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down the chain relating to the provision of services, including the benefits available to the Medi-Cal beneficiaries who will receive those services.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of December, 2020, in Redding, California.

[redacted]

Exhibit D
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF RICARDO ROMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Ricardo Roman, declare as follows:

1. I am the Chief Financial Officer ("CFO") at Family Health Centers of San Diego ("FHCSD") and have held this role since September 2010. As CFO, I report directly to the Chief Executive Officer ("CEO") and am responsible for leading and

overseeing all financial aspects of FHCSD, including accounting, financial reporting, budgeting, and other financial matters. In addition, I am responsible for the oversight of our 340B program. I have reviewed the data and associated outcomes relevant to the impact of the Medi-Cal Rx Transition on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives federal grant funding under Section 330 of the Public Health Service Act. FHCSD meets all current statutory requirements under Section 330 of the Public Health Service Act. FHCSD has served the medically underserved communities of San Diego County since 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health Center, the flagship clinic of FHCSD. FHCSD has since transformed into the tenth largest health center in the country (47 service delivery sites), providing care to over 149,000 patients each year, of whom 90 percent are low income (under 200% of Federal Poverty Level) and 31 percent are uninsured. FHCSD serves all patients regardless of their ability to pay.

3. FHCSD provides pharmaceutical services primarily through one hundred and eighty one (181) 340B contract pharmacies.

4. In order to comply with applicable State and Federal law relating to the 340B program, FHCSD has registered each of our FQHC sites that dispenses drugs to Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B drugs to our Medi-Cal fee-for-service patients.

5. FHCSD does not dispense 340B drugs (or any drugs) to Medi-Cal beneficiaries who are reimbursed by Medi-Cal's fee-for-service system through contract pharmacies. We exclude the dispensing of 340B drugs to Medi-Cal fee-for-service beneficiaries, in part because the reimbursement does not cover our cost of dispensing drugs under the fee-for-service reimbursement methodology, under which we would be

paid at "actual acquisition cost" plus a $10.05 or $13.20 dispensing fee.

6. FHCSD's in-house pharmacies dispense an extremely limited volume of drugs to Medi-Cal fee-for-service beneficiaries since the majority of our Medi-Cal patients are enrolled in managed care plans. Medicaid managed care plans, under non-discrimination provisions of State and Federal law, are prohibited from paying FQHCs less than they pay to other health care providers furnishing similar services.

7. Fee-for-service reimbursement paid to 340B Covered Entities, including FHCSD, is limited to the "actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee" of either $10.05 or $13.20, depending on the pharmacy's dispensing volume. This has not had a significant negative impact on FHCSD to-date, since we have had few prescriptions reimbursed under this methodology.

8. If the Medi-Cal Rx Transition becomes effective on April 1, 2021, we would entirely discontinue dispensing drugs to Medi-Cal beneficiaries through our contract pharmacies, and we would need to identify additional funds to subsidize our existing pharmacy facility and drug costs.

9. According to the most recent FHCSD Uniform Data System (UDS) report submitted to the federal Health Resources & Services Administration (HRSA) for 2019, FHCSD conducted clinic visits with the following distribution of services for the 149,244 unduplicated FQHC patient population.

Clinical Service	Number of Patients	Percent of Patients	Number of Visits	Percent of Visits
Medical (Primary Care)	126,178	84.54%	457,021	50.73%
Dental	24,344	16.31%	70,816	7.86%
Mental Health	18,819	12.61%	110,624	12.28%
Substance Abuse	1,504	1.01%	18,046	2.00%
Other Professional Services	28,844	19.33%	121,286	13.46%

Vision	13,149	8.81%	16,120	1.79%
Enabling Services	28,560	19.14%	107,022	11.88%
Total	**N/A**	**N/A**	**900,935**	**100.00%**

Note: Total number and percent of patients is not applicable since individual patients may have received more than one visit across the seven categories of patient visits or encounters.

10. The distribution of FHCSD patients as a percentage of federal poverty guidelines in 2019 was 109,876 (73.62%) at or below 100 percent of the federal poverty guideline and 134,225 (89.94%) at or below 200 percent of the federal poverty guideline. Please note: the percent of patients at or below 100 percent of the federal poverty guideline, is included in the value for the patients at or below 200 percent of the federal poverty guideline.

11. In 2019, FHCSD's payer mix included the following key groupings:

- Medicaid/CHIP 87,330 patients (58.51%)
- None/Uninsured 46,966 patients (31.47%)
- Medicare 8,159 patients (5.47%)
- Other Third-Party Payers 5,688 patients (3.81%)
- Dually Eligible 1,101 patients (.74%)

12. Other population and/or patient important demographic and clinical management-related indicators reported in the 2019 FHCSD filed UDS report included:

Indicator	Number of Patients	Percent of Patients
Special Populations		
Homeless	26,859	18.00%
School-Based	9,131	6.12%
Veterans	1,841	1.23%
Agricultural	1,214	.81%
Age		
Children (<18 years)	36,659	24.56%
Adults (18 to 64 years)	102,429	68.63%
Adults (65 and over)	10,156	6.80%

Race		
Asian	9,506	6.37%
Native Hawaiian/Other Pacific Islander	1,090	.73%
Black/African American	13,331	8.93%
American Indian/Alaska Native	839	.56%
White	91,968	61.62%
More than 1 Race	6,249	4.19%
Race Unreported/Refused	26,261	17.60%
Ethnicity		
Hispanic/Latino	81,076	54.33%
Non-Hispanic	56,032	37.54%
Ethnicity Unreported/Refused	12,136	8.13%
Medical Conditions		
Hypertension	23,482	15.73%
Diabetes	13,015	8.72%
Asthma	7,025	4.71%
Symptomatic/Asymptomatic HIV	1,361	.91%
Prenatal Care Patients		
Number of Patients	3,650	100.00%
Number of Patients who Delivered	2,017	55.26%
Chronic Disease Management		
Use of Appropriate Meds for Asthma	1,127	93.70%
Statin Therapy for Prevention & Treatment of Cardiovascular Disease	13,663	78.70%
Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	2,245	89.67%
Controlling High Blood Pressure	21,886	69.74%
Diabetes: Controlling Hemoglobin A1c	12,656	64.08%
% of Patients Seen for Follow-up within 90 days of first ever HIV diagnosis	46	86.96%

13. The purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." FHCSD's participation in the 340B program allows the organization to stretch scarce resources to meet the needs of the medically underserved residents of San Diego County. This includes the most vulnerable high-risk populations (*e.g.*, uninsured, underinsured, elderly, and disabled patients). Under federal law, regulation, and program guidance, grantee programs are expected to reinvest their 340B net savings directly back into services provided to their patient populations. From July 1, 2018 to June 30, 2019, FHCSD's 340B onsite pharmacy and contract pharmacy

programs recognized total gross revenues from the Medi-Cal managed care ("MCO") patient population of $13,329,936 with a net program savings (gross revenues less program and drug replenishments costs) of $5,113,166. FHCSD utilized these net 340B savings to fund the following services and programs in circumstances where health reimbursements do not keep up with the costs.

- Affordable Patient Medication & Pharmacy Programs
- HIV and Hep C Patient Screening and Care Management
- Expanded Patient Vision Services
- Increased Access to Mobile Medical & Mental Health Services
- Expanded Older Adult Patient Services
- Critical Workforce Development Initiatives
- Expanded Clinical Patient Services
- Patient Weight Management Program
- Expanded Patient Health Education
- Urgent Care Services
- Patient Clinical Care Coordination/Patient Case Management
- Expanded Patient Specialty Services
- Patient Quality Improvement Staff and Programs
- Clinical Computer Upgrades
- Clinical Infrastructure Upgrades
- Patient Substance Abuse and MAT Programs
- Clinical Lab and Point of Care Testing Upgrades
- Expanded Podiatry Services
- Patient Security Control
- PHI Security and Server Upgrades

14. Under HRSA regulation and grantee scope of service requirements and guidance, FQHCs utilize their 340B net savings to:

- Provide uninsured patients with access to prescription drugs paid for by the health center;
- Subsidize care for the patient population with incomes below 200 percent of federal poverty guidelines who participate in FHCSD's sliding-scale payment programs; and
- Subsidize care not covered under Medi-Cal or other key payers (e.g., Medicare, California Children's Services, etc.).

15. FHCSD's MCO patient population accounts for approximately 71 percent of the 340B savings achieved through FHCSD's onsite pharmacy and contract pharmacy programs. From July 1, 2020 to June 30, 2021 (annualized), the FHCSD 340B pharmacy programs are anticipated to generate gross revenues of $39,107,192 with net program savings (gross revenues minus program and drug replenishment costs) of $17,256,644. This is based on estimates of filling 709,156 prescriptions (annualized) or 59,096 pharmacy claims per month. The estimated loss in net 340B benefits due to the Medi-Cal pharmacy program transition will be $12,164,687 (71 percent of total net 340B Program savings). These lost savings will have a negative impact on access, targeted patient clinical disease state programs, and enabling services for the most vulnerable patients. As a result, an unnecessary adverse impact will occur in such important quality and cost related indicators including: unnecessary emergency room/urgent care utilization, increased hospital admissions, increases in diabetes complications rates, lower health screening rates, and lower improvement of disease management outcomes.

16. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes prescription drugs affordable for all FQHC patients, including the uninsured and underinsured. In addition, the savings retained by FHCSD allow it to continue to serve more patients and to increase comprehensive services at no cost to the taxpayer. Because of the action taken by California's Governor to eliminate 340B savings, patient services and programs described above are at risk of being reduced significantly or

eliminated entirely. Patients will see longer wait times for appointments and decreased access to key support services such as patient-centered care coordination. Additionally, there will be an impact to the ratio of provider and clinic support staff to patients, resulting in negative patient outcomes. The Medi-Cal program and entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (e.g., diabetes, congestive heart failure), and decreased ability to provide such services as diabetes patient support, medication therapy management, and expanded access to primary care, mental health, and substance abuse treatment. Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and diabetes support will be impacted severely. The effect of this pharmacy transition is a major threat to the sustainability of California's primary care safety net program.

17. FHCSD is also at the heart of the battle against the COVID-19 pandemic in San Diego County. As the largest community clinic organization serving the area, FHCSD's clinics are located in already disadvantaged communities and those hardest hit by the pandemic. As evidenced by the positivity rates seen at FHCSD, health center patients carry more COVID-19 burden than the general population. Since the pandemic onset, FHCSD has performed 35,213 COVID-19 PCR tests with a 16.9% overall test positivity rate. Despite that high positivity over many months, each week in November and December 2020, our test positivity continued to climb to a current rate of 28.5%, more than double California's current test positivity rate of 12.2%. In short, FHCSD and FQHCs across the state are at ground zero of the COVID-19 pandemic. Eliminating the savings realized through the current 340B structure would be devastating to our ability to continue to care for a population with such high test positivity rates. As we near 2021, the drain on FHCSD resources has made it increasingly difficult to maintain quality healthcare for the communities we serve. With high levels of virus in the community, our

providers and support staff are also testing positive at higher rates than the County average. The resulting personnel shortage and dual struggle of increased demand for testing while trying first to vaccinate our staff and then the high-risk populations we care for are placing an unprecedented burden on our health care delivery system.

18. Over the years, FHCSD has submitted change-in-scope-of-services requests ("CSOSRs") to DHCS in connection with changes in the scope of FHCSD's services that increased costs and constituted grounds for an adjustment to FHCSD's prospective payment system rates. In connection with each of these CSOSRs, at the end of the audit process, DHCS applied the 80% adjustment factor to reduce the increase in FHCSD's actual and reasonable costs by 20% before adding the adjusted increase to FHCSD's PPS rates.

19. FHCSD has other concerns about the CSOSR process, as well. For example, as part of the CSOSR process, a health center with multiple sites is required to submit a home office cost report in addition to a cost report for each site that is seeking a change to its rate based on a change in the scope of its services. 340B drug costs associated with a health center's contract pharmacy arrangements are not included in the reimbursable costs of the health center because the contract pharmacy (such as a Walgreen's or CVS or corner drug store) incurs all of the costs associated with managing and dispensing the drugs, with the exception of the payment for the replenishment of the drugs, which is paid for by the health center. In connection with an FHCSD CSOSR that is currently under consideration by DHCS, DHCS is proposing to treat FHCSD's 340B drug costs as a non-reimbursable cost center and to allocate an amount of FHCSD's total overhead costs to the non-reimbursable cost center based on the proportion of overall costs represented by the "costs" of the 340B drugs. This proposed adjustment to the home office cost report will result in lower rates for the sites that are undergoing the CSOSR because a disproportionate amount of home office costs will be allocated to the 340B drug costs and away from sites that actually use and benefit from the costs

associated with FHCSD's home office. This is just one example of a variety of adjustments made by DHCS to a health center's CSOSR that result in the lowering of the adjustment to the health center's PPS rate in addition to the 20% haircut, also in violation of federal law.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of December 2020, in San Diego, California.

[redacted]

Ricardo Roman

Exhibit E
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF DAVID BRINKMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, David Brinkman, declare as follows:

1. I am the Chief Executive Officer ("CEO") at Desert AIDS Project ("DAP") and have held this role since 2006. As CEO, I am responsible for overseeing the Federally Qualified Health Center ("FQHC") and our 340B Program. I have reviewed the data and associated outcomes relevant to the impact of the Medi-Cal Rx Transition on

DAP in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. DAP was founded in 1984 by a group of community volunteers in the face of the AIDS crisis. Since that time, DAP has been named one of the "Top 20 HIV/AIDS Charities" and has expanded its mission to other disenfranchised members of the Coachella Valley community. Today, DAP is a FQHC that serves over 7,000 active clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS. The majority of DAP's clients are low-income, with more than 75 percent of the immediate population living under 200 percent of the Federal Poverty Level. DAP receives federal grant funding under Section 330 of the Public Health Service Act. DAP meets all current statutory requirements under Section 330 of the Public Health Service Act. DAP also is a 340B-eligible Ryan White Part A (RWI) grantee provider organization.

3. According to the most recent DAP Uniform Data System ("UDS") report submitted to the federal Health Resources and Services Administration ("HRSA") for 2019, DAP conducted clinic visits with the following distribution of services for the 7,487 unduplicated FQHC patient population.

Clinical Service	* Number of Patients	* Percent of Patients	Number of Visits	Percent of Visits
Medical (Primary Care)	5,359	49.05%	19,247	47.29%
Dental	1,031	9.44%	5,275	12.96%
Mental Health	888	8.13%	5,492	13.49%
Substance Abuse Disorder	23	0.21%	130	0.32%
Enabling Services	3,624	33.17%	10,554	25.93%
Total	**10,925**	**N/A**	**40,698**	**100.00%**

* Total percent of patients is not applicable since individual patients may have received more than one visit across the four categories of patient visits or encounters.

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4. The distribution of DAP patients as a percentage of federal poverty guidelines in 2019 was 3,992 (53.32%) at or below 100 percent of the federal poverty guideline and 5,830 (77.87%) at or below 200 percent of the federal poverty guideline. Please note: the percent of patients at or below 100 percent of the federal poverty guideline, is included in the value for the patients at or below 200 percent of the federal poverty guideline.

5. In 2019, DAP's payer mix included the following key groupings:

- Medicaid 2,019 patients (26.97%)
- Other Public & Private Insurance 1,181 patients (15.77%)
- None/Uninsured/Sliding Scale 3,245 patients (43.34%)
- Medicare 731 patients (9.76%)
- Dually Eligible 311 patients (4.15%)

6. Other population and/or important patient demographic and clinical management-related indicators reported in the 2019 DAP filed UDS report included:

Indicator	Number of Patients	Percent of Patients
Special Populations		
Homeless	11	0.15%
Lesbian or Gay	5,070	67.72%
Transgender	406	5.42%
Veterans	362	4.84%
Other	1,638	21.88%
Age		
Children (<18 years)	6	0.08%
Adults (18 to 64 years)	6,101	81.49%
Adults (65 and over)	1,380	18.43%
Race & Ethnicity		
Racial and/or Ethnic Minority	1,147	15.32%
Hispanic/Latino	1,689	22.56%
Non-Hispanic White	4,478	59.81%
Asian	173	2.31%
Medical Conditions		
Hypertension	1,542	20.60%
Diabetes	506	6.76%
Sexually transmitted infections	1,067	14.25%

Asthma	252	3.37%
Symptomatic/Asymptomatic HIV	2,186	29.20%

7. The purpose of the 340B Program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." DAP's participation in the 340B Program allows the organization to stretch scarce resources to meet the needs of the medically underserved residents of the Coachella Valley and surrounding communities. This includes the most vulnerable high-risk populations (e.g., uninsured, underinsured, HIV/AIDS patients). Specifically, as a Ryan White/ HIV/ FQHC provider, DAP's population is heavily weighted (over 33%) with Ryan White clients. DAP also is a Hepatitis Center of Excellence that provides medication therapy to a number of patients diagnosed with Hepatitis C. Under federal law, regulation, and program guidance, grantee programs are expected to reinvest 340B net savings directly back into services provided to the organization's patient populations. In 2018 and 2019, DAP's Medi-Cal 340B claims from 340B contract pharmacies were estimated to be 10,300 and 9,300 respectively. DAP's Medi-Cal 340B contract pharmacy program recognized a net program savings (gross revenues less program and drug replenishments costs) of approximately $3,200,000 and $3,050,000 in 2018 and 2019, respectively. DAP utilized these net 340B funds to:

- Continue HIV and STD testing services aimed at stopping the spread of the HIV epidemic;
- Continue providing timely access to primary care, mental health, substance abuse, and prescription drug outpatient services for its patient population;
- Provide Medication Assistance for patients who could not afford medications otherwise;
- Pay for DAP's four Infectious Disease Physicians; and

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- Increase services (dental, housing, community health, STI clinic, and various vocational programs).

Under HRSA regulation and grantee scope of service requirements and guidance, FQHCs utilize their 340B net savings to:

- Provide uninsured patients with access to prescription drugs paid for by the health center;
- Subsidize care for the patient population with incomes below 200 percent of federal poverty guidelines who participate in DAP's sliding-scale payment programs; and
- Subsidize care not covered under Medi-Cal or other key payers.

8. DAP's 340B Program utilizing contract pharmacy has continued to grow significantly. In 2020 (based on YTD reporting), the DAP 340B contract pharmacy program is anticipated to generate gross revenues of $27,600,000 with net program savings (gross revenues minus program and drug replenishment costs) of $11,932,123. The estimated loss in net 340B benefits due to the Medi-Cal pharmacy program transition will be $3,000,000 (approximately 30 percent of total net 340B Program savings).

9. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes prescription drugs affordable for all FQHC patients, including the uninsured and underinsured. In addition, the savings retained by DAP allows it to continue to serve more patients and to increase comprehensive services at no cost to the taxpayer. Because of the action taken by California's Governor to eliminate 340B savings, patient services and programs described above are at risk of being reduced significantly or eliminated entirely. DAP's anticipated impact of eliminating $3,000,000 in funding would put 30-40 jobs at risk in DAP's community health, client support services, and HIV/STD testing programs. Furthermore, patients will see longer wait times for appointments and decreased access to key support services such as patient-centered care coordination. Additionally, there will be an impact to the ratio of provider and clinic support staff to

patients, resulting in negative patient outcomes. The Medi-Cal program and the entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (*e.g.*, HIV, Hepatitis, congestive heart failure), and decreased ability to provide such services as medication therapy management, and expanded access to primary care, mental health, and substance abuse treatment. Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and STD testing will be impacted severely. The effect of this pharmacy transition is a major threat to the sustainability of California's primary care safety net program.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16th day of December 2020, in Palm Springs, California.

[redacted]

David Brinkman

Exhibit F
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF DR. KELVIN VU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Dr. Kelvin Vu, declare as follows:

1. I am currently a family physician at Open Door Community Health Centers ("Open Door"), where I have worked for the last ten years. I also currently serve as Chief Medical Officer at Open Door. I received my medical training from Western University and completed my Family Medicine Residency at the University of California, Davis

Medical Center, where I also served as Chief Resident in my final year. As a family physician, I regularly interact with patients, prescribe medications, and ensure my patients are receiving their medications and following the treatment regimens. As the Chief Medical Officer, I also receive reports from the other physicians about the provision of services to their patients, including concerns about challenges and suggestions for improving services. The majority of Open Door's patients are Medi-Cal beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a Preliminary Injunction.

2. Open Door is a Federally Qualified Health Center that receives federal grant funds under Section 330 of the Public Health Services Act. Open Door is committed to providing excellent health care and health education to medically underserved patients in the Humboldt and Del Norte Counties, two rural counties in the far northwest region of Northern California along the coast. Open Door currently operates twelve community health centers across both counties, serving more than 55,000 patients each year while employing nearly 700 members of the community.

3. Humboldt and Del Norte Counties are predominately rural, and tend to rank near the bottom for health outcomes among California counties. Like many rural areas, our patients struggle with widespread problems of poverty, opioid use disorder, lack of health education, lack of reliable housing and transportation, and numerous other socio-economic barriers to health care that directly affect their well-being in the short and the long term. As a physician who has worked in this community for ten years, I am well-aware that these socio-economic problems often cause my patients to forego necessary medical treatments in order to focus on other urgent aspects of their lives, such as going to work to support their families, or using their limited incomes to buy food or pay rent instead of paying for their prescribed medications.

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4. Open Door is committed to meeting our patients where they need us to be. To that end, we operate under a patient-centered medical home model ("Medical Home") that allows us to coordinate an individual patient's care across specialties so that we treat the whole person, rather than individual symptoms. As their Medical Home, Open Door proudly serves as a one-stop-shop for all of our patients' medical needs, as well as their unique needs for accessing transportation assistance, housing, and food. The Medical Home also helps patients follow their medical treatment plans because they do not need to go to multiple facilities – all of their providers are in one place, which greatly improves the patients' overall health outcomes.

5. The Medical Home includes coordination with pharmacy services and the MCP member services team. The ability for me as a prescribing physician to work directly with the MCP and case managers greatly improves my patients' ability to access necessary treatments. For example, if I prescribe a Lidocaine patch – a non-opioid chronic pain treatment – I will have access to real-time information regarding what the cost will be to the patient, when and if the patient is able to pick up the patch, or if the patch is not covered by the patient's plan. If the Lidocaine patch is not available for some reason, I am able to find out immediately and make same-day adjustments to the treatment plan so that my patient's needs are met. This is just one concrete example of how the pharmacy benefit's inclusion in managed care facilitates medical services for both doctors and patients, leading to better care and outcomes for the most vulnerable, medically underserved people in California.

6. The inclusion of the pharmacy benefit in managed care also enables me to tailor my treatment plan to the patient's needs. With the pharmacy and medical benefits linked, the current managed care model allows me to see and track if my patients are getting their prescriptions, taking them on schedule, re-filling them as prescribed, and returning for medical follow-ups on time. This information is critical to creating a treatment plan for my patients, tracking their progress and condition, and scheduling necessary follow-up appointments.

7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative will transfer the pharmacy benefit out of managed care and into a fee-for-service model. This will directly undermine Open Door's Medical Home model and my ability to treat my patients effectively. For example, disconnecting pharmacy services from medical services will require our patients to take multiple trips to receive their care and their medication. For most of my patients, this is not simply one more errand in their day – it is an insurmountable barrier because they do not have access to reliable transportation to make multiple trips, or they cannot take additional time from work during the day, or they need to be home to take care of children or other family members.

8. Additionally, Medi-Cal Rx will fundamentally alter the way I and other Medi-Cal providers at FQHCs will be able to treat our patients. For example, I will no longer have access to real-time information as to the availability of medications or my patients' adherence to the treatment plan. Using the example of the Lidocaine patch discussed above, under the Medi-Cal Rx fee-for-service model, I would prescribe the patch and my patient would have to make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it in stock or the pharmacist needs prior authorization, I will no longer be notified as part of managed care and will not necessarily be advised that my patient was unable to pick up their prescription. Because of the type of patients I work with and the challenges they face in making multiple trips to different healthcare providers, there is a high likelihood that my patient would forego the treatment altogether. I would not discover the problem until months later in a follow-up visit with my patient, at which point their condition and pain has worsened because they could not access the treatment I prescribed.

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9. It is also my understanding that Medi-Cal Rx will also change Open Door's and other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount program. I am gravely concerned that the proposed fee-for-service reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the cost of providing necessary pharmacy services to my patients.

10. In addition, the savings and reimbursement Open Door receives from the 340B program go directly to providing additional, much-need services for our patients that are not otherwise reimbursed by Medi-Cal. One key example is Open Door's Medication Assistance ("MAT") Program. MAT provides access to the medication buprenorphine, also known as Suboxone, which is scientifically proven to help patients struggling with opioid use disorder to overcome and manage their addiction. The drug is very expensive, so without 340B pricing, our patients would not be able to receive it at all. Additionally, MAT includes support groups that help patients maintain sobriety, which requires efforts from case managers and member services staff. However, these counseling services are not reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue and savings. Without services like our MAT Program, Open Door's patients will be denied access to a highly effective treatment option that can help them get away from opiates and improve their overall lifestyle.

11. Based on my experience as a family physician at an FQHC, I believe that Medi-Cal Rx will create additional barriers to healthcare services that my patients are already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well as how those patients access their Medi-Cal benefits. I am greatly concerned that removing the pharmacy benefit from managed care will directly prevent Open Door's ability to serve as the one-stop-shop Medical Home that our patients depend on to treat their unique and varied needs. Additionally, the loss of 340B revenue will force Open Door to cut off critical resources for patients who are struggling with opioid use disorder and other chronic conditions.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 2 day of February, 2021, in Arcata, California.

DR. KELVIN VU

Exhibit G
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Dr. Paramvir Sidhu, declare as follows:

1. I am currently a family physician at Family Health Care Network ("FHCN"), where I have worked for the last ten years. I also currently serve as Chief Clinical Officer at Family Health Care Network. I received my medical training in India and completed my residency in family medicine at the Riverside Community Medical Center, Riverside,

California. As a family physician, I regularly interact with patients, prescribe medications, and ensure my patients are receiving their medications and following the treatment regimens. As the Chief Clinical Officer, I also receive reports from the other physicians about the provision of services to their patients, including concerns about challenges and suggestions for improving services. The majority of FHCN patients are Medi-Cal beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). Although FHCN is not a named plaintiff in this action, it is an affiliate of the Community Health Center Alliance for Patient Access. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a Preliminary Injunction.

2. FHCN is a Federally Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Services Act. FHCN is committed to providing excellent health care and health education to medically underserved patients in the Tulare, Kings and Fresno Counties, three rural counties in the San Joaquin Valley of Central California. FHCN currently operates forty-one (41) community health centers across these counties, serving more than 221,000 patients each year while employing nearly 1,500 members of the community.

3. The patients we serve from Tulare, Kings and Fresno counties are predominately from rural communities, and tend to rank near the bottom for health outcomes among California counties. Our patients struggle with widespread problems of poverty, lack of health education, lack of reliable housing and transportation, and numerous other socio-economic barriers to health care that directly affect their well-being in the short and the long term. A large majority of our patients are Seasonal and Migrant farmworkers who suffer from severe health care disparities. As a physician who has worked in this community for ten years, I am well aware that these socio-economic problems often cause my patients to forego necessary medical care in order to focus on other urgent aspects of their lives. These patients have to choose between utilizing their

limited resources to either buy food or pay rent to support their families, or pay for their prescribed medications.

4. FHCN is committed to meeting our patient's needs and provide access to quality medical care to everyone. We are Joint Commission Accredited clinics and we operate under a patient-centric medical home model ("Medical Home") that allows us to coordinate an individual patient's care across specialties so that we treat the whole person, rather than individual symptoms. As their Medical Home, FHCN proudly serves as a one-stop-shop for all of our patients' medical needs, as well as their unique needs for accessing transportation assistance, housing, and food and connect the patients with resources in the communities. The Medical Home also helps patients follow their medical treatment plans because they do not need to go to multiple facilities – all of their providers are in one place, which greatly improves the patients' overall health outcomes.

5. A part of the Medical Home also includes pharmaceutical services for our patients. Having pharmacies in our health centers and medications under the 340B program allows me as a prescribing physician to work directly with the pharmacists and greatly improve my patients' ability to access necessary treatments. For example, if I prescribe Insulin– a lifesaving treatment for diabetes – I will have access to real-time information as to when and if the patient is able to pick up the medication at a very affordable price. If the Insulin is not available for some reason or not covered by the patient's plan, the pharmacist is able to call and inform me and provide alternatives to the medication. This allows me to make same-day adjustments to the treatment plan and patient leaves the visit with medications. Relatedly, our in-house pharmacists have access to a patient's Electronic Health Record, allowing them to track prescription dosages and types, which enhances patient safety. For example, our pharmacist can see and verify the weight of a pediatric patient who is prescribed antibiotics for an infection, verify the dosage calculation, and consult with me prior to the patient leaving the health center. Another example would be the pharmacist reviewing the medical record and noting additional medications or supplements listed in the patient's medication

list that could have contraindications when taken with the prescribed medication. Again, this can be discussed with me before the patient leaves the health center. These are just a few concrete examples of how the pharmacy benefit's inclusion in managed care facilitates medical services for both doctors and patients, leading to better care and outcomes for the most vulnerable, medically underserved people in California.

6. The inclusion of the pharmacy benefit in managed care also enables me to tailor my treatment plan to the patient's needs. First, with the pharmacy and medical benefits linked, the current managed care model allows me to see if my patients are getting their prescriptions, taking them on schedule, re-filling them as prescribed, and returning for medical follow-ups on time. This information is critical to creating a treatment plan for my patients, tracking their progress and condition, and scheduling necessary follow-up appointments. Second, the 340B savings allow us to operate a robust in-house pharmacy program, including a Director of Pharmacy who sits on our Medical Director Team. This coordination allows us to create a formulary for our pharmacy specific to the clinical needs of our patient population and at the lowest acquisition price possible, benefiting our patients both clinically and financially. Without the 340B program, this cross-collaboration and comprehensive care management will not be possible, as the dramatic cuts that would need to be made to our in-house pharmacies would no longer allow us to have a Director of Pharmacy, and pharmacists would no longer be able to dedicate time to comprehensive care management.

7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative will transfer the pharmacy benefit out of managed care and into a fee-for-service model. This will directly undermine FHCN's Medical Home model and my ability to treat my patients effectively. For example, disconnecting pharmacy services from medical services will require our patients to take multiple trips to receive their care and their medication. For most of my patients, this is not simply one more errand in their day – it is an insurmountable barrier because they don't have access to reliable transportation to make multiple trips, or they cannot take additional time from work during the day, or they

need to be home to take care of children or other family members.

8. It is also my understanding that Medi-Cal Rx will also change FHCN's and other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount program. I am gravely concerned that the proposed fee-for-service reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the cost of providing necessary pharmacy services to my patients. It will also impact our ability to provide other benefits that are significant to our patients. For instance, we currently have an extensive patient transportation program that provides door-to-door service from a patient's home to the health center, which we would need to be scaled back or eliminated if we no longer received revenue from the 340B program. Additionally, we will have to increase the nominal fee offered to uninsured patients on our pharmacy sliding fee scale, which will increase the costs for patients who cannot afford higher out-of-pocket expenses for medical care. Such a change could result in uninsured patients forgoing prescriptions, leading to worse health outcomes.

9. Medi-Cal Rx will also fundamentally alter the way I and other Medi-Cal providers at FQHCs will be able to treat our patients. For example, FHCN has a Diabetic clinic where the goal is to provide coordinated diabetic care to patients. This includes the patient getting education about diabetes from health educators, necessary screenings and immunizations, and behavioral-health counseling. These services are in addition to medical care and treatment the physicians provide during the same (single) visit for the patient. Using the example of the Insulin discussed above, under the Medi-Cal Rx fee-for-service model, I would have to prescribe the Insulin and my patient would have to make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it in stock, the cost is too high, or the pharmacist needs prior authorization, I will not be notified immediately that my patient was unable to pick up their prescription. Because of the type of patients I work with and the challenges they face in making multiple trips to different healthcare providers, there is a high likelihood that my patient would forego the treatment altogether. I would not discover the problem until months later in a follow-up

visit with my patient, at which point their condition has worsened and severe complications developed because they could not access the treatment I prescribed, or the supportive Diabetic clinic services. The result for that patient is deteriorated clinical outcomes and, most likely, costly trips to the emergency room paid for by the Medi-Cal program for a Medi-Cal beneficiary.

10. In addition, the savings and reimbursement FHCN receives from the 340B program go directly to providing additional, much-need services for our patients that are not otherwise reimbursed by Medi-Cal. One key example is FHCN's Medication Assistance Program ("MAT"). MAT provides access to the medication buprenorphine, also known as Suboxone, which is scientifically proven to help patients struggling with opioid addiction to overcome and manage their addiction. The drug is very expensive, so without 340B pricing, our patients would not be able to receive it at all. Additionally, the MAT clinic includes counseling that help patients maintain sobriety, which requires efforts from Behavioral Health and member services staff. However, some of these ancillary services provided in the MAT clinic as well as the above mentioned Diabetic clinic are not reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue and savings. Without programs like MAT, FHCN's patients will be denied access to a highly effective treatment option that can help them get away from opiates and improve their overall lifestyle.

11. Based on my experience as a family physician at an FQHC, I believe that Medi-Cal Rx will create additional barriers to healthcare services that my patients are already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well as how those patients access their Medi-Cal benefits. I am greatly concerned that removing the pharmacy benefit from managed care will directly interfere with FHCN's ability to serve as the one-stop-shop Medical Home that our patients depend on to treat their unique and varied needs. Additionally, the loss of 340B revenue will force FHCN to cut off critical resources for patients who are struggling with opioid addiction and other chronic conditions like Diabetes.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 5 day of February, 2021, in Visalia, California.

[redacted]

DR. PARAMVIR SIDHU

Exhibit H
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF FRAN BUTLER-COHEN IN OPPOSITION TO MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Judge: Hon. John A. Mendez
Date: February 23, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Fran Butler-Cohen, declare:

1. I am the Chief Executive Officer ("CEO") at Family Health Centers San Diego ("FHCSD") and have held this role since 1986. I have reviewed the data and associated outcomes relevant to the impact of Medi-Cal Rx on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth

herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives federal grant funding under Section 330 of the Public Health Services Act. FHCSD has served the medically underserved communities of San Diego County since 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's flagship clinic. FHCSD has since transformed into the tenth largest health center in the country, providing care to over 149,000 patients each year, of whom 90 percent are low income and 31 percent are uninsured. FHCSD serves all patients regardless of their ability to pay.

3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020, FHCSD has provided free COVID-19 testing to as many patients as the staff can manage. During this time, demand for FHCSD services has skyrocketed. To try to meet our patients' testing needs, FHCSD has purchased additional lab equipment and increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid testing and notification systems to quickly identify patients with COVID-19 and reduce community spread. Additionally, we have set up a separate obstetrics clinic for mothers who have tested positive for COVID-19. These steps have proven necessary, since, among the patients we serve, the COVID positivity rate in the second week of January 2021 was 35 percent, more than double the average statewide rate for the same time period.

4. In an effort to take care of patients and to avoid sending them to hospitals – which currently cannot handle an additional influx of patients – FHCSD has also ramped up its ability to care for the sickest, non-emergent patients. Instead, we have started Monoclonal Antibody administration for the sickest, non-emergent patients at one of our clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as soon as possible.

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5. Despite the heroic efforts of our health care workers – who have shouldered the burden of coming to work every day risking their own health and the health of their families – FHCSD staff is stretched beyond its limits and is struggling to continue. We currently have seventy (70) members of our team out of work due to COVID, which hurts FHCSD's ability to meet patients' needs and county demands. We have started an emergency child care program to keep our workers on the job when they have no other childcare options. We have also started an Employee Food Pantry Program so that employees who have lost income can feed their families.

6. Now, with the development of a COVID-19 vaccine, San Diego County is asking FHCSD to submit information regarding how many vaccinations we could administer to the general public, which requires me and the FHCSD staff to study guidance from the Centers for Disease Control and the Department of Defense to implement massive public vaccination events, in addition to juggling the current emergency needs of our patients and community.

7. Simultaneously, FHCSD is still required to commit time to fielding government audits and meet with the State and Managed Care Organizations on metric performance. In addition, FHCSD is currently in the beginning stages of a random federal 340B audit that has already taken several hundred hours of staff time in preparation and document submission. At the same time, the Health Resources and Services Administration is requesting capital funding grantees submit previously unrequired data and qualitative information to help them design future grant programs, Moreover, FHCSD has had to make significant modifications to contract pharmacy arrangements to ensure our patients receive affordable medications due to the attack on the 340B program by pharmaceutical manufacturers. All of this comes against the backdrop of the State of California awarding a contract valued at approximately $80 million annually to a for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by Centene, a publicly traded NYSE corporation worth $76 billion for $2.2 billion dollars to

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facilitate the state in their plan that will remove hundreds of millions of dollars from the state's health care safety-net.

8. It is unconscionable that during this time of perpetual crisis, when our staff and other healthcare workers have sacrificed so much to serve the communities that need them most, FHCSD and other FQHCs are required to prepare and plan for Medi-Cal Rx, which will result in drastic funding reductions due to changes in reimbursement. Additionally, the loss of 340B funding that helps stretch our resources to expand healthcare access will further reduce staff and desperately needed health services.

9. Although the "effective" date of Medi-Cal Rx has been moved to April 1, 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring health centers to adjust our conduct in a number of ways. Examples of some of the activities FHCSD has had to undertake in anticipation of the "go live" date for Medi-Cal Rx include:

- A complete budget review and assessment of programs currently funded through 340B savings, including the potential for lay-offs, elimination of support programs, and reduction in hours and types of services provided to our patients.
- Meetings with vendors that currently support in-house pharmacy operations to ensure systems remain compliant following full implementation.
- Subscribe to and dedicate staff time to monitor, review and bring forward issues noted in regular updates from the Medi-Cal Rx Subscription Service
- Secure Provider Portal access and enroll approximately 250 prescribing providers into the provider portal, necessitating hundreds of hours of administrative staff time.

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- Review all medication and pharmacy related policies and protocols across the organization to align with new systems and ensure compliance.
- Educate providers about the transition from the MCO formulary to using drugs on the FFS formulary.
- Educate providers on the new Prior Authorization (PA) systems as drugs prescribed that are therapeutic substitutions for more commonly prescribed drugs not found on the CDL, including any step therapy or pre-requisite therapies.
- Educate clinic directors, billing staff and other administrative personnel as to the new systems, how to use them and how to trouble shoot difficulties for patients and providers.
- Review how FHCSD payor mix will change given the pharmacy transition and evaluate whether it's beneficial for FHCSD and our patients to maintain current contract pharmacy relationships or cancel them.

10. The state and local governments still expect FHCSD to maintain the same quality of care and to serve more patients in more ways while implementing Medi-Cal Rx, which will squeeze FHCSD's resources at precisely the wrong time. Without the 100 percent reimbursement rate guaranteed by federal Medicaid law and the 340B savings FHCSD relies on, we simply will not be able to provide the same level of care for the patients we have worked tirelessly to serve. I fear that the healthcare workers and

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patients who have suffered the most throughout the COVID-19 emergency will also bear the burden of the Medi-Cal Rx initiative's consequences.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 20th day of January, 2021, at San Diego, California.

FRAN BUTLER-COHEN

Exhibit I
to letter dated 4/16/2021

Medi-Cal Rx Monthly Bulletin

April 1, 2021

The monthly bulletin consists of alerts, bulletins and notices posted to the Medi-Cal Rx Web Portal within the previous month.

Contents

1. Changes to the Contract Drugs List Effective April 1, 2021

The below changes have been made to the Contract Drugs List effective April 1, 2021.

For more information, see the Contract Drugs List on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Asenapine	FDA-approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Cabotegravir/Rilpivirine	Added to CDL with a restriction.	April 1, 2021
Exenatide	Extended release injectable suspension vial obsolete. Removed from CDL.	April 1, 2021
Leuprolide Acetate	Injection and powder for injection removed from CDL. Labeler restriction updated to 00074 only.	April 1, 2021

Drug Name	Description	Effective Date
Lurasidone Hydrochloride	FDA approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Morphine Sulfate/Naltrexone	Drug obsolete. Removed from CDL.	April 1, 2021
Nevirapine	Labeler restriction (00597) added to liquid only.	April 1, 2021
Propranolol	Additional liquid strength (1.28 mg/ml) added to CDL with a restriction.	April 1, 2021
Relugolix	Added to CDL with a restriction.	April 1, 2021
Sodium Zirconium Cyclosilicate	Added to CDL with labeler code restriction.	April 1, 2021

2. Updates to the List of Covered Enteral Nutrition Products

Effective for dates of service on or after March 1, 2021, the List of Covered Enteral Nutrition Products has been updated on the Medi-Cal Rx Web Portal. Effective for dates of service on or after April 1, 2021, products deleted from the List of Covered Enteral Nutrition Products will no longer be reimbursable, even with an approved prior authorization. The Maximum Acquisition Cost (MAC) for these products is no longer guaranteed.

3. Medi-Cal Provider Training Schedule

The transition of all administrative services related to Medi-Cal pharmacy benefits billed on pharmacy claims from the existing intermediaries, Medi-Cal Fee-for-Service (FFS) or Managed Care Plan (MCP) providers, will transition to the new Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (MMA).

This article serves as a guide to outline the trainings planned for March 2021 until the Medi-Cal Rx implementation that will assist pharmacy providers, prescribers, and their staff as they transition to Medi-Cal Rx.

User Administration Console Training

All Medi-Cal Rx pharmacy providers, prescribers, and their staff will need to complete registration in order to access the secure areas of the Medi-Cal Rx Web Portal. Access to the secured Medi-Cal Rx Provider Portal starts with registration via the User Administration Console (UAC) application.

Training Information:

To assist pharmacy providers, prescribers, and their staff with UAC registration, there are job aids and computer-based trainings (CBTs) available to walk users through the registration process. Those materials are as follows:

- UAC Quick Start Guide
- UAC Tutorial #1: Start Registration Process
- UAC Tutorial #1 Supplement: Alternate Address Instructions
- UAC Tutorial #2: Complete Registration
- UAC Tutorial #4: Granting Access for Yourself and Staff

If you run into any issues or have any questions about the UAC registration process, feel free to attend an office hours session with one of our Pharmacy Representatives (PSRs) who can assist with the process.

To register for a UAC office hours session, please email the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of Office Hours session

As of April 1, 2021 UAC Office Hours Sessions will be offered on an as-needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Saba LMS Training

Saba is the one-stop shop for Education and Outreach information for Medi-Cal Rx pharmacy providers and prescribers. Topics to be covered during the Saba training sessions include how to view the Education and Outreach events calendar, how to register to attend an event or take an online course, and how to complete evaluations of training effectiveness.

Training Information:

Training for Saba includes a job aid with step-by-step instructions:

Medi-Cal Rx Saba℠ Provider Job Aid

In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via Hewlett Packard Enterprise (HPE) MyRoom™. To register to attend a live webinar, please email Medi-Cal Rx Education and Outreach at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of training session

Before enrolling in a Saba training session, providers will need to confirm in their email if they have completed the following tasks:

- Registered successfully for UAC
- Received a PIN letter and completed UAC registration
- Registered as the Delegated Administrator or have been created as a user by the Delegated Administrator
- Have added or been granted access to the Saba application

As of April 1, 2021, Saba Training Sessions will be offered on an as needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Medi-Cal Rx Transition and Resources and Web Portal Training

This training is intended to give pharmacy providers and prescribers an overview of the Medi-Cal Rx Transition and the resources that are available on the Medi-Cal Rx Web Portal. Topics that will be covered in this training include the following:

- Medi-Cal Rx background and high-level changes affecting pharmacy providers and prescribers
- Point-of-Sale (POS) Technical and Operational Readiness
- Web Claims Submission and overview of the Finance Portal

Training Information:

Training will be available via job aids and live webinars coming April 2021.

Training sessions for Medi Cal Rx Transition and Resources and Web Portal will be offered via a series of videos and job aids with step-by-step instructions. In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via HPE MyRoom™. To register to attend a live webinar, please refer to the Saba Training Calendar for specific dates and times.

Pharmacy providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to the Saba application.

Medi-Cal Rx Transition and Resources and Web Portal Training Sessions (April 2021)	
Dates	**Times**
April 2021	Please refer to the Saba Training Calendar for specific dates and times.

Prior Authorization Training

A Prior Authorization (PA), previously known as a Treatment Authorization Request (TAR), requires providers to obtain approval before rendering certain services such as prescriptions.

This training will be intended for pharmacy providers and prescribers that plan to use the new Medi-Cal Rx Secured Portal to submit PAs.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available, live webinar training will be available via Saba. Providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and PA applications.

Web Claims Submission Training

This training will give providers an overview of the new Medi-Cal Rx Web Claims Submission system. Providers currently using a POS system to process prescription claims can still continue to submit web claims via this channel.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available live webinar trainings will be available via Saba. Pharmacy providers and prescribers and their staff that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and Medi-Cal Rx Web Claims Submission applications.

4. Prescriber Phone Campaign

Pharmacy Service Representatives (PSRs) will begin reaching out by phone to introduce the new Medi-Cal Rx Web Portal and available resources and functionality. This outreach to prescribers will accomplish the following:

- Provide guidance on how to start registration for the Secured Provider Portal.
- Inform prescribers of currently available training and resources for Medi-Cal Rx.

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure Web Portal registration in order to access Education and Outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba, and providers will have the ability to enroll in web-based, instructor-led, or computer-based training.

To access Saba, providers need to utilize the User Administration Console (UAC) application. Click the **Medi-Cal Rx Training** hyperlink on the Education & Outreach page of the Medi-Cal Rx Web Portal or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration.

To register for an Office Hours session, please email MediCalRxEducationOutreach@magellanhealth.com and include the following information:

1. Name of Individual
2. Provider Name
3. National Provider Identifier (NPI)
4. Phone Number
5. Email Address
6. Preferred Date and Time of Office Hours Session

5. Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey

How do you and your peers currently conduct business for Medi-Cal pharmacy services? We'd love to hear from you! The results of the Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey will be used to tailor training offerings for Medi-Cal Rx to ensure you are prepared for the upcoming transition. The information you provide is confidential and will be used only for future training.

6. Pharmacy Provider Self-Attestation Period Begins April 2021

Although currently delayed, Medi-Cal pharmacy benefits will eventually be transitioned to and thereafter administered through the Fee-for-Service (FFS) delivery system for all Medi-Cal beneficiaries (generally referred to as "Medi-Cal Rx"). The Department of Health Care Services (DHCS) has partnered with Magellan Medicaid Administration, Inc. (MMA) to provide a wide variety of administrative services and support for Medi-Cal Rx.

MMA has contracted with Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to administer the annual pharmacy provider self-attestation survey for professional dispensing fee reimbursement. The objective of the next self-attestation survey is to assign professional dispensing fee rates for Medi-Cal-enrolled pharmacies beginning July 1, 2021 and ending June 30, 2022.

DHCS, through Mercer, will be initiating the provider self-attestation process in April 2021 for the 2020 calendar year reporting period for those pharmacy providers seeking the higher of two professional dispensing fee rates determined by annual prescription volume. Key changes to the self-attestation process include the following:

- The provider self-attestation period for the calendar year 2020 reporting period will run from April 1 through April 30, 2021 (in previous years, the survey period was January 15 through the end of February).
- Mercer, on behalf of MMA and DHCS, will administer the provider self-attestation survey with options for online submission or an email submission of a Microsoft® Excel®-formatted template.
- In addition to the standard online submission, pharmacies will have an additional survey submission option that will allow a bulk submission for multiple locations. The new template will allow a corporate office for chain-affiliated stores under common ownership to submit multiple stores in one self-attestation survey file.

As in previous years, newly approved FFS pharmacy providers that are notified of their Medi-Cal enrollment approval after the attestation period closes will automatically receive the higher dispensing fee. However, those same providers will have to attest for subsequent reporting periods in order to continue to be eligible for the higher dispensing fee in subsequent fiscal years.

Pharmacy providers may refer to the updated Pharmacy Provider Self-Attestation FAQs for more information.

DHCS reminds the Medi-Cal pharmacy FFS provider community to closely monitor upcoming Medi-Cal pharmacy bulletins for additional information regarding future updates by signing up via the Medi-Cal Rx Subscription Service.

For updates on Medi-Cal Rx, please visit the Medi-Cal Rx Web Portal and the DHCS Medi-Cal Rx Transition website. In addition, DHCS encourages stakeholders to review the Medi-Cal Rx Frequently Asked Questions (FAQ) document, which continues to be updated as the project advances.

7. Portal Registration

What is Medi-Cal Rx and When Does it Happen?

Medi-Cal Rx is the name the Department of Health Care Services (DHCS) has given to the collective pharmacy benefits and services that will be administered through the Fee-for-Service (FFS) delivery system by its contracted vendor, Magellan Medicaid Administration, Inc. (MMA). Medi-Cal Rx will include all pharmacy services billed as a pharmacy claim, including but not limited to outpatient drugs (prescription and over the counter), Physician-Administered Drugs, enteral nutrition products, and medical supplies.

DHCS is delaying the planned Go-Live date of April 1, 2021, for Medi-Cal Rx. For more information, please see the Important Update on Medi-Cal Rx alert dated February 17, 2021.

What Should I Do Now?

Start by visiting the new Medi-Cal Rx Web Portal to review general information about the transition and to access registration and training for the Web Portal. This website serves as a platform to educate and communicate on Medi-Cal Rx resources, tools, and information. To stay informed, sign up for the Medi-Cal Rx Subscription Service (MCRxSS). Similarly, closely monitor Medi-Cal Rx news and bulletins for additional information regarding any future updates.

Next, register for the secure Medi-Cal Rx Provider Portal. Providers will need to complete registration for the User Administration Console (UAC) application. UAC is a registration tool that controls and manages a user's access to the secure section of the Medi-Cal Rx Web Portal and associated applications.

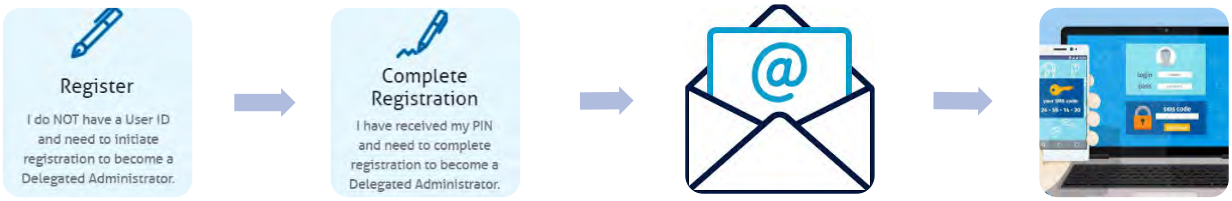
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- Prior Authorization System
- Secure Chat and Messaging Features
- Beneficiary Eligibility Lookup
- Web and Batch Claims Submission
- Education & Outreach Calendar and Training Registration

Refer to the UAC Quick Start Guide (PDF) and the information below for assistance with registering for UAC.

UAC Registration

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure web portal registration in order to access education and outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba and providers will have the ability to enroll in web-based, instructor-led, or computer-based training. To access Saba, providers need to utilize the UAC application. Click the hyperlink under **Medi-Cal Rx Training** on the Education & Outreach page of the Medi-Cal Rx Web Portal, or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration. To register for an Office Hours session, please email MediCalRxEducationOutreach@MagellanHealth.com and include the following information in your email: name of individual, provider name, National Provider Identifier (NPI), phone number, email address, and preferred date and time of Office Hours session.



To register, visit https://uac.magellanrx.com.

- Click **Register**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering as many IDs as necessary
- Click **Submit**

You will receive a letter with a PIN number.

- Return to the UAC website
- Click **Complete Registration**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering and validating all necessary IDs
- Click **Submit**

You will receive an email with an activation link (check spam or junk folder).

- Click activation link
- Confirmation screen appears indicating *You Have Been Successfully Added*
- Click on link in confirmation screen directing you to UAC application
- Here you can assign access and create accounts

Assign access/privileges and organizations.

- The first time you log into UAC, set up multifactor authentication
- Continue with sections 2.0, 3.0, and 4.0 in the Medi-Cal Rx UAC Quick Start Guide located at https://medi-calrx.dhcs.ca.gov/home/education

Christopher M. House

From: UPS <pkginfo@ups.com>
Sent: Monday, April 19, 2021 7:22 AM
To: Christopher M. House
Subject: [EXTERNAL] UPS Delivery Notification, Tracking Number 1ZA47F260198305886

Hello, your package has been delivered.

Delivery Date: Monday, 04/19/2021
Delivery Time: 10:20 AM
Left At: DOCK
Signed by: ANDRE

HANSON BRIDGETT LLP

Tracking Number:	1ZA47F260198305886
Ship To:	CENTER FOR MEDICAID & CHIP SERVICES 7500 SECURITY BOULEVARD, MAIL STOP S2-25-26 BALTIMORE, MD 212441850 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	2.0 LBS
Reference Number:	37366.3
Reference Number:	FHCSD / CHCAPA
Reference Number:	KATHRYN DOI

Download the UPS mobile app

Comments on the Proposed CalAIM Section 1115 Demonstration Application

CAADS appreciates the continued inclusion of Community Based Adult Services (CBAS) in the Section 1115 Demonstration Application and notes the expectation of increased enrollment into CBAS over the 5-year period as dual eligible beneficiaries are moved into MLTSS and aligned D-SNPs. We note that there is not enough capacity within the existing center-based structure of CBAS without expansion to underserved and unserved areas. This takes time and start-up funds. But using the lessons learned during the Public Health Emergency, we believe there are solutions to more quickly increase access to person-center care and these solutions, as outlined below, should be included in this next 5-year waiver period to demonstrate innovation and creative use of existing resources, consistent with the goals of the waiver.

In general, we support the California Department of Aging proposal to use the renewal of the 1115 Waiver through CalAIM to modernize the Medi-Cal funded CBAS model, incorporating lessons learned during the Public Health Emergency and aligning those lessons with the goals of the Master Plan for Aging to improve access to Home and Community Based Services throughout the state. We believe that the flexibility granted through a demonstration and research model lends itself to such innovation. However, we would go further. In that spirit of improving access to community based care, we offer the following recommendations for consideration by DHCS.

1) **Adopt TAS modalities as an Ongoing Feature:** The Temporary Alternative Services (TAS) model has shown how to fully use the expertise and person-centered approach embedded within CBAS by empowering the CBAS MDT navigate outside of the four walls of the facility to "meet people where they are" in their home and community. This has deeply enriched the relationship between the center team and participants, and importantly, the unpaid caregiver and others providing support. CalAIM is an opportunity to demonstrate the durability of this PHE model that has enhanced the ability of the center teams to flexibly navigate within and outside of the center walls in a way that combines intensive care management with the unique benefit of center-based services delivered by an interdisciplinary team. This aligns perfectly with the Enhanced Care Management model envisioned in CalAIM as a separate billable service but could also be built into a "CBAS Plus" model with an enhanced rate.

2) **Add Research Component for CBAS:** There has already been published research on the benefits of an ADHC-based Community Based Health Home model designed as a pilot project unique to California.[1] Further research has explored the impact of the COVID emergency on participants and families who lost full access to congregate services during the PHE. [2] We would like to see a

[1] Sadarangani, T., Missaelides, L., Eilertsen, E., Jaganathan, H., & Wu, B. (2019). A Mixed-Methods Evaluation of a Nurse-Led Community-Based Health Home for Ethnically Diverse Older Adults With Multimorbidity in the Adult Day Health Setting. *Policy, politics & nursing practice*, *20*(3), 131–144. https://doi.org/10.1177/1527154419864301

[2] Vora, P., Missaelides, L., Trinh-Shevrin, C., & Sadarangani, T. (2020). Impact of Adult Day Service Center Closures in the Time of COVID-19. *Innovation in Aging*, *4*(Suppl 1), 949. https://doi.org/10.1093/geroni/igaa057.3472
Tina Sadarangani, Jie Zhong, Paayal Vora & Lydia Missaelides (2021) "Advocating Every Single Day" so as Not to be Forgotten: Factors Supporting Resiliency in Adult Day Service Centers Amidst COVID-19-Related Closures, *Journal of Gerontological Social Work,* 64(3), 291-302, DOI: 10.1080/01634372.2021.1879339

research component built into CalAIM specific to CBAS, building on existing literature and the national movement toward common outcome measures.

3) **Define presumptive eligibility for CBAS to expedite access to needed care**: We have learned through TAS that many people who are discharged from a hospital or nursing facility and could benefit from CBAS right away or may need continued recovery and care management prior to being able to attend the center for required services during a 4-hour service day. Individuals who are within 60 days of a nursing home or hospital stay and who meet medical necessity criteria should be presumptively eligible for enrollment in CBAS without delay. The current process for enrolling a person into Medi-Cal managed care (if they are Medi-Cal beneficiaries or dual eligible) and being approved by that Medi-Cal managed care organization (MCO) can stretch into many months. The extended time spent in the enrollment process is not in the best interest of the person or the Medi-Cal system, as these periods of transitions back into the community are critical, as proper care can help prevent re-admission to institutionalized or acute care. The current process has also been a problem during wildfire emergencies when delays in getting approval for CBAS enrollment has delayed lifesaving care and, in some cases, led to preventable homelessness, nursing home placement or hospitalization. Case studies of these negative impacts of approval delays can be provided as examples.

4) **Encourage Enhanced Care Management as a feature of CBAS and CBAS Plus:** We would like to see active encouragement of MCOs to contract with CBAS providers for Enhanced Care Management now in order to meet the demand for services when dual eligibles transition to Medi-Cal Managed Care as well as the growing population Medi-Cal only beneficiaries. See also recommendation #1 for building a CBAS Plus model for efficiency.

5) **Create a CBAS STCs & SOP Work Group**: The ability of DHCS, CDA and the CBAS leadership to work together during the PHE toward a common goal of supporting access to services while ensuring safety of participants and caregivers was exemplary. We would like to offer the expertise of the Vision Team that was first mobilized during the PHE to continue to work with DHCS and CDA to modernize the STCs and SOPs for CBAS. There are obsolete provisions and fresh refinements based on the ten years of experience in managed care should be incorporated to continue to evolve the CBAS program.

6) **Transition to State Plan**: Federal policy is leading in the direction of prioritizing and expanding access to non-institutional settings in the community. We would like to see CBAS transitioned back to a State Plan Benefit by the end of the next 1115 Waiver demonstration period.

May 4, 2021

Will Lightbourne, Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

Will be submitted via email to CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on California 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne,

Peach Tree Health appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

Peach Tree Health commends the Administration's commitment to implement CalAIM, an initiative that will lead to broad delivery system, program, and payment reforms across Medi-Cal. We see many positive changes in the proposal. However, we do have concerns and recommendations, and would like to share them below for your review and consideration. Specifically, In the paragraphs below, we detail the following:

- DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.
- DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).
- DHCS must ensure the public has opportunity to review and comment on all policy changes.

We thank you for your continued work on this important initiative and look forward to working with the Department on CalAIM implementation.

Comments

1. ***DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.***

We are aware of the time and investment the state committed to the design and vision of Medi-Cal Rx. However, providers and health plans have systems in place today that ensure pharmacy access for Medi-Cal beneficiaries. Delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine already strained delivery systems and further confuse and worry Medi-Cal beneficiaries. To that end, we ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic. Peach Tree Health provides services in rural areas with limited access to pharmacies and transportation. Delaying would allow us the opportunity to refocus our efforts after COVID-19, but we are not out of the pandemic. Recognizing the rapidly evolving pandemic response, as well as the current challenges and unknown resolution to conflict concerns with the project's contractor vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

2. ***DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.***

The CalAIM proposal will ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which often can be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. For that reason, we applaud the Administration proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal that will ensure provider's ability to render necessary medical services to patients. However, questions remain as to how providers can comply with, and bill for, those services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan. Health centers often are the entry into the SMH/SUD system, yet few health centers are contracted providers with their county SMH/SUD health plans. This arrangement often leaves health centers in a financially disadvantaged position where they must provide needed services under federal law but cannot bill for those services. Peach Tree relies on a Bi-County Behavioral Health system that does not contract out for SUD services and we have limited resources in our community to turn to for full spectrum SUD services. For that reason, we ask DHCS to provide clarification on how non-contracted providers can provide medically necessary services prior to an assessment.

3. ***DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.***

The Cal AIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although we recognize a statewide need to enhance access to both sets of services in a coordinated manner, we see several issues that need to be addressed in order to ensure that counties are prepared to adequately meet the demand for services and patients/families can be assured they are receiving the highest quality of care. Most notably, we are concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs are

consolidated. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, 2017/18 External Quality Review Organization (EQRO) reported that several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care. Thus, while Peach Tree Health agrees that the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure access to timely and quality SMH/SUD services.

4. ***DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).***

Peach Tree Health is pleased to see the inclusion of Enhanced Care Management and In-lieu-of Services in the Cal AIM proposal as well as the Administration's commitment to ensure adequate funding is allocated for these services in this year's budget. However, to ensure successful implementation of these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to work together. We are encouraged by the inclusion of the Providing Access and Transforming Health Supports, which is necessary to transition existing services and build up capacity, including payments for new staffing and infrastructure. Supports are also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care.

We are concerned with several program elements that might impact their current operation and infrastructure, namely implementation of a new care management system and process, new care referral process or new claim submission process, new patient assignment process and other. Yet more is needed. Therefore, we respectfully ask DHCS to ensure ample resources and support available to ECM and ILOS providers.

5. ***DHCS must ensure the public has opportunity to review and comment on many policy changes that are described in the waivers but are not included as part of the waiver proposal.***

While we appreciate the opportunities to comment on the 1115 and 1915(b) waivers and expect DHCS will release other policy changes for public comment in the future, we would like to underscore the importance of gathering and incorporating stakeholder input into final policies. Specifically, we request extensive public comment and engagement on the following items noted in the proposal:

- A standardized screening tool for county Behavioral Health plans and Medi-Cal managed care plans to use to guide beneficiaries toward the delivery system that is most likely to meet their needs.
- A standardized transition tool for MHPs and MCPs to use when a beneficiary's condition changes and they would be better served in the other delivery system.
- A process for facilitated referral and linkage from county correctional institution release to county specialty mental health, Drug Medi-Cal, DMC-ODS, and Medi-Cal MCPS when the inmate

was receiving behavioral health services while incarcerated, to allow for continuation of behavioral health treatment in the community.

****

As providers continue to support the Administration in COVID-19 vaccination effort, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operation.

Again, Peach Tree Health appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Meredith Evans at (530) 749-3242 ext 1356.

Sincerely,

[redacted]

Meredith Evans, LMFT
Director of Integrated Behavioral Health
Peach Tree Healthcare

California Association of Health Plans

1415 L Street, Suite 850
Sacramento, CA 95814
916.552.2910
www.calhealthplans.org

May 4, 2021

Jacey Cooper
Chief Deputy Director and State Medicaid Director
California Department of Health Care Services
1501 Capitol Avenue
Sacramento, CA 95814

SUBJECT: **Support for DHCS Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration, Section 1915(b) Waiver Renewal**

Via e-mail: Jacey.Cooper@dhcs.ca.gov

Dear Ms. Cooper:

On behalf of our member Medi-Cal managed care plans (MCPs) that arrange for the care of nearly 11 million Medi-Cal members, the California Association of Health Plans (CAHP) supports the California Department of Health Care Services' (DHCS) *Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: California Advancing and Innovating Medi-Cal (CalAIM) Demonstration* and *CalAIM 1915(b) Waiver Overview,* released for public comment on April 6.

The five-year renewal of some of the waiver and expenditure authorities contained in the Medi-Cal 2020 Section 1115 demonstration, as well as certain new authorities, will enable California to complete the transition to the new structure envisioned under the CalAIM initiative. Collectively, the Section 1115 CalAIM demonstration and consolidated 1915(b) waiver, along with related contractual and State Plan changes, will enable California to fully implement the CalAIM initiative.

CAHP appreciates DHCS' long history of and commitment to innovation in care delivery to better support Medi-Cal members. CAHP acknowledges the incredible opportunity to implement California's whole person care approach statewide — first authorized under the "Medi-Cal 2020" Section 1115 demonstration — with a clear focus on improving health and reducing health disparities and inequities.

Our members look forward to partnering with DHCS, county partners, provider partners, community-based organizations, and other key stakeholders to achieve the three primary goals envisioned under CalAIM:

- Identify and manage beneficiary risk and need through whole person care approaches and addressing social determinants of health;
- Move Medi-Cal to a more consistent and seamless system by reducing complexity and increasing flexibility; and
- Improve quality outcomes, reduce health disparities, and drive delivery system transformation and innovation through value-based initiatives, modernization of systems, and payment reform.

CAHP appreciates the opportunity to support DHCS' waiver renewal and amendment request. CAHP looks forward to collaborating with DHCS on development of DHCS' initiative to provide targeted Medi-Cal services to eligible justice-involved populations 30 days pre-release from county jails, state prisons, and youth correction facilities. In addition, CAHP looks forward to our continued collaboration with DHCS to address the many outstanding concerns and recommendations that CAHP submitted to DHCS on March 20 and March 22, informed by lessons learned from the Whole Person Care Pilots and Health Homes Program. The recommendations included, but were not limited to, the following:

- CalAIM implementation timeline
- List of ECM providers
- ECM target populations
- Authorization of ECM, ILOS
- Provision of in-person ECM
- Proposed credentialing of ECM, ILOS providers
- Data-sharing
- Provider submission of encounter data
- Supplemental reporting requirements
- Outstanding information needed for MCPs to develop contracts

If you have any questions, please feel free to contact me at (916) 802-4069.

Amber Kemp, MBA
Vice President, State Medicaid Policy

cc:

Mr. Will Lightbourne, Director, DHCS
Mr. Aaron Toyama, Senior Advisor, Health Care Programs, DHCS
Ms. Susan Philip, Deputy Director, Health Care Delivery Systems, DHCS

DAP Health

1695 North Sunrise Way
Palm Springs, CA 92262

May 6, 2021

Will Lightbourne, Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

Will be submitted via email to CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on California 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne,

Desert AIDS Project d/b/a DAP Health, appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

DAP Health commends the Administration's commitment to implement CalAIM, an initiative that will lead to broad delivery system, program, and payment reforms across Medi-Cal. We see many positive changes in the proposal. However, we do have concerns and recommendations, and would like to share them below for your review and consideration. Specifically, In the paragraphs below, we detail the following:

- DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.
- DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).
- DHCS must ensure the public has opportunity to review and comment on all policy changes.

We thank you for your continued work on this important initiative and look forward to working with the Department on CalAIM implementation.

Comments

1. ***DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.***

We are aware of the time and investment the state committed to the design and vision of Medi-Cal Rx. However, providers and health plans have systems in place today that ensure pharmacy access for Medi-Cal beneficiaries. Delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine already strained delivery systems and further confuse and

worry Medi-Cal beneficiaries. To that end, we ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic. The proposed changed in Medi-Cal Rx reimbursement rates is devastating to DAP Health. Not only will services be reduced, there will be substantial job cuts and sick people turned away from treatment. Recognizing the rapidly evolving [redacted] as well as the current challenges and unknown resolution to conflict concerns [redacted] tractor vender, we recommend the department delay the pharmacy transition [redacted] the transition from its waiver proposal.

2. ***DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.***

The CalAIM proposal will ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which often can be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. For that reason, we applaud the Administration proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal that will ensure provider's ability to render necessary medical services to patients. However, questions remain as to how providers can comply with, and bill for, those services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan. Health centers often are the entry into the SMH/SUD system, yet few health centers are contracted providers with their county SMH/SUD health plans. This arrangement often leaves health centers in a financially disadvantaged position where they must provide needed services under federal law but cannot bill for those services.

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****

As providers continue to support the Administration in COVID-19 vaccination effort, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operation.

Again, DAP Health appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Carl Baker at (760) 323-2118.

Sincerely,

[redacted]

Carl Baker
Director of Legal and Legislative Affairs

To whom it may concern,

[redacted] I urge you to adhere to the following:

Resist pathologizing adversity—as evidenced by proposed tools to “screen in for a high risk score” for ongoing services. We must honor the wisdom and intelligence of low income communities to determine their own definition of medical necessity. Any positive screen, and more importantly, any request for support from a beneficiary should qualify a child for services and support. Period.

Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan--or if such a tool is to be used it must only be used during the course of treatment and treatment can not be stopped or interrupted until or if there is a transition in care. When we know better we do better.

Clarify unanswered questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

California’s most vulnerable children are depending on you to consider their overall health and well being for the long term… not just dollar signs and billing insurance for profits today. Children and families have needs that can not be met within the parameters of the medical model or managed care.

Sincerely,
Jessica

From: Jennifer Hinkel <jhinkel@telecarecorp.com>
Sent: Tuesday, May 4, 2021 3:49 PM
To: DHCS Cal AIM Waiver <CalAIMWaiver@dhcs.ca.gov>; DHCS CalAIM <CalAIM@dhcs.ca.gov>
Cc: Jennifer Hinkel <jhinkel@telecarecorp.com>
Subject: [External]Feedback - Peer Support Certification - Supervision

Greetings DHCS,

Thank you for the 2nd CalAIM Section 1115 Demonstration & Section 1015(b) Waiver public hearing yesterday.

On SLIDE 22 of the presentation today the below statement was drawn out of the DHCS Peer Support Certification program overview.

Participating counties will provide supervision of specialists by behavioral health professionals trained in the peer recovery model

This statement is very concerning.

During both DHCS listening sessions on Peer Support Certification several people strongly insisted that the supervision of peer support specialist include supervision from a CA Certified Peer Support Professional.

The group felt that dual supervision by a BH professional and a CA Certified Peer Professionals was acceptable – however the Peer Professional MUST receive supervision from someone in their profession – just like most other certified or licensed professions. Saying that the behavioral health professionals will be trained in peer recovery model is just not sufficient. This is considered best practice nationally, and California has the opportunity to learn from the current state of the profession.

Also attached a previous letter and feedback from Telecare sent to the head of MediCal in December and to Kelly Pfeifer.

Thank you for your time and attention to this important feedback.
Jennifer

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Jennifer Hinkel| Vice President for Development| www.telecarecorp.com

510-671-4600 Cellular/Text | jhinkel@telecarecorp.com

Our Mission is to deliver excellent and effective behavioral health services that engage individuals with complex needs in recovering their Health, Hopes and Dreams. Join us!

TELECARE
CORPORATION

December 15, 2020

Via Email: Jacey.Cooper@dhcs.ca.gov

Jacey Cooper Chief Deputy Director,
Health Care Programs and State Medicaid Director
California Department of Health Care Services 1501 Capitol Avenue, MS 4000
Sacramento, CA 95899-7413

Subject: Telecare Comments – CalAIM Behavioral Health Proposals on Medical Necessity and Peer Services

Dear Ms. Cooper:

We appreciate the opportunity to comment on the most recent proposed polices to improve the overall system of care and find most of the work very helpful in terms of improving access for persons needing care. We are especially supportive of the "no wrong door" approach and appreciate the efforts to enhance co-occurring disorder treatment by allowing a provider to bill to either DMC or the MHP. We hope this will increase access to MAT and also mean more timely treatment.

We wanted to also offer a few specific recommendations.

Inpatient Medical Necessity Criteria

We were so pleased to see AB 890 pass last session and begin to anticipate the benefits of having nurse practitioners have full scope authority. This is already the case in Washington State where Telecare operates seven acute "Evaluation and Treatment" programs, equivalent to California Psychiatric Health Facilities. There Advanced Registered Nurse Practitioners (ARNP's) can provide psychiatric services in the inpatient setting and this has been a tremendous benefit in terms of meeting the workforce challenges and the needs of acutely ill clients. ARNPS's are more available and more willing to spend extended time with patients.

Here in California Telecare operates seven Psychiatric Health Facilities in multiple counties and have struggled to maintain appropriate psychiatric staffing, particularly child psychiatry. We have found that Nurse Practitioners are far more available and use them extensively in our more than forty community based programs such as Full Service Partnerships, Crisis Residential programs and Crisis Stabilization programs. But they are not currently able to serve in PHF's. This is due to current licensing requirements (Attached) and as specified in the W & I Code, 5152, only Psychiatrists can lift 72 hour holds. As we plan for the future, it is important to prepare the way for the new law and begin to address a critical workforce challenge.

Unfortunately, the current language in the medical necessity section has the following:

Telecare Corporation
1080 Marina Village Parkway Alameda, CA 94501-1043
(510) 337-7950 www.telecarecorp.com

"Continued Stay Requirements for Acute Psychiatric Hospitalization:
A physician (or a nurse practitioner, physician assistant or psychologist acting within their scope of practice and under the supervision of a physician) must certify that the beneficiary, as the result of a mental health condition, or substance use-induced mental health impairment, meets, meets one of the two requirements below..."

We believe the medical necessity criteria should be aligned with the new law and support this expanded use of nurse practitioners. We also recommend a fuller discussion of how Nurse Practitioners can be utilized in the system of care, and how best to address the other barriers contained in licensing regulations and the W & I code.

Peer Support Services

We are grateful for the extensive coalition that successfully advocated for SB 803 to finally be approved. The Peer Support Services description provided by DHCS was a thoughtful effort to guide the implementation of that law. Attached is a marked up version of that description, with some suggested edits. You will no doubt see this is based on a more strength-based approach, rather than deficit approach, something our peers have taught us!

The main policy issue we wanted to bring forward is the area of supervision. We currently employ over 230 peer professionals at every level of care that Telecare operates. And we have found that best practice means a career ladder for peers, including a job we title "Peer Team Lead" who supervises other peers. During our discussion on December 11th, it was clear DHCS does not want to limit eligible supervisors to behavioral health professionals. At the same time, some counties or providers might want to allow for that, so the language is intended to be permissive not a requirement. This is with the understanding that all the other requirements for "Head of Service" apply. We would like to recommend that you specify "or":

Peer support specialists must provide services under the consultation, facilitation, or direct supervision *of a Peer Professional Leader or* a behavioral health professional within their scope of practice.

Please feel free to contact me at frichie@telecarecorp.com if I can answer any questions. Thank you for this opportunity to provide input and we look forward to more continued discussions on CalAIM proposals.

Sincerely,

[redacted]

Faith Richie
SVP & Chief Development Officer
Telecare Corporation

Cc: Dr. Kelly Pfeifer, DHCS

Attachments

Telecare Corporation
1080 Marina Village Parkway Alameda, CA 94501-1043
(510) 337-7950 www.telecarecorp.com

Peer Support Services– Seeking Federal Authorities

The use of peer support specialists (peers) has been demonstrated to be a cost-effective and evidence-based practice for individuals experiencing mental health conditions and substance use disorders.

Currently, peers are only authorized to deliver covered services in the Medi-Cal program in a limited fashion. Specifically, peer-to-peer services are covered as a component of recovery services under the Drug Medi-Cal Organized Delivery System (DMC-ODS). With regards to specialty mental health services (SMHS), peers are not currently included in California's Medicaid State Plan as providers for Medi-Cal Rehabilitative Mental Health and Targeted Case Management services. They are similarly not included under the State Plan Drug Medi-Cal program.

Pursuant to SB 803 (Beall, Chapter 150, Statutes of 2020), DHCS will seek federal approval to establish peers as a provider type, with associated Healthcare Common Procedure Coding System codes, allowed to provide distinct peer support services under the SMHS and DMC-ODS programs. While services provided by peers can currently be claimed under the provider type "other qualified provider" within the SMHS program, DHCS is proposing to add peers as a unique provider type with specific reimbursable services and to allow counties to opt-in to provide this valuable resource. By July 1, 2021, DHCS will determine the peer certification standards in alignment with the provisions of Senate Bill (SB) 803 (Beall, Chapter 150, Statutes of 2020), and in accordance within CMS' guidance, with the new benefit in place by January 1, 2022.

Definition of Peer Support Specialists

Peer support specialists are people who have been successful in their own recovery and who help others experiencing similar behavioral health treatment and recovery life situations. Peer Support Specialists include individuals in recovery with lived experience of mental health conditions, ~~severe emotional disturbances~~, and/or substance use disorders as well as family partners with experience assisting loved ones with these conditions. With a certification and through shared understanding, respect, and mutual empowerment, peer support specialists help beneficiaries become and stay engaged in the recovery process and reduce the likelihood of relapse.

Delivery Systems

If counties choose to administer a peer support specialist certification program in accordance with DHCS statewide standards, certified peers can deliver services under the Specialty Mental Health System and/or the Drug Medi-Cal Organized Delivery System.

Services Provided

Structured, scheduled interactions and activities that promote socialization, recovery, self-advocacy, relapse prevention, development of natural supports, and maintenance

Commented [JH1]: would really like to not see these professionals nicknames 'peers'. Why not say PSS if you need to shorter title?

Commented [JH2]: an we lead with evidence-based Recovery practice vs cost effective – and do we even need to say 'cost effective'?

Commented [JH3]: PSS

Commented [JH4]: Mental health recovery vs conditions?!

Commented [JH5]: Family is a very limiting term today – maybe family and supporters?

Commented [JH6]: Strengthen (become assumes they are not involved at all)

Commented [JH7]: Why not start with recovery – vs socialization?

Commented [JH8]: Life goal planning and implementation

of community living skills will be provided by Certified Peer Support Specialists under the consultation, facilitation or direct supervision of a behavioral health professional. Services are directed toward the achievement of the specific, individualized, and result-oriented goals defined by the beneficiary and specified in the treatment and/or recovery plan. Additionally, this service provides support and coaching interventions to individuals to promote behavioral health recovery and healthy lifestyle choices. Supportive interactions can include motivational interviewing, recovery planning, resource utilization, strengths identification and development, support in considering theories of change, building recovery empowerment and self-efficacy. There is also advocacy support with the beneficiary to have recovery dialogues with their identified natural and formal supporters.

Self-help support groups, telephone support lines, drop-in centers, and sharing the peer support specialist's own life experiences will build alliances that enhance the beneficiary's ability to function in the community. These services may occur in a clinic or facility based setting and/or at locations in the community as allowed under the DMC-ODS and SMHS waivers.

Levels of Care

In all levels of care for SMHS and DMC-ODS networks, peer support specialists can provide services in combination with other medically necessary mental health or substance use services or as an independent service to maintain beneficiaries' recovery.

Supervision

Peer support specialists must provide services under the consultation, facilitation, or direct supervision of a behavioral health professional within their scope of practice.

Commented [JH9]: Why does supervision have to be from a Behavioral Health professional?

Commented [JH10]: Agree – could add WRAP here unless you don't want to name a 'brand'.

Commented [JH11]: Add 1:1 peer recovery coaching conversations

Commented [JH12]: And at a person's home

Commented [JH13]: In combination or stand alone (thinking of all peer programs – wellness centers, etc – which are not linked but could establish medically necessary services on their own.

Commented [JH14]: Strongly disagree with supervision under a BH Professional. If anything, should be added that Peer Professionals will receive consultation, facilitation and direct supervision by a Peer Professional Leader – at a minimum in conjunction with clinical supervisor?!

From: John Valencia <john@valencialobby.com>
Sent: Tuesday, May 4, 2021 5:35 PM
To: DHCS Cal AIM Waiver <CalAIMWaiver@dhcs.ca.gov>
Subject: [External]"CalAIM Section 1115 & 1915(b) Waivers" - Contingency Management as a New DMC-ODS Service Component (1915(b)(3))
Importance: High

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

RE: Support for Contingency Management - New DMC-ODS Service Component (1915(b)(3)) – Prescription Digital Therapeutics

To the Department of Health Care Services:

On behalf of our client, Pear Therapeutics, Inc. ("Pear"), I write to express the company's support for the Department's 1915(b) Waiver request for authority to add Contingency Management ("CM") services as a new component of existing DMC-ODS services. Pear heartily agrees that CM has been established as an evidence-based treatment for substance use disorder (SUD) by combining motivational incentives with behavioral health treatments. In fact, CM is an important part of Pear's prescription digital therapeutics, or PDTs, reSET® and reSET-O®.

Pear's lead product, reSET®, for the treatment of substance use disorder, was the first PDT to receive marketing authorization from FDA to treat disease. Pear's second product, reSET-O®, for the treatment of opioid use disorder, was the first PDT to receive Breakthrough Designation.

PDTs are prescription-only software apps that deliver evidence-based therapeutic interventions to patients via smartphones or tablets to prevent, manage or treat a medical disorder or disease. PDTs are categorized by FDA as Software as a Medical Device, or SaMD - software intended for medical purposes that performs those purposes without being part of a hardware medical device. In short, during the course of treatment, patients interact with treatment modules that deliver cognitive behavioral therapy and contingency management to reinforce adherence to therapy.

To be well-positioned to act on CMS approval of the Department's request, Pear is recommending that the Waiver request incorporate a modest, inclusive amendment to secure specific authority, guidance and direction on coverage, utilization and reimbursement for PDTs utilizing CM in SUD and OUD treatment.

Pear stands ready to assist the Department with any aspect of this recommendation to further the prospect of success of Federal approval of the Department's request for authority to add Contingency Management services as a DMC-ODS service.

Respectfully submitted,

John Valencia

John R. Valencia
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1001 K Street, 6th Floor
Sacramento, CA 95814
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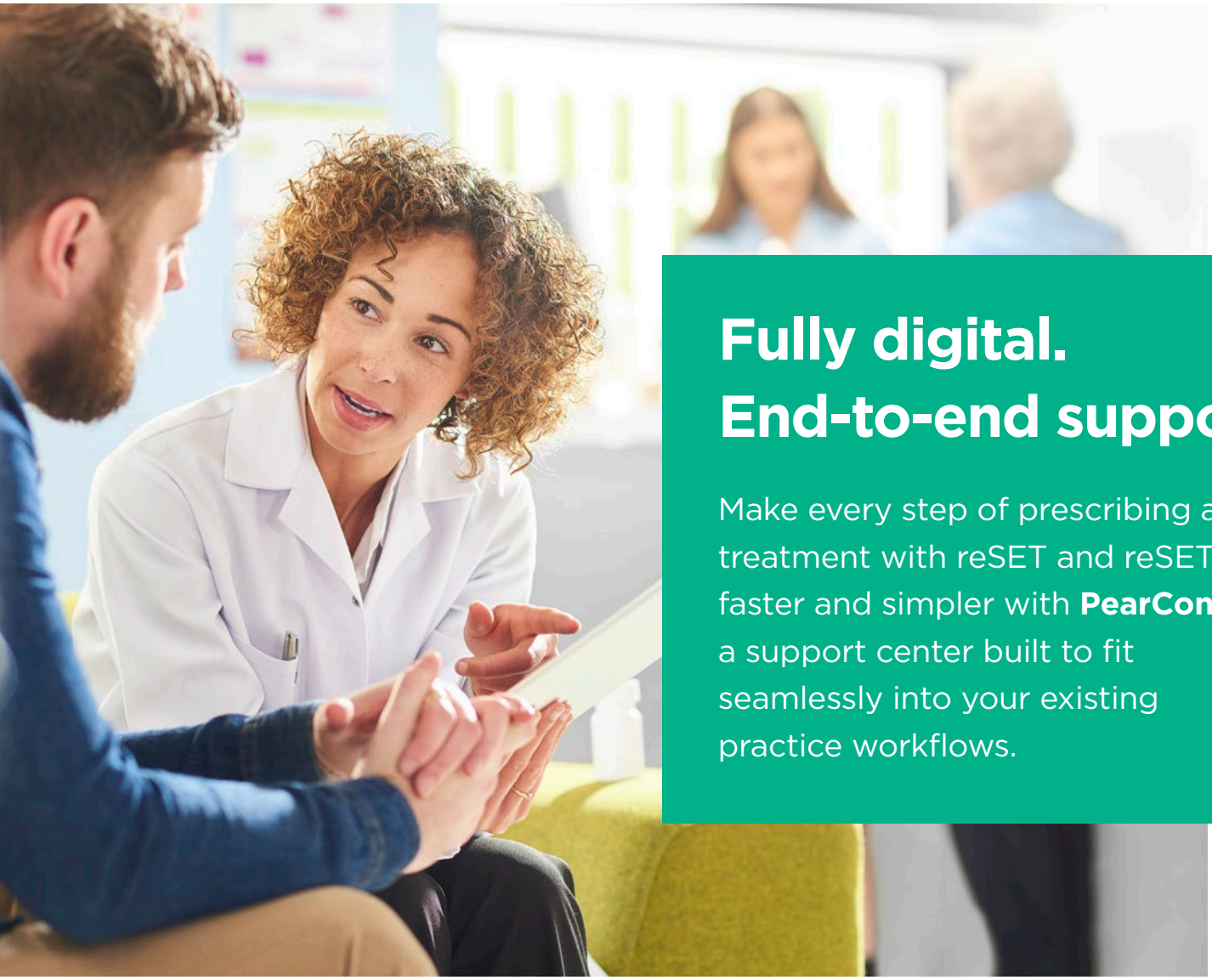

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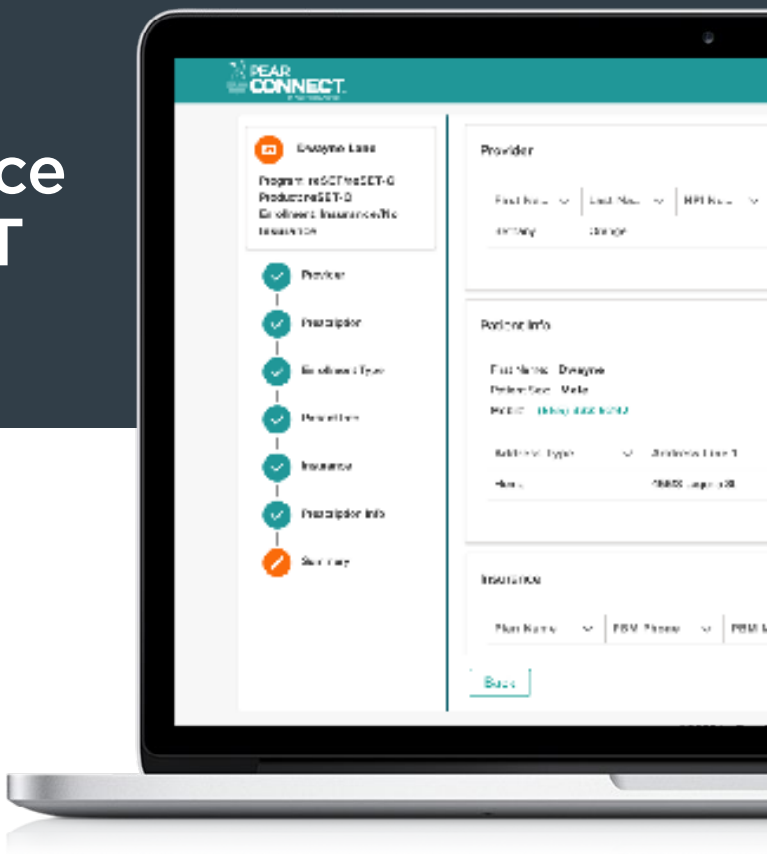

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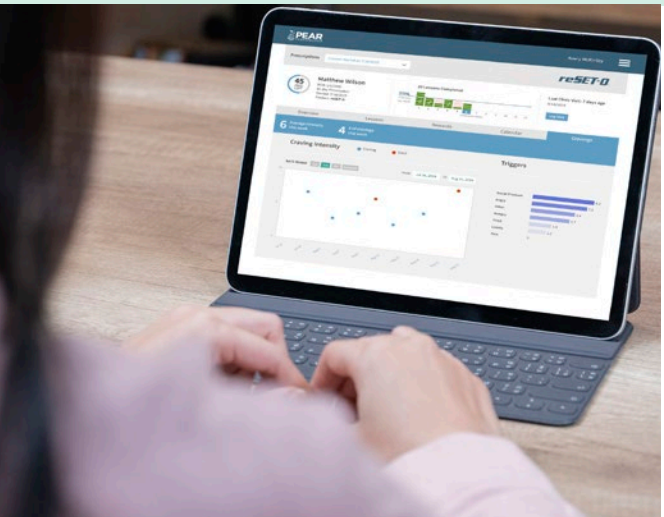
eRx from your own EHR system*

PDF enrollment form



Ongoing patient engagement

With the **Pear.MD Clinician Dashboard**, you can monitor your patients as they work through the reSET or reSET-O program, completing lessons and tracking cravings and triggers. In doing so, you can be there instantly at key points in the recovery journey and provide consistent feedback on their progress.

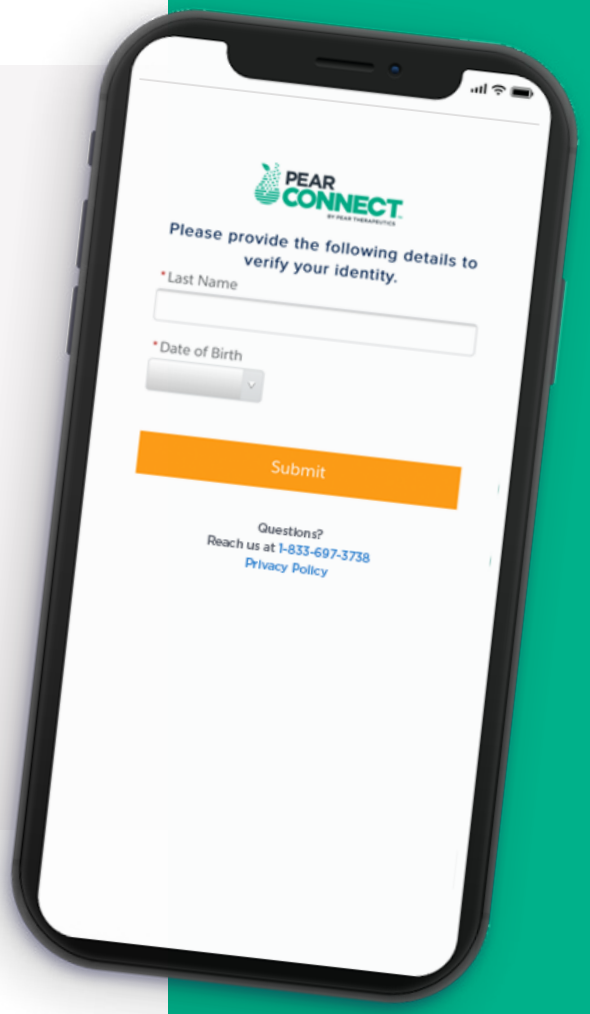
*Requires current compendia, as of 2019.

PearConnect offers assistance for your patients.

Personalized guidance and support

PearConnect offers personalized onboarding, product education, therapy and adherence check-ins, and technical support.

Whether you are treating your patient in-office or virtually, PearConnect engages your patient in real time via their phone to capture their consent and quickly dispense their prescription digital therapeutic.



Streamlined process

Time to dispense prescription **is a few short minutes** for most patients

No need to answer calls to provide consent

Simple **2-step, real-time, text-based** consent and onboarding process

- Text #1: engage patient and capture digital consent
- Text #2: onboard patient and deliver access code, allowing patient to download the app and go

Assistance with access and payment

Pear Therapeutics offers 2 assistance programs:

PEAR Assistance Program, which ensures eligible patients have access to FDA-authorized prescription digital therapeutics for addiction treatment. The program provides access to reSET or reSET-O, free of charge, to qualifying patients who are currently under the supervision of a licensed US healthcare provider on an outpatient basis.

Copay Program for eligible commercially insured patients to help lower the copay for reSET or reSET-O. Once enrolled, commercially insured patients may pay as low as $0 for their prescription.

Please call us at 1-833-697-3738 for more information.

reSET®

INDICATIONS FOR USE

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90-day) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
- increase retention in the outpatient treatment program.

IMPORTANT SAFETY INFORMATION

Warnings: reSET is intended for patients whose primary language is English and whose reading level is at the 7th grade level or above and who have access to an Android/iOS tablet or smartphone.

reSET is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Clinicians should not use reSET to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

reSET is not intended to be used as a stand-alone therapy for substance use disorder (SUD). reSET does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider.

reSET should not be used by individuals outside active enrollment in a SUD treatment program. It should only be used as an adjunct to face-to-face counseling and contingency management. reSET is not intended to reduce the amount of face-to-face clinician time.

The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12-weeks in the SUD population. The ability of reSET to prevent potential relapse after treatment discontinuation has not been studied.

The effectiveness of reSET has not been demonstrated in patients currently reporting opioids as their primary substance of abuse.

reSET-O®

INDICATIONS FOR USE

reSET-O is intended to increase retention of patients with Opioid Use Disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

IMPORTANT SAFETY INFORMATION

Warnings/precautions: Do not use reSET-O to communicate any emergency, urgent or critical information. reSET-O does not include features that can send alerts or warnings to your clinician. If you have feelings or thoughts of harming yourself or others, please dial 911 or go to the nearest emergency room.

reSET-O is not intended to be used as stand-alone therapy for Opioid Use Disorder (OUD) and does not replace care by your provider. reSET-O is not a substitute for your medications. You should continue to take your medications as directed by your provider.

reSET-O should only be used by individuals who are enrolled or participating in an OUD treatment program. It should be used with outpatient clinician treatment, buprenorphine treatment, and contingency management (a program that provides incentives for achieving behavior goals). It is not intended to replace outpatient treatment.

reSET-O is intended for patients whose primary language is English, who have access to an Android/iOS tablet or smartphone and are familiar with the use of smartphone applications (apps). You should be able to upload data periodically, i.e. have internet/wireless connection access.

PEAR THERAPEUTICS

Contact Us

Call: 1-833-697-3738
Fax: 1-877-256-1320
Hours: 8 AM-8 PM ET Mon-Fri
Email: PearConnect@peartherapeutics.com

PEAR-MKT-0278 2020_10

PEAR THERAPEUTICS

peartherapeutics.com

Redefining Medicine

Pear Therapeutics is the leading developer of Prescription Digital Therapeutics (PDTs).

PDTs are a new therapeutic class that use software to treat disease. Similar to traditional biologics or drugs, some PDTs:

- Treat diseases
- Demonstrate safety and effectiveness in randomized clinical trials
- Require premarket review and authorization by the U.S. Food and Drug Administration
- Must be prescribed by a licensed health care provider (MD, DO, NP, PA)

Rather than swallowing a pill or taking an injection, ***patients leverage software to treat their disease,*** all through their smartphone or tablet.

Prescription digital therapeutics:

Using software to treat human disease

- Available by prescription only (They are not just health and wellness apps)
- Evaluated in randomized, clinical studies resulting in validated safety and effectiveness
- FDA regulated software as a medical device
- Provide 24/7access to care
- Help providers and patients stay connected

Through these clinically validated software-based therapeutics, Pear aims to provide engagement and insight tools for clinicians and patients, and cost-effective solutions for payers.

The first three FDA-authorized PDTs —

reSET®

For the treatment of substance use disorder

reSET-O®

For the treatment of opioid use disorder

Somryst™

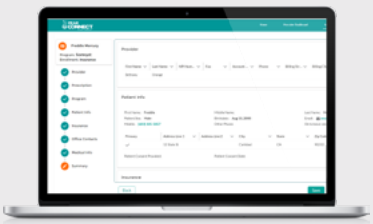
For the treatment of chronic insomnia

Please see Important Safety Information and Indications for Use

Please see Important Safety Information and Indications for Use

The industry's first patient service center for PDTs

PEAR CONNECT™ BY PEAR THERAPEUTICS



Pear has built the first scalable platform infrastructure to discover, develop, and deliver PDTs to patients. Our commitment to developing PDTs is further demonstrated by our comprehensive pipeline of product candidates across therapeutic areas, including specialty psychiatry, specialty neurology, and a host of other non-CNS diseases.

For more information about Pear and our products visit:

www.peartherapeutics.com

PEAR THERAPEUTICS

peartherapeutics.com

Hi,

Please add the below as my public comment on the 1915b waiver process.

I am a pediatrician, public health advocate, and scholar who writes and teaches about the impacts of structural racism and inequity on health. I have serious concerns with the 1915(b) waiver, which as currently proposed by DHCS, erodes critical advancements in addressing the ways racism and inequity shape children and adolescents' behavioral health outcomes.

First, requiring a threshold ACEs score to be eligible for services makes ACEs screening coercive rather than the choice of families and caregivers. It removes the right to informed refusal, which is critical for patient autonomy. This approach also entrenches a single measure of adversity, one that ignores the sociopolitical roots of adversity, as the primary gatekeeper for services that should be available to children without having to endure such invasive questions or center their care around their deficits/most traumatic moments.

Scholars, including the original author of the ACEs study Dr. Robert Anda, have cautioned against the use of the ACEs score in this way, because as they noted: "Despite its usefulness in research and surveillance studies, the Adverse Childhood Experience (ACE) score is a relatively crude measure of cumulative childhood stress exposure that can vary widely from person to person. Unlike recognized public health screening measures, such as blood pressure or lipid levels that use measurement reference standards and cut points or thresholds for clinical decision making, the ACE score is not a standardized measure of childhood exposure to the biology of stress. The authors are concerned that ACE scores are being misappropriated as a screening or diagnostic tool to infer individual client risk and misapplied in treatment algorithms that inappropriately assign population-based risk for health outcomes from epidemiologic studies to individuals. Such assumptions ignore the limitations of the ACE score." (reference: Anda RF, Porter LE, Brown DW. Inside the Adverse Childhood Experience Score: Strengths, Limitations, and Misapplications. Am J Prev Med. 2020 Aug;59(2):293-295. doi: 10.1016/j.amepre.2020.01.009.)

Second, scholars have also raised concerns about the ways current ACEs screens are being used to inappropriately over-refer families of color into the child protection services and child welfare system. By scrutinizing the experiences of caregivers and children, and over-sampling families on Medicaid (who are the primary utilizers of the screener), this results in a system that compounds the historically racist depictions of parents of color and families who live in poverty, as unfit, and risks exacerbating forms of family separation that already exist. Requiring threshold scores for services will only further this problem.

Third, requiring ACEs screeners for accessing services exhausts precious resources that could be used to address forms of structural inequality and racism that underpin childhood adversity. This compounds the ways many children are already denied access to vital behavioral health services.

I beseech those in power to NOT require threshold ACEs scores, which is another manifestation of medical necessity, for accessing behavioral health services for children and adolescents. The risks of this approach are widely known, which makes the harms this approach could cause,

completely preventative. At a time when the nation's consciousness about the harms of racism is growing, it would be shameful to see an approach like this advance in a state as progressive as California, given the predictable toll it will take on families and children of color.

Respectfully submitted,
Rhea Boyd, MD, MPH

SHASTA COMMUNITY HEALTH CENTER
californiahealth+

COMMUNITY HEALTH CENTER FQHC QUALITY SM

P.O. Box 992790, Redding, California 96099-2790
(530) 246-5710

May 5, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Shasta Community Health Center (Shasta CHC) writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, Shasta CHC urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

Shasta CHC is an FQHC that cares for Medi-Cal and uninsured patients in the Shasta County with locations in Redding, Anderson and The City of Shasta Lake. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through 30 contract pharmacies located throughout our service region providing convenience to our patients who often have to travel long distances for basic services.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Shasta CHC to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, Shasta CHC annually saves an estimated $2.4 million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Shasta CHC to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, specialty care telemedicine, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care system, Shasta CHC patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[2] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which Shasta CHC incorporates by reference into this letter. Shasta CHC fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, Shasta CHC urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Shasta CHC and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. Shasta Community Health looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

Good morning,

As the social work department supervisor at Among Friends ADHC, I am writing to voice my support for the California Department of Aging's proposal to use the renewal of the 1115 Waiver through CalAIM, to modernize the Medi-Cal funded CBAS model, and goals of the Master Plan for Aging to improve access to Home and Community Based Services throughout the state.

Since the pandemic caused us to move forward with the Temporary Alternative Services (TAS) model, our multi-disciplinary team has worked tirelessly to assist our participants in facing new obstacles using a person-centered approach. County offices were closed, doctors were unable to provide in-person services, participants were without access to their medications, and others with little to no family support became at risk of becoming food insecure. Still others faced language barriers when accessing services, which became much more difficult to assist with without their attending the center in-person. The pandemic triggered a crisis mode for the more than 200 participants enrolled at Among Friends for services.

We sought to identify our most vulnerable seniors and persons with mental illness by immediately implementing a specific Telehealth phone questionnaire designed by our program manager. This included a checklist to identify whether they had symptoms of COVID, or were at-risk of being exposed so they could be referred to testing if needed. The questionnaire also served as a bio/psycho/social wellness check to identify any new mental health symptoms, lack in access to food or caregiver support, and establishment of a healthy routine during stay-at-home orders. Service coordination was then addressed. Had they been taking their medication, or needed help attaining/refilling medication? Did they need assistance accessing or re-ordering incontinence supplies? Had they experienced any recent falls, hospitalizations, or ER visits which could be addressed by our nurses, and therapy department?

As we identified these barriers, our multi-disciplinary team coordinated care, provided teachings, counseling, and reached out to agencies to refer them to services. Social workers assisted with applying for home meal delivery, and Cal-Fresh food benefits. Pop-up food pantries and Senior Nutrition Program meal sites were shared as they became available. Participants immediately received home delivered meals from our facility, every day they were scheduled, along with wellness checks and COVID screening from the social workers. For those suffering increased mental health symptoms, grief/loss, or faced harmful living situations - care was coordinated with the county crisis team, and Adult Protective Services. Additionally, our center has sought out and delivered dozens of donated adaptive equipment devices -shower chairs, walkers, wheelchairs, and commodes - to assist vulnerable homebound seniors facing further health decline. Our activities department also sent puzzles, painting, and other crafts to combat boredom at home. We also offered a daily Zoom class for exercises, health teachings, and reminiscence and coping skills – conducted by our activity coordinator, social workers, nurses, PT and dietician.

These services continue to be provided as we move into our 14th month of Temporary Alternative Services. It has deeply enriched our relationships with our participants, family members, and local resources. It would be greatly beneficial and efficient to incorporate the recommendations being made by CAADS in their comments on the Proposed CalAIM Section 1115 demonstration application as we continue to maneuver the future of person-centered care for our seniors.

Thank you for your time and consideration,

Donelle Conley, MSW
Social Services Department Manager| Among Friends ADHC
Tel: 805-385-7244 | Fax: 805-385-7246
851 South A St | Oxnard, CA. 93030
www.amongfriends.org

SHASTA COMMUNITY HEALTH CENTER
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COMMUNITY HEALTH CENTER FQHC QUALITY SM

P.O. Box 992790, Redding, California 96099-2790
(530) 246-5710

May 5, 2021

Will Lightbourne, Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

Will be submitted via email to CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on California 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne,

Shasta Community Health Center (SCHC) appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

Shasta Community Health commends the Administration's commitment to implement CalAIM, an initiative that will lead to broad delivery system, program, and payment reforms across Medi-Cal. We see many positive changes in the proposal. However, we do have concerns and recommendations, and would like to share them below for your review and consideration. Specifically, In the paragraphs below, we detail the following:

- DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.
- DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).
- DHCS must ensure the public has opportunity to review and comment on all policy changes.

We thank you for your continued work on this important initiative and look forward to working with the Department on CalAIM implementation.

Comments

1. ***DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.***

We are aware of the general concept around Medi-Cal RX and its intended purposes. However, in its current form we do not believe this change will do what its intended to do (i.e. save money to the State) without severely hurting the State's medical care delivery system, particularly Community Health Centers who disproportionately care for the low income and special needs of our State. We continue to press for the delay of this action and would strongly press for the elimination of this effort, or at least, significantly modify the effort to mitigate the serous collateral damage it will impose on the Safety Net. We have sent a more specific letter on this subject to you earlier today. That said, delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine already strained delivery systems and further confuse and worry Medi-Cal beneficiaries. To that end, we ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic. Recognizing the rapidly evolving pandemic response, as well as the current challenges and unknown resolution to conflict concerns with the project's contractor vender, we recommend the department delay the pharmacy transition and strongly recommend the removal of the transition from its waiver proposal for various serious issues as outlined in our letter from earlier today.

2. ***DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.***

The CalAIM proposal will ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which often can be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. For that reason, we applaud the Administration proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal that will ensure provider's ability to render necessary medical services to patients. However, questions remain as to how providers can comply with, and bill for, those services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan. Health centers often are the entry into the SMH/SUD system, yet few health centers are contracted providers with their county SMH/SUD health plans. This arrangement often leaves health centers in a financially disadvantaged position where they must provide needed services under federal law but cannot bill for those services. While we have an agreement with the County to provide some mental health services from our psychiatric team, clarity and support to allow us bill for services under Medi-Cal, taking into full account the cost of doing so, is strongly recommended. For that reason, we ask DHCS to provide clarification on how non-contracted providers can provide medically necessary services prior to an assessment.

3. ***DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.***

The Cal AIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although we recognize a statewide need to enhance access to both sets of services in a coordinated manner, we see several issues that need to be addressed in order to ensure that counties are prepared to adequately meet the demand for services and patients/families can be assured they are receiving the highest quality of care. Most notably, we are concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs are consolidated. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, 2017/18 External Quality Review Organization (EQRO) reported that several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care. Thus, while Shasta Community Health Center agrees that the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure access to timely and quality SMH/SUD services.

4. ***DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).***

Shasta Community Health Center is very pleased to see the inclusion of Enhanced Care Management and In-lieu-of Services in the Cal AIM proposal as well as the Administration's commitment to ensure adequate funding is allocated for these services in this year's budget. However, to ensure successful implementation of these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to work together. Additionally, such services should be paid according to reasonable costs of providing such services if these efforts are truly going to pay off in both helping patients in need and saving the State resources in the longer run. That said, we are encouraged by the inclusion of the Providing Access and Transforming Health Supports, which is necessary to transition existing services and build up capacity, including payments for new staffing and infrastructure. Supports are also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care.

We are concerned with several program elements that might impact their current operation and infrastructure, namely implementation of a new care management system and process, new care referral process or new claim submission process, new patient assignment process and other. Yet more is needed. Therefore, we respectfully ask DHCS to ensure ample resources and support available to ECM and ILOS providers.

5. ***DHCS must ensure the public has opportunity to review and comment on many policy changes that are described in the waivers but are not included as part of the waiver proposal.***

While we appreciate the opportunities to comment on the 1115 and 1915(b) waivers and expect DHCS will release other policy changes for public comment in the future, we would like to underscore the importance of gathering and incorporating stakeholder input into final policies. Specifically, we request extensive public comment and engagement on the following items noted in the proposal:

- A standardized screening tool for county Behavioral Health plans and Medi-Cal managed care plans to use to guide beneficiaries toward the delivery system that is most likely to meet their needs.
- A standardized transition tool for MHPs and MCPs to use when a beneficiary's condition changes and they would be better served in the other delivery system.
- A process for facilitated referral and linkage from county correctional institution release to county specialty mental health, Drug Medi-Cal, DMC-ODS, and Medi-Cal MCPS when the inmate was receiving behavioral health services while incarcerated, to allow for continuation of behavioral health treatment in the community.

****

As providers continue to support the Administration in COVID-19 vaccination effort, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operation.

Again, Shasta Community Health appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Dean Germano, dgermano@shastahealth.org; (530) 246-5704.

Planned Parenthood
Act. No matter what.
Planned Parenthood Affiliates of California

May 6, 2021

Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95814

Submitted Electronically to CalAIMWaiver@dhcs.ca.gov

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Director Lightbourne:

Planned Parenthood Affiliates of California (PPAC), writes on behalf of the seven separately incorporated Planned Parenthood affiliates in California, to provide input on the Department of Health Care Services (DHCS) proposed Section 1115 Demonstration and 1915(b) Waiver Applications, which implement key provisions of the California Advancing & Innovating Medi-Cal (CalAIM) initiative. California's Planned Parenthood affiliates collectively operate over 100 health centers statewide and nearly 85% of the patients they serve are enrolled in Medi-Cal or limited scope Medi-Cal programs, such as the Family Planning, Access, Care, and Treatment (Family PACT) program. In 2020, Planned Parenthood health centers provided over 1 million visits to patients enrolled in Medi-Cal and Family PACT.

As safety net providers serving vulnerable patient populations, PPAC supports DHCS's efforts to reduce complexity for Medi-Cal enrollees accessing care, improve health outcomes, and reduce health disparities by implementing whole person care approaches and delivery system modernization. PPAC supports many of the initiatives outlined in the proposed waivers and believes they will provide an opportunity to expand the work many Planned Parenthood health centers are already engaged in. However, we also have concerns that as DHCS focuses on care integration for those populations enrolled in managed care, that care for the large proportion of health center patients who are not eligible for that delivery model will become increasingly fragmented. Accordingly, PPAC looks forward to working in partnership with DHCS to ensure that as the CalAIM initiative is implemented, the cost effective, integrated, and culturally responsive health care services that Planned Parenthood health centers provide, as well as their longstanding relationships with community-based organizations, are leveraged in a way that reduces health inequities and improves health outcomes.

Planned Parenthood Health Centers and the CalAIM Framework

As one of the state's largest providers of sexual and reproductive health care services, Planned Parenthood serves a population that disproportionately face barriers to health care, including a significant

number of foster and former foster youth, transgender individuals, individuals experiencing intimate partner violence, individuals with behavioral health conditions, individuals with substance use disorders, justice-involved individuals, and individuals experiencing homelessness. Accordingly, PPAC supports DHCS's proposal to provide Medi-Cal services to eligible justice-involved populations 30 days prior to release from incarceration and believes that this effort to link these patients to care early will result in better health outcomes. PPAC also supports DHCS's proposals to continue Medi-Cal eligibility for former foster youth as well as for pregnant individuals with incomes between 109% and 138% of the Federal Poverty Level.

While many of the services Planned Parenthood health centers provide are related to sexual and reproductive health care, for many patients, these health centers serve as their primary source of health care. To address patients' clinical and social needs, Planned Parenthood affiliates have implemented programs to provide exactly the kind of integrated, whole person care the proposed CalAIM waivers seek to support:

- Behavioral Health Services. To better address the needs of their patient population, several Planned Parenthood affiliates have either begun providing or are planning to provide behavioral health services at their health centers. These affiliates cite challenges with care coordination, fragmentation of care related to the existing "carve-out" for Medi-Cal managed care patients, ineffective reimbursement structures, and communication challenges between providers as barriers to implementing behavioral health services at their health centers. Accordingly, PPAC supports DHCS's proposals to carve-in behavioral health services to Medi-Cal managed care plan responsibility, to reform behavioral health services reimbursement, to expand access to substance use disorder services, and to increase oversight of how these services are delivered.

- Enhanced Care Management. Given that many Californians use Planned Parenthood health centers as their primary provider of health care services, California affiliates have long provided services like those envisioned by DHCS in the CalAIM waiver proposals to better address their patients' needs. These services include patient navigation support, care coordination, management of referrals, and health education programs. PPAC supports DHCS's efforts to incentivize provision of these services by making them reimbursable within managed care. We ask DHCS to recognize that family planning and other safety net providers, like Planned Parenthood, serve as a provider of primary care services for many patients and urge DHCS to implement the Enhanced Care Management and In Lieu of Services components of the proposal in a way that allows health centers to continue and expand the provision of these services.

- Population Health. With over 100 health centers statewide, including the nation's largest Planned Parenthood affiliate, Planned Parenthood's California affiliates have considerable expertise in data-driven population health management and, for example, have partnered with academic experts and the California Department of Public Health to measure, address, and improve disparities in rates of sexually transmitted infections in patient populations. This expertise has allowed them to continuously improve the services they provide, and as a result, to improve health outcomes for their patients. PPAC is encouraged by DHCS's proposal to implement an overall population health management strategy as part of the CalAIM initiative. We urge DHCS, as it designs and implements this overall strategy, to ensure safety net providers like the Planned Parenthood health centers, which have extensive experience in population health management, will be considered as key partners in this effort.

Fee-For-Service and Family PACT Patients

Statewide, nearly 85% of the patients Planned Parenthood's health centers serve are enrolled in either the Medi-Cal or the Family Planning, Access, Care, and Treatment (Family PACT) program. Of this group, nearly half are enrolled in the Family PACT program while nearly 10 percent access Medi-Cal on a fee-for-service basis. In 2020, Planned Parenthood health centers provided nearly 575,000 patient visits to Medi-Cal or Family PACT enrollees outside the managed care delivery system. Planned Parenthood affiliates are also the largest cumulative provider of services to Family PACT patients. These patients, which include individuals that are undocumented and individuals seeking pregnancy-related services or services for treatment of a sexually transmitted infection, are some of the state's most vulnerable and most in need of support to improve their health outcomes. As DHCS advances the important work of care coordination and delivery of quality care for Medi-Cal beneficiaries through the proposed CalAIM 1115 and 1915(b) waivers, PPAC urges DHCS to ensure that those individuals who receive care outside of the Medi-Cal managed care delivery model are not further marginalized.

Planned Parenthood health centers serve as the primary health care provider for many patients who access Medi-Cal through the fee-for-service delivery model or who receive care through Family PACT. These health centers provide patient-centered, culturally responsive services that promote better care coordination and health outcomes such as patient navigation services, health education, data-driven population management, and behavioral health services to patients, regardless of how they access or pay for care. As a safety net provider, PPAC urges DHCS to take steps to support better care coordination and integration for Californians who will continue to receive care outside the managed care delivery model, especially given the ongoing need for access to same-day sensitive services. We look forward to working with DHCS to ensure that patients who encounter the greatest barriers to care, and the providers that treat them, are able to benefit from whole person care approaches.

_____

PPAC appreciates the opportunity to provide feedback on DHCS's proposed Section 1115 Demonstration and 1915(b) Waiver Applications to implement key provisions of the CalAIM initiative and is generally supportive of these proposals. We look forward to working in partnership with DHCS to ensure that all Californians receive high-quality, coordinated, culturally responsive heath care. Please contact Stacey Wittorff at stacey.wittorff@ppacca.org or Andrea San Miguel, PPAC's Policy Director, at andrea.sanmiguel@ppacca.org if you have any questions regarding PPAC's comments.

Sincerely,

Stacey Wittorff
Associate General Counsel
Planned Parenthood Affiliates of California

P O Box 228
29632 Highway 299E
Round Mountain, CA 96084
530.337.5750, phone
530.337.5754, fax
www.hillcountryclinic.org
Health Care for the Whole Community

May 5, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Hill Country Community Clinic (Hill Country) writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, Hill Country urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

Hill Country is a rural FQHC that cares for Medi-Cal and uninsured patients in Shasta County. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through fifteen contracted pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Hill Country to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, Hill Country annually saves an estimated $400,000 through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Hill Country to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care

system, Hill Country patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[2] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which Hill Country incorporates by reference into this letter. Hill Country fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, Hill Country urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Hill Country and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. Hill Country looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Lynn Dorroh
Chief Executive Officer

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

My name is Manooch Pouransari, Program Director at Grace ADHC, A CBAS Program. We appreciates the continued inclusion of Community Based Adult Services (CBAS) in the Section 1115 Demonstration Application and notes the expectation of increased enrollment into CBAS over the 5-year period as dual eligible beneficiaries are moved into MLTSS and aligned D-SNPs. We note that there is not enough capacity within the existing center-based structure of CBAS without expansion to underserved and unserved areas. This takes time and start-up funds. But using the lessons learned during the Public Health Emergency, we believe there are solutions to more quickly increase access to person-center care and these solutions, as outlined below, should be included in this next 5-year waiver period to demonstrate innovation and creative use of existing resources, consistent with the goals of the waiver.

We support the California Department of Aging proposal to use the renewal of the 1115 Waiver through CalAIM to modernize the Medi-Cal funded CBAS model, incorporating lessons learned during the Public Health Emergency and aligning those lessons with the goals of the Master Plan for Aging to improve access to Home and Community Based Services throughout the state. We believe that the flexibility granted through a demonstration and research model lends itself to such innovation. However, we would go further. In that spirit of improving access to community based care, we offer the following recommendations for consideration by DHCS.

1) Adopt TAS modalities as an Ongoing Feature: The Temporary Alternative Services (TAS) model has shown how to fully use the expertise and person-centered approach embedded within CBAS by empowering the CBAS MDT navigate outside of the four walls of the facility to “meet people where they are” in their home and community. This has deeply enriched the relationship between the center team and participants, and importantly, the unpaid caregiver and others providing support. CalAIM is an opportunity to demonstrate the durability of this PHE model that has enhanced the ability of the center teams to flexibly navigate within and outside of the center walls in a way that combines intensive care management with the unique benefit of center-based services delivered by an interdisciplinary team. This aligns perfectly with the Enhanced Care Management model envisioned in CalAIM as a separate billable service but could also be built into a “CBAS Plus” model with an enhanced rate.

2) Add Research Component for CBAS: There has already been published research on the benefits of an ADHC-based Community Based Health Home model designed as a pilot project unique to California. Further research has explored the impact of the COVID emergency on participants and families who lost full access to congregate services during the PHE. We would like to see a research component built into CalAIM specific to CBAS, building on existing literature and the national movement toward common outcome measures.

3) Define presumptive eligibility for CBAS to expedite access to needed care: We have learned through TAS that many people who are discharged from a hospital or nursing facility and could benefit from CBAS right away or may need continued recovery and care management prior to being able to attend the center for required services during a 4-hour service day. Individuals who are within 60 days of a nursing home or hospital stay and who meet medical necessity criteria should be presumptively eligible for enrollment in CBAS without delay. The current process for enrolling a person into Medi-Cal managed care (if they are Medi-Cal beneficiaries or dual eligible) and being approved by that Medi-Cal managed care organization (MCO) can stretch into many months. The extended time spent in the enrollment process is not in the best interest of the person or the Medi-Cal system, as these periods of transitions back into the community are critical, as proper care can help prevent re-admission to institutionalized or acute care. The current process has also been a problem during wildfire emergencies when delays in getting approval for CBAS enrollment has delayed lifesaving care and, in some cases, led to preventable

homelessness, nursing home placement or hospitalization. Case studies of these negative impacts of approval delays can be provided as examples.

4) Encourage Enhanced Care Management as a feature of CBAS and CBAS Plus: We would like to see active encouragement of MCOs to contract with CBAS providers for Enhanced Care Management now in order to meet the demand for services when dual eligibles transition to Medi-Cal Managed Care as well as the growing population Medi-Cal only beneficiaries. See also recommendation #1 for building a CBAS Plus model for efficiency.

5) Create a CBAS STCs & SOP Work Group: The ability of DHCS, CDA and the CBAS leadership to work together during the PHE toward a common goal of supporting access to services while ensuring safety of participants and caregivers was exemplary. We would like to offer the expertise of the Vision Team that was first mobilized during the PHE to continue to work with DHCS and CDA to modernize the STCs and SOPs for CBAS. There are obsolete provisions and fresh refinements based on the ten years of experience in managed care should be incorporated to continue to evolve the CBAS program.

6) Transition to State Plan: Federal policy is leading in the direction of prioritizing and expanding access to non-institutional settings in the community. We would like to see CBAS transitioned back to a State Plan Benefit by the end of the next 1115 Waiver demonstration period.

Regards,
Manooch Pouransari,
Program Director
Grace ADHC (CBAS)

Dear Angeli Lee and Amanda Font,

The attached document is AmeriHealth Caritas' comments for the CalAIM Section 1115 & 1915(b) Waivers. We appreciate the opportunity to provide feedback and recommendations to DHCS and would welcome an opportunity to further discuss any of our responses, or additional topics.

Please confirm receipt of this email and attachment.

Thank you,
Peter Jakuc

AmeriHealth Caritas
200 Stevens Drive
Philadelphia, PA 19113

May 5, 2021

SUBMITTED VIA EMAIL

Attn: Angeli Lee and Amanda Font
Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413
CalAIMWaiver@dhcs.ca.gov

RE: CalAIM Section 1115 & 1915(b) Waivers

To the California Department of Health Care Services:

The AmeriHealth Caritas Family of Companies (AmeriHealth Caritas) is pleased to provide comments to the draft CalAIM Section 1115 Demonstration Application and Section 1915(b) Waiver. These recommendations and observations are based on our more than 38 years of experience as a managed care organization supporting Medicaid populations. AmeriHealth Caritas currently serves more than 4.6 million members in 13 states and the District of Columbia through Medicaid, Medicare, behavioral health, long-term services and supports, and pharmacy benefit management contracts. We are pleased to share our experience in, and insights on, Medicaid programs to support California Department of Health Care Services' goal of enhancing the Medi-Cal program through the CalAIM Waiver.

Our mission is to help beneficiaries get care, stay well, and build healthy communities. Care is truly the heart of our work. We look forward to the opportunity to demonstrate this through further discussion of our capabilities. Please feel free to contact me or my colleague, Erin Colgan, with any additional questions or comments regarding this response. I can be reached at pjakuc@amerihealthcaritas.com or 314-488-4963, and Erin can be reached at ecolgan@amerihealthcaritas.com or 610-804-8948.

Sincerely,

[redacted]

Peter A. Jakuc
Senior Vice President & Chief Development Officer
AmeriHealth Caritas

Integrating and Streamlining the Medi-Cal Delivery Systems

The AmeriHealth Caritas Family of Companies (AmeriHealth Caritas) commends the California Department of Health Care Services (DHCS) on its commitment to improving outcomes for Medi-Cal beneficiaries through the continuous improvement of the Medi-Cal program. We believe that DHCS' proposed goals will move the State toward a more integrated and streamlined delivery system for beneficiaries, improve quality outcomes, reduce health disparities, and address social determinants of health.

Strong partnerships between counties and Managed Care Plans (MCPs) are key to ensuring quality, integrated care for beneficiaries. AmeriHealth Caritas firmly believes in caring for members in a holistic manner, meeting them where they are, and helping to ensure they get the care they need when they need it. This includes being a good partner to the State and county organizations — including county behavioral health plans and county-based organizations — and caring for California's Medi-Cal beneficiaries in order to break down silos of care for those beneficiaries, especially those in need of mental health and substance use disorder (SUD) services. To help achieve that goal, DHCS will need to delineate services and other beneficiary engagement responsibilities that may be duplicated between the MCPs and counties, such as care coordination through Enhanced Care Management. Ensuring guardrails are in place for those services will create a less confusing system for beneficiaries and improve partnerships among parties with a shared responsibility to provide care, and thus, ease access to care.

In addition to delineating services between MCPs and county organizations, the MCPs and county organizations must be able to share data and other information in a way that ensures that no matter who the beneficiary contacts first, they are able to get the answer they seek and access to the care they need. By sharing data regardless of which door the beneficiary enters, the entities involved in that beneficiary's care will receive updates and can follow up with the beneficiary. DHCS should also continue to actively engage stakeholders to help create innovative solutions to barriers that create health disparities.

Also, as the State continues to encourage the use of value-based initiatives (VBI), it should build in flexibilities for both the types of VBIs offered and the types of providers that VBIs are offered to. The flexibilities for MCPs must be balanced and include some standard guidelines to avoid overburdening providers. However, being overly prescriptive will create a disincentive and inhibit MCPs from innovating value-based models to the unique needs of beneficiaries, providers, and the populations being served.[1] **AmeriHealth Caritas is proud of its work in creating VBIs, designing VBI models that meet the providers where they are, and encouraging improved health outcomes in the communities we serve.**

Peer Support Services Pilot

AmeriHealth Caritas supports California's proposed Peer Support Services Pilot Program as described in both the **Section 1115 and 1915(b) Waivers.** Peer support specialists play a critical role in helping beneficiaries with mental health and SUD needs and are an important part of the continuum of care for these beneficiaries. Drawing from similar experiences as the beneficiaries they support, peer support

[1] https://www.macpac.gov/wp-content/uploads/2020/03/Final-Report-on-State-Strategies-to-Promote-Value-Based-Payment-through-Medicaid-Mananged-Care-Final-Report.pdf

specialists are able to build a rapport with beneficiaries that instills hope that their recovery can lead to better health and life outcomes.[2]

We also commend DHCS for conducting listening sessions on peer supports during the pilot development process; we encourage DHCS to continue engaging stakeholders across California as it moves forward toward implementing the pilot.

We understand that the pilot will be run by counties that volunteer to participate, and applaud this as a significant step in moving toward a statewide program. A strong partnership between participating counties and MCPs will be critical to achieving quality outcomes for Medi-Cal beneficiaries and ensuring a successful pilot. As the State continues to develop the continuum of care for beneficiaries with mental health and SUD needs in the future, it should consider implementing this service statewide.

Guidelines for peer specialists who relapse should also be considered as DHCS continues to develop and implement the pilot, as mentioned during the listening sessions. One of the strengths of peer support specialists is that they are in recovery themselves and therefore share similar experiences with those for whom they are providing care. To allow peer support specialists to make a career of being a specialist, the State should ensure they receive a living wage and are able to access services and supports for their own recovery. In the event of a relapse, there should be a clear route to return to providing services that protects both the peer support specialist and the beneficiary they were treating, and that allows the specialist to resume and continue building their career.

Dental Services

AmeriHealth Caritas supports the inclusion of a Caries Risk Assessment Bundle and silver diamine fluoride for children and certain adults with special health care needs under CalAIM. Good oral health is key to an individual's overall health. Individuals who do not have sufficient access to preventive dental services have greater rates of oral disease. A Government Accountability Office report highlighted that accessing dental care is especially difficult for low-income children. While access has improved in recent years, it is known that children in public programs, such as Medicaid and Children's Health Insurance Program, visit the dentist less often than children with private health coverage.[3]

We also support the expansion of pay-for-performance and other provider incentives that reward an increase in preventive dental services (prophylaxis, fluoride, and sealants) in conjunction with a decrease in preventable services, such as restorations and sedation. As DHCS moves forward with its dental quality initiatives, it should also consider incentives that promote increased utilization of services for special needs populations and that support the use of teledentistry services.

DHCS should also consider improving and ensuring data sharing between MCPs and the fee-for-service dental contractors and/or the dental MCPs. Data sharing, with the necessary protections in place for sharing sensitive health information and cooperation among parties involved in the beneficiary's care is an important element in effective care coordination, including appropriate referrals. This is especially true for MCPs that are accountable for arranging transportation to and from dental appointments for beneficiaries who need it.

Specialty Mental Health Services No Wrong Door Policy

COVID-19 has highlighted the importance of access to mental health and SUD services and has

[2] https://www.samhsa.gov/sites/default/files/programs_campaigns/brss_tacs/value-of-peers-2017.pdf

[3] https://www.healthypeople.gov/2020/topics-objectives/topic/oral-health#one

illuminated how barriers to care have led to health disparities and contributed to poor outcomes. AmeriHealth Caritas supports the ability to access behavioral health services through multiple systems without barriers. The ability to provide and connect beneficiaries to a broad range of mental health and SUD services will aid DHCS in making lasting progress toward addressing health disparities and improving health outcomes.

For a successful and seamless execution of this policy, DHCS must have a strong information system in place that allows for data exchange between payers and providers and that includes protocols that permit the sharing of sensitive data. When multiple programs and delivery systems exist, the various entities accountable for one person's care needs must be able to collaborate and share information as quickly and seamlessly as possible. Access to this necessary data helps to meet the needs of the beneficiary while avoiding duplication of services within systems.

As DHCS moves forward with this initiative, it should include a robust stakeholder process. Engaging stakeholders, including advocates, caregivers, beneficiaries, and county-based organizations, will give the State the ability to find and close gaps in the system more quickly. This in turn will aid in the long-term success of the program.

Justice-Involved 30 Day Pre-Release Services

AmeriHealth Caritas supports the ability to conduct in-reach and provide targeted services prior to release for individuals who are incarcerated. Studies have shown that in the two weeks after release from prison, individuals have 12.7 times the normal mortality rate, with overdoses driving much of the disparity.[4] Providing targeted services prior to release would allow MCPs to mitigate issues and set the beneficiaries up with necessary appointments and referrals to resources to provide the best possible chance for success, leading to reduced recidivism.

Continuity of care is critical for this population. As DHCS considers the operationalization of clinical consultation services and the Justice-Involved Pre-Release program as a whole, it should keep in mind the need for a warm transfer between the providers who care for the beneficiary pre- and post-release. The State should also have a system in place that includes a consent process that allows for information exchange between pre- and post-release providers, as well as the MCPs. Relevant information being exchanged from the pre-release care team to the specialty mental health provider and other providers caring for the beneficiary in the community is critical for the beneficiary to be successful, alongside communication and cooperation between MCPs and county behavioral health programs.

To also promote the success of the program, DHCS should leverage telehealth arrangements for meetings among beneficiaries, MCPs, and providers prior to release from incarceration. The MCP care manager can use telehealth to meet with the beneficiary to complete screenings and develop an individualized plan of care prior to release. Using telehealth also lessens administrative burden, making it easier to schedule meetings in a timely fashion.

As the State builds and implements this program, it should hold regular stakeholder meetings that include the Medi-Cal community, the Department of Corrections, and others to identify any barriers, gaps in the program, and best practices. Stakeholder engagement is critical to building long-term support for the program, helping to provide expertise and becoming program champions.[5]

[4] https://www.commonwealthfund.org/sites/default/files/2019-01/Guyer_state_strategies_justice_involved_Medicaid_ib.pdf

[5] https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/hcbs/medicaidmgmt/mm2.html

[redacted]

encompass
COMMUNITY SERVICES

CHANGING LIVES, BUILDING COMMUNITY SINCE 1973

May 5, 2021

[redacted]

5(b) Waivers

Services of Santa Cruz County, thank you for providing an
nts in response to the State of California Department of
of the CalAIM Initiative.

e largest human services agency in Santa Cruz County,
ncompass Community Services operates approximately 40
counseling for individuals, families, and youth; substance
nt treatment; reentry services; housing support; payee
Our agency served over 2,000 unique individuals in the

ngly supports the following proposed DMC-ODS

**e number of residential treatment episodes that can be
riod.** Our clients struggle more than they anticipate in
lapse is a common occurrence. Removing the limitation on
atment episodes acknowledges that recovery is not a linear
access treatment when they are ready to do so throughout
ation also allows clients the flexibility to attend to personal
ent. For example, one of our clients needed to abruptly
family emergency during the pandemic. The client was not
sing a treatment episode and their family; they were able
to their emergency and subsequently return to complete

**e that all DMC-ODS providers demonstrate they either
ve referral mechanisms for MAT.** Our internal MAT team

[redacted]

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[redacted]s from heroin to suboxone on a regular basis. This is a
[redacted]s rigorous medical oversight. Our MAT services allow
[redacted]atial treatment services without needing to wait for an
[redacted]nt bed, which is extremely limited in our county.

[redacted]pportunity for stakeholder input. Please do not hesitate to

[redacted]

[redacted]nt Analyst
[redacted]nt Department

[redacted]5060

[redacted]

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 6, 2021

Mark A. Ghaly
Secretary
Health and Human Services Agency
1600 Ninth Street, Room 460
Sacramento, CA 95814

Will Lightbourne
Director
Department of Health Care Services
P.O. Box 997413
Sacramento, CA 95899

Sent via email to: CalAIMWaiver@dhcs.ca.gov

Re: California Advancing and Innovating Medi-Cal (CalAIM) Proposal

Dear Secretary Ghaly and Director Lightbourne:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments on the *California Advancing and Innovating Medi-Cal (CalAIM) Proposal*. The comments and recommendations outlined below focus on opportunities for the Department of Health Care Services (DHCS) to leverage community pharmacies to advance the next phase of the Medi-Cal program as the imperative of DHCS continues to focus on further improving quality and outcomes for beneficiaries while managing costs. To realize the full value of pharmacy care services and program improvement, CalAIM should deploy community pharmacy care and correspondingly address operational barriers.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. In California, NACDS members operate more than 4,300 pharmacies that employ nearly 205,000 people. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Background. Pharmacists' accessibility can be particularly impactful in extending health care services in rural areas or for populations traditionally underserved. A study of high-risk Medicaid beneficiaries found that they visited pharmacies 35 times per year, compared to seeing their primary care doctors 4 times per year, and specialists 9 times per year.[1] Since the emergence of COVID-19 in the U.S., community pharmacies and their staff have served in critical roles as part of the pandemic response. Specifically, pharmacies have leveraged their accessibility and clinical expertise to help improve access to COVID-19 testing and vaccinations as a key pillar of the nation's COVID-19 pandemic response. For example, the Department of Health and Human Services (HHS) with the Centers for

[1] Moose J, Branham A. (2014). Pharmacists as Influencers of Patient Adherence. Pharmacy Times.

Disease Control and Prevention (CDC) developed the Federal Retail Pharmacy Program, which includes about 40,000 total pharmacies across the nation, to improve equitable access to COVID-19 vaccines.[2] Within the Federal Retail Pharmacy Program, at least 45 percent of sites were located in zip codes with high social vulnerability scores – a CDC index that uses 15 U.S. census variables to identify communities that may need support.[3] Additionally, when only 17,000 of the 40,000 pharmacies were activated, the program still provided over 5 million vaccinations in just four days.[4] In California, about 20% of COVID-19 vaccines in the state have been available through the Federal Retail Pharmacy program.[5] Pharmacies are also partnering directly with state and local public health departments to provide access to COVID-19 vaccinations.

Additionally, HHS in partnership with national pharmacy and retail chains launched the Community Based Testing Site program to expand COVID-19 testing across all 50 states, DC and Puerto Rico. Over 70 percent of the programs' testing sites are located in communities with moderate to high-social vulnerability—demonstrating the role these pharmacies can play in increasing access and reaching vulnerable communities. As of March 8th, more than 6,000 live testing sites were established under this public-private partnership with over 9.8 million samples processed. Leveraging pharmacies to provide such essential patient care services enhances patient choice, convenience, and access to quality care.

Further, pharmacists have advanced clinical training and are able to provide a broad range of services including preventive services (e.g., recommended immunizations and screenings), chronic disease management, medication optimization services (including reconciliation and drug therapy problem identification and resolution), and more. Given these factors, community pharmacies are particularly well-positioned to meaningfully contribute to efforts that improve population health as well as value-based initiatives that aim to improve quality of care and health outcomes, and to reduce costs.

NACDS shares DHCS's goals of providing whole-person care, reducing complexity for patients, and advancing value-based initiatives that improve outcomes and support transformations in payment and delivery. Significant opportunities exist to integrate pharmacists and pharmacy services into health care delivery system transformation efforts, given the broad range of preventive, chronic care management, and medication management services pharmacists provide to the patients they serve—which can be especially impactful for low-income, vulnerable patients. As such, community pharmacies are a strong partner in helping to drive California's broader health care transformation efforts as well as supporting specific initiatives outlined in the CalAIM proposal.

NACDS Recommendations. NACDS appreciates DHCS's effort to engage stakeholders on the CalAIM proposal and offers the following recommendations for how to leverage the value, expertise, and position of community pharmacycare to meet the state's goals for the next phase of the Medi-Cal program. NACDS' recommendations center on the potential for community pharmacies to support broad efforts to expand access to essential services, improve outcomes and reduce costs during the pandemic and beyond. NACDS recommendations include:

Community Pharmacy Should Be Further Leveraged to Support the CalAIM Initiative

1. To meaningfully improve access to care, expand the list of reimbursable pharmacy services to best take advantage of the clinical expertise and position of community pharmacists. Include all facets of evidence-based care delivered at California pharmacies within existing scope of practice, such as:
    - Point-of-care testing and screening (CLIA-waived tests) and initiation of treatment pursuant to the result of a CLIA-waived test
    - Chronic disease management

[2] https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html
[3] https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/
[4] https://www.politico.com/news/2021/03/29/covid-vaccine-sites-478233
[5] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/jurisdiction-portfolios.html

- Transitions of care interventions
- Medication adherence interventions
- Medication optimization such as drug therapy problem identification
- Substance use disorder treatment services such as Screening, Brief Intervention, and Referral to Treatment (SBIRT) and support of Medication-assisted treatment (MAT)
- Other behavioral health interventions including screening, support and linkage to care for depression and anxiety

2. Incentivize managed care plans to partner with community pharmacies to deliver patient-centered care, including preventive, chronic care management and medication optimization services, especially as part of managed care plans' population health management programs and under the proposed enhanced care management benefit
3. Promote policies that enable all providers—including pharmacists—to practice at the top of their licensure, which will help drive delivery of innovative, high-value, cost-effective healthcare that can improve the health and wellbeing of all Californians

Pharmacy Should be Integrated into Value-Based Care and Delivery Initiatives

4. Given the position of pharmacy to improve patient outcomes, experience and reduce costs, develop opportunities for pharmacies to participate directly in the QIP (Quality Incentive Program)
5. Ensure value-based initiatives include meaningful measures, including standardized pharmacy-level quality metrics
6. In the alternative to direct payment opportunities for pharmacy within QIP, require and incentivize participants in QIP to include community pharmacists as part of patient care teams, given community pharmacists' accessibility to patients and their ability to provide multiple interventions and patient-centered services. It also will ensure better care coordination across the continuum.
7. Create a standard contract or collaborative practice agreement that Medicaid managed care plans (MCOs) or providers could use to partner with community pharmacies to advance value-based initiatives

Clinical Pharmacy Care Services Should Not be Carved Out of Medicaid Managed Care

8. Clarify that the carve-out of dispensing prescription drugs based on the Governor's Executive Order in 2019 only applies to dispensing of prescription drugs and not pharmacy clinical care services. Carving out clinicalpharmacy services creates misaligned incentives for managed care plans to promote the uptake of pharmacy care services to improve health.

We appreciate the opportunity to offer comments on the state's proposal and hope to continue to support DHCS as it works to refine and implement the initiatives included in the CalAIM proposal.

I. Community Pharmacy Can Help Drive CalAIM Goals of Managing Population Health, Improving Outcomes/Quality and Controlling Spending

Pharmacists are among the most accessible health care providers, providing a broad range of services including preventive health and chronic disease management, and medication optimization services. More recently, pharmacies stepped up during the COVID-19 pandemic, enhancing access and offering patients additional healthcare destinations throughout surrounding communities. Pharmacies were open when some other providers of care were harder to access. Research has shown a positive impact on pharmacists' ability to improve outcomes and quality, while reducing costs.[6,7] Their close proximity to the vast majority of American homes allows community pharmacies to deliver care that is readily accessible and to support patients with a wide range of health care needs—which is particularly important in servingthe Medicaid population as it has diverse and unique health care

[6] NACDS Economics Department. (2017).

[7] Manolakis PG, Skelton JB. (2010). Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Provider. Am J Pharm Educ.

needs and can face a variety of barriers to accessing care. Furthermore, in addition to proximity and convenience of pharmacies, pharmacists are capable of addressing observed social determinants of health within the surrounding community such as transportation affecting access to care and health literacy rates impacting patients' ability to comprehend the care they receive.

Supporting Population Health and Enhanced Care Management. Community pharmacies are well-positioned to support implementation of newly outlined requirements for managed care plans related to population health and enhanced care management. The state proposes to require MCOs to implement a patient-centered population health management strategy to address member needs across the care continuum—including preventive and wellness services, screenings for high-risk patients, support during care transitions and promotion of health equity. As outlined, community pharmacies can support and provide services that MCOs would be required to include in these strategies such as preventive care, screenings, and medication optimization and adherence services to support patients with chronic conditions or those undergoing care transitions. Community pharmacies are also well placed to serve as part of provider teams delivering care as proposed under the statewide enhanced care management benefit—which would entail a collaborative approach to providing comprehensive care management services to designated beneficiaries, including high-utilizers and certain individuals with behavioral health needs.

Evidence for expanded list of services. NACDS appreciates the opportunity for pharmacists to provide a subset of clinical services to Medicaid beneficiaries. Further, we would encourage the state to expand this list for more broad, comprehensive access to care delivery for patients. As noted above, pharmacy services include not only dispensing of medication, but also a variety of essential care such as immunizations, point of care testing (e.g., COVID, flu, strep throat, cholesterol, blood pressure, Hemoglobin A1c), the initiation of therapy pursuant to a CLIA-waived test result, medication adherence interventions, patient education, risk assessment, screening for mental and behavior health, including opioid and substance misuse and abuse, acute care and treatment, and more. Research has shown that pharmacy-based services and programs can improve access, outcomes and reduce costs.[8,9,10,11] A subset of examples is included below.

Pharmacist Ability to Improve Care: Point-of-care testing and screening (CLIA-waived tests) and initiation of therapy pursuant to a result of a CLIA-waived test

- A review of research studies on the provision of services recommended by the US Preventive Services Task Force identified examples of community pharmacists' provision of clinical preventive services such as screening, education, and recommendations to patients (e.g., education around folic acid supplementation among pregnant women, tobacco use cessation among smokers), chronic and infectious disease screening, and referrals to other providers for follow-up testing and care (e.g., screening for osteoporosis or HIV), further demonstrating the vast range of services pharmacists can provide.[12]

[8]Bartsch, S., Taitel, M., DePasse., et al. (2018). Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine,36(46), 7054–7063. doi: 10.1016/j.vaccine.2018.09.040.
[9] Spence, M., Makarem, A., Reyes, S., et al. (2014). Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes AmongPatients with Diabetes and/or Coronary Artery Disease. Journal of Managed Care Pharmacy 2014 20:10, 1036-1045.
[10] Pringle JL, et al. (August 2014). The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs. Health Affairs.
[11] Bartsch SM et al. (2018). Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine.
[12] Kelling SE, Rondon-Begazo A, DiPietro Mager NA, Murphy BL, Bright DR. (December 2016). Provision of Clinical Preventive Services by Community Pharmacists.[Addendum appears in Prev Chronic Dis 2016;13. http://www.cdc.gov/pcd/issues/2016/16_0232e.htm.] Prev Chronic Dis 2016;13:160232.

- One study evaluated the cost-effectiveness of community pharmacist-provided diagnosis and treatment of pharyngitis caused by group A streptococcus (GAS) as compared with the standard of care and found that pharmacists provided the most cost-effective treatment.[13]
- A literature review showed that community pharmacy conducted and analyzed point-of-care tests had satisfactory analytical quality. This review further supports that community pharmacies are well-positioned to deliver a wide range of point-of-care tests and will allow for patients to have increased access to various screenings.[14]
- 18 states currently allow pharmacists to conduct test and initiation of treatment services for illnesses such as flu and strep.
- A 2018 study determined that from a sample of over a half a million antibiotic prescriptions, approximately 46% were prescribed without an infection-related diagnosis.[15] Through test and treat services, pharmacists will be able to conduct the test, receive the result, and prescribe the necessary and appropriate treatment.

Pharmacist Ability to Improve Care: Chronic Disease Management

- A review by the Department of Veterans Affairs of over 60 research studies found that patients receiving chronic care management from a pharmacist had a higher likelihood of meeting blood pressure, cholesterol and blood glucose goals, compared to those receiving usual care.[16,17]
- A review of 22 studies analyzing community pharmacist-led interventions showed that these services improve patients' adherence and contribute to improved blood pressure control, cholesterol management, and chronic obstructive pulmonary disease and asthma control.[18]
- A retrospective study assessed clinical outcomes in patients with diabetes, with and without management by a pharmacist. The pharmacy intervention group had statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment. In this study, 40% of patients in the pharmacist intervention group achieved all 3 clinical goals after intervention, compared with only 12% of patients in the usual care group.[19]

Pharmacist Ability to Improve Care: Transitions of Care Interventions

- A meta-analysis of 32 articles focused on pharmacy-supported transitions of care programs found that, compared to usual care, these programs resulted in a significant 32% reduction in the odds of readmission.[20]
- A community pharmacy-based transitions of care program demonstrated that patients' risk of readmission can be decreased by 28% and 31.9% at 30 and 180 days, respectively, when pharmacists are added to usual care. In this program, pharmacist interventions focused on patient education, resolving medication-related problems, and facilitating access to post-discharge appointments and medications.[21]

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[13] Klepser D, Bisanz SE, Klepser ME. Cost-effectiveness of pharmacist-provided treatment of adult pharyngitis. The American Journal of Managed Care. April 2012.https://europepmc.org/abstract/med/22554040

[14] Buss V.H., Naunton M. Analytical quality and effectiveness of point of care testing in community pharmacies: A systematic literature review. Res. Soc. Adm. Pharm.2019;15:483–495. doi: 10.1016/j.sapharm.2018.07.013.

[22] SB 159.

[15] Linder JA, Brown T, Lee Jy, et al. Non-Visit-Based and Non-Infection-Related Ambulatory Antibiotic Prescribing. Oral Abstract Session: ID Week. October 2018.https://idsa.confex.com/idsa/2018/webprogram/Paper71530.html

[16] Carmichael, J. et al. (October 2016). Healthcare metrics: Where do pharmacists add value? Am J Health-Syst Pharm. 2016; 73: 1537-47.

[17] Greer N, Bolduc J, Geurkink E et al. (April 26 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared withusual care. Ann Intern Med. Epub ahead of print.

[18] Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: asystematic review. International Journal of Pharmacy Practice. 2018; 26(5).

[19] Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal
Attainment in a Patient-Centered Medical Home. JMCP. 2018;24(5):423-429.

[20] Rodrigues, C.R., Harrington, A.R., Murdock, N. et al. Effect of pharmacy-supported transition-of-care interventions on 30-day readmissions: a systematic review andmeta-analysis. Ann Pharmacother. 2017; 51: 866–889

[21] Ni W., Colayco D., Hasimoto J., Komoto K., Gowda C., Wearda B., McCombs J. Impact of a pharmacy-based transitional care program on hospital readmissions.Am. J. Manag. Care. 2017;23:170–176.

- A budget impact analysis of a pharmacist-provided transition of care program predicts a potential cost savings of $25 million to a managed Medicaid plan over a period of 2 years, corresponding to over $4 per member per month.[22]

Pharmacist Ability to Improve Care: Medication Adherence Interventions

- CMS's 2018 National Impact Assessment Report determined that Medicare Advantage (MA) plans and prescription drug plans (PDPs) that focused on improving adherence for select medications to treat cholesterol, hypertension and diabetes saw an estimated $4.2 to $26.9 billion in avoided costs between 2011 and 2015.[23]
- A study assessing pharmacy-based medication synchronization programs for Medicaid FFS beneficiaries with certain conditions (e.g., hypertension, hyperlipidemia, and diabetes) found improved adherence to cardiovascular medications, cardiovascular clinical outcomes and significantly lower rates of hospitalization and emergency department visits, compared to a control group.[24]
- An evaluation of the Pennsylvania Project—a pharmacy-based medication adherence program that operates across almost 300 pharmacies—found a statistically significant improvement in adherence across five classes of medications examined and an estimated $241 in annual savings per patient from improved adherence to oral diabetes medications and $341 from improved adherence to statin medications.[25]

Pharmacist Ability to Improve Care: Medication Optimization

- A recent analysis of literature focused on health care system waste estimated that up to $21.9 billion could be saved within the US healthcare system by optimizing medication use.[26]
- The University of Southern California and AltaMed received a CMMI grant to fund a collaborative program that aimed to optimize patient health, reduce avoidable hospitalizations and emergency visits by integrating pharmacists into safety-net clinics in Southern California. This collaborative program resulted in reduced rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in elevated LDL with 14% more patients controlled, and improvements in blood pressure with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians only). The program resulted in a 33% reduction in readmissions per patient per year, primarily attributed to medications estimated at 6 months. Through this project, pharmacists identified 67,169 medication-related problem in 5,775 patients. The top actions made by pharmacists to resolve these problems included: 14,981 dose change/drug interval, 5,554 medications added, 4,230 tests ordered, 3,847 medications discontinued, and 2,665 medication substituted.[27]

Pharmacist Ability to Improve Care: Substance use disorder treatment services such as Screening, Brief Intervention, and Referral to Treatment (SBIRT) and support of Medication-assisted treatment (MAT)

- The urgency and widespread nature of the opioid epidemic requires innovative solutions, leveraging the

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[22] Ni W, Colayco D, Hashimoto J, et al. Budget impact analysis of a pharmacist-provided transition of care program. J Manag Care Spec Pharm. 2018;24(2):90-96.

[23] CMS. (February 28, 2018). National Impact Assessment of the Centers for Medicare & Medicaid Servi)ces (CMS) Quality Measures Report.

[24] Krumme A. Glynn, R., Schneeweiss, S. et al. (2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use.Health Affairs 37(1)125-133.

[25] Pringle JL, et al. (2013). The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs. Health Affairs, 33(8),1444-1452.

[26] Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. Published online October 07,2019322(15):1501–1509. doi:10.1001/jama.2019.13978

[27] Chen SW, Hochman M, Olayiwola JN, Rubin A. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations May 2015. https://www.careinnovations.org/wp-content/uploads/2017/10/USC.CEPC_.pharm_webinar_FinalV.pdf

Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf ;

expertise and access of the entire healthcare continuum, especially those on the frontlines of care, including community pharmacists. Community pharmacies can support CalAIM proposals related to expanding Substance Use Disorder (SUD) services. Pharmacists are the face of neighborhood health care and are a trusted health care provider that serves as a regular point ofcontact for patients, and their training positions them well to serve patients with SUD. Further, the COVID-19 pandemic has introduced tremendous new challenges for people battling opioid and substance use disorders including loss of access to in-person treatment and recovery support, isolation, gaps in medication treatment access, and elevated levels of stress. In fact, the CDC issued a warning in December, citing "a concerning acceleration of the increase in drug overdose deaths" that had resulted in "the largest number of drug overdoses for a 12-month period ever recorded" attributed likely to illicitly manufactured fentanyl.[28] Just as pharmacies have supported their communities on the frontlines of the COVID-19 pandemic, pharmacies have directly battled the opioid epidemic for years. In fact, pharmacist involvement in opioid use disorder care helps improve access and outcomes, while reducing the risk of relapse.[29,30] A recent article by Pringle, Aruru, and Cochran[31] noted that by allowing community pharmacists to be more involved in direct patient care, community pharmacists can help eliminate gaps and barriers in treatment and increase access to naloxone and medication assisted therapy (MAT) services as well as play a critical role in implementing strategies to help reduce population opioid use disorder risk. In addition, community pharmacies can provide screening and treatment for substance use disorder, such as Screening, Brief Intervention, and Referral to Treatment and support of medication assisted treatment. Further, pharmacists are already playing a role in delivering care to individuals with SUD—including education on safe opioid use, safe storage and disposal, alternative approaches to pain management, increasing access to naloxone, needle exchange programs, and opioid use disorder awarenessmanagement and prevention programs. DHCS should look to efforts in other states as it refines its proposals. For example:

- Pennsylvania, Virginia, and Ohio are currently implementing pharmacy-based SBIRT services and, in Virginia, pharmacist-provided SBIRT services are reimbursed by Medicaid.
- Rhode Island has implemented a pilot MAT initiative involving six pharmacies. As part of the pilot, patients receive an initial MAT prescription from a physician from a large addiction-treatment program and, once the physician determines a patient is stable on their medication, a pharmacist—working under a collaborative practice agreement—oversees the patient's care. Patients visit the pharmacy up to two times a week and meet privately with the pharmacists who takes steps to ensure medication adherence and counsel patients around recovery goals, struggles, and successes.
- Colorado enacted legislation in 2018 that allows pharmacists—working under a collaborative practice agreement—to administer injectable MAT for SUD and receive an enhanced dispensing fee under Medicaid for the administration.[32]
- Texas submitted a State Plan Amendment requesting to expand the pharmacy benefit to reimburse pharmacists for administering Vivitrol to Medicaid beneficiaries.[33]
- Further, as the state aims to support more counties in electing to cover additional MAT services that provide for ordering, prescribing, administering and monitoring of medications for SUD treatment, it should assess opportunities for community pharmacies to support expanded access. While offering additional MAT is an optional benefit that each county can elect to cover, the state is proposing to clarify that all SUD managed care providers offer or have a referral mechanism to MAT. Community pharmacies have the capability and expertise to support substance use disorder treatment for Medicaid patients and could partner with manage care plans to serve as a provider of MAT. Finally,

[28] https://emergency.cdc.gov/han/2020/pdf/CDC-HAN-00438.pdf

[29] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192, available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

[30] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321.

[31] Pringle JL, Aruru M, Cochran J, Role of pharmacists in the Opioid Use Disorder (OUD) crisis, *Research in Social & Administrative Pharmacy* (2018), doi: https://doi.org/10.1016/j.sapharm.2018.11.005.

[32] Colorado General Assembly. (2018). HB18-1007. Substance Use Disorder Payment and Coverage.

[33] Texas Health and Human Services Commission. (May 10 2019). Public Notice: Pharmacist Reimbursable Services.

community pharmacies could also potentially expand access to and support delivery of the state's proposed physician consultation services optional benefit, which aims to support consultation between physicians and addiction medicine physicians, addiction psychiatrists, or clinical pharmacists related to developing beneficiary treatment plans for SUD.

Pharmacist Ability to Improve Care: Behavioral Health Screening

- Pharmacies can also help to advance access to care for other behavioral health needs, such as screening for anxiety and depression with education and counseling and linkage to follow up care as needed. For example:
- A study included 3,726 patients screened for depression by pharmacists. Of the patients who completed the screening (PHQ-9), approximately 25% met the criteria for consideration of diagnosis and were referred to their physician. Five patients presented with suicidal thoughts and were referred for urgent treatment. Approximately 60% of patients with a positive PHQ-9 had initiated or modified treatment at the time of follow-up. The author concluded that a screening program for depression can be successfully developed and implemented in the community pharmacy setting. Using the PHQ, pharmacists were able to quickly identify undiagnosed patients with symptoms of depression. The majority of patients with a positive screening had initiated or modified treatment at the time of follow-up.[34]
- A separate study, conducted in Australia, examined the impact of community pharmacists performing screenings and risk assessments for depression and found that pharmacists were able to provide screening and risk assessment services and make referrals as needed – which could facilitate early intervention and reduce the overall burden of disease associated with depression.[35]

The proven and positive impact that community pharmacy care can have on health, outcomes and costs highlights the significant opportunity DHCS has to leverage community pharmacies to help advance its goals of improving population health and value under the proposed CalAIM initiative. NACDS believes there is great opportunity for DHCS to leverage the capabilities of community pharmacies and their position as a key access point for patients across communities as it advances comprehensive reforms that aim to deliver whole person care, reduce complexity, increase flexibility within the Medi-Cal program, improve quality and support delivery system transformation.

To Improve Care, NACDS Recommends CalAIM Better Deploy Pharmacy:

1. To meaningfully improve access to care, expand the list of reimbursable pharmacy services to best take advantage of the clinical expertise and position of community pharmacists. Include all facets of evidence-based care delivered at CA pharmacies within pharmacists existing scope of practice, such as:
    - Point-of-care testing and screening (CLIA-waived tests)
    - Chronic disease management
    - Transitions of care interventions
    - Medication adherence interventions
    - Medication optimization such as drug therapy problem identification
    - Substance use disorder treatment services such as Screening, Brief Intervention, and Referral to Treatment (SBIRT) and support of Medication-assisted treatment (MAT)
    - Other behavioral health interventions including screening, support and linkage to care for depression and anxiety
2. Incentivize managed care plans to partner with community pharmacies to deliver patient-centered care, including preventive, chronic care management and medication optimization services, especially as part of managed care plans' population health management programs and under the proposed enhanced care management benefit
3. Promote policies that enable all providers—including pharmacists—to practice at the top of their licensure,

[34] Rosser S, Frede S, Conrad WF, Heaton PC. Development, implementation, and evaluation of a pharmacist-conducted screening program for depression. J Am Pharm Assoc. 2013 Jan-Feb;53(1):22-9. doi: 10.1331/JAPhA.2013.11176. https://www.ncbi.nlm.nih.gov/pubmed/23636152

[35] O'Reilly CL, Wong E, Chen TF. A feasibility study of community pharmacists performing depression screening services. Res Social Adm Pharm. 2015 May-Jun;11(3):364-81. https://www.ncbi.nlm.nih.gov/pubmed/25438728

which will help drive delivery of innovative, high-value, cost-effective healthcare that can improve the health and wellbeing of all Californians.

II. Community Pharmacies Can Drive Improved Outcomes, Quality and Controlled Costs Under Value-Based Initiatives

Considering the growing evidence that pharmacists can provide services that improve outcomes and quality, while controlling costs across the care continuum, NACDS believes there is important potential for integration of pharmacists and pharmacy services into value-based models. Doing so could help strengthen delivery of patient-centered care, improve care coordination, and support provision of the right care in the most appropriate settings. Evidence on the impact of pharmacy care services as well as early findings from efforts by payers and states to integrate pharmacy services into value-based initiatives further point to the positive impact integrating pharmacy under the proposed Quality Incentive Program, behavioral health value-based initiatives—or other value-based initiatives not included in the current CalAIM proposal—could have on health outcomes, quality and costs.

For example, a number of payers and states are already implementing value-based payment and care delivery initiatives that integrate pharmacists and are seeing positive results. For example:

- **Inland Empire Health Plan's Pharmacy P4P Program**, which launched in 2013 and includes Medicaid managed care and Medicare Advantage enrollees, has included several phases aimed at improving member health and reducing costs. The medication safety component of the program entails pharmacies receiving a payment per prescription claim if they complete specific actions related to drug utilization review (DUR) alerts. Pharmacists may also be eligible for bonus payments. Participating pharmacies also receive bonus payments for meeting quality measures and for certain actions (e.g., sending text notifications to plan members). Under previous phases of the program, pharmacists significantly increased medication adherence rates and under the current DUR program, overridden DUR alerts are trending downwards.[36,37]
- **Community Care of North Carolina's Enhanced Pharmacy Services Network**, which was launched using funding from the Innovation Center, uses a collaborative care, medical home model to serve Medicaid, Medicare, dual eligible and low-income children and families. Pharmacists participating in the program receive a risk-adjusted per patient, per month payment for which they must deliver enhanced services and document interventions, as well as meet certain criteria. They have access to information including claim and adherence data, and population management tools. Pharmacies in the program verify patient needs before a prescription fill and provide patient counseling, adherence coaching and support medication reconciliation after a hospital discharge. Preliminary results indicate that high-risk Medicaid patients who receive care at a Community Pharmacy Enhanced Services Network (CPESN) pharmacy are 45 percent less likely to have an inpatient admission, 35 percent less likely to have a preventable admission or readmission, 20 percent more adherent to medications and 25 percent more likely to engage with their primary care provider.[38,39]
- **Wellmark BCBS' Value-Based Pharmacy Program** involves beneficiaries enrolled in Medicare, Medicaid and commercial coverage and targets patients with certain chronic conditions (e.g. asthma, diabetes, cardiovascular disease risk, and depression) to increase medication adherence, improve clinical markers including A1c and blood pressure, and over time lower ED visits, hospital readmission, and the cost of care. Participating pharmacies offer clinical services (e.g. immunization program, medication review, health screenings, medication synchronization programs) and are paid a prospective per member per month fee with the opportunity to receive a bonus payment based on shared savings. The pilot program was launched in July 2017 and included 62 pharmacies across 12 organizations, but was expanded in early 2018 to 74

[36] NACDS.(April 15 2018). Letter to Health Care Innovation Caucus.
[37] Pharmacy Today. (March 2016). As Pay For Performance Grows, Health Plans Work With Pharmacies.
[38] Community Pharmacy Enhanced Services Network. (2019). Pharmacist Spotlight: Charlie Barnes.
[39] NACDS. (August 15, 2018). Letter to the Health Care Innovation Caucus.

pharmacies across 16 organizations. The initial 3-year pilot phase ended in the summer of 2020.[40] The 3-year pilot wrapped up in June of 2020, and while the impact is still being evaluated, the Continuous Medication Monitoring (CoMM) pharmacy pilot—on whichthe Wellmark VBPP builds and which was designed to assess the effects of continuous medication monitoring on total costs of care, proportion of days covered rates and the use of high-risk medications by elderly patients—demonstrated lower total costs of care and meaningfully better medication adherence. Specifically, patients who received medications only from pharmacies offering the CoMM program had approximately $300 lower per member per month costs, compared to patients receiving medications from other pharmacies.[41] Additionally, broader evaluations from the first two years of the program show that pharmacists interventions reduced health care costs by $25 million.[42] Additional accounts of the pilot indicate a 4.6% reduction in per-member-per-month costs based on real-world outcomes relative to total cost of care (stabilizing at 3% post pilot). [43]

- **The Center for Medicare and Medicaid Innovation's Comprehensive End Stage Renal Disease (ESRD) Care** is an ACO model with shared savings and risk for dialysis providers who commit to improving care for Medicare beneficiaries with ESRD. An evaluation of the model found that ACOs participating in the model partnered with a range of outside providers, including pharmacists, and that all small- and medium-sized dialysis organization participants (i.e., chains with fewer than 200 dialysis facilities or independent or hospital-based facilities) leveraged pharmacists to support medication therapy management—further indicating that providers participating in value-based models are recognizing the value of integrating pharmacy.[44]

NACDS Recommendations to Better Leverage Pharmacy to Improve Care:
As DHCS develops value-based initiatives under the QIP as part of behavioral health reforms—or under additional programs—that aim to support hospitals and partnering providers in improving quality and outcomes, NACDS offers the following recommendations and considerations:

4. **Deploy community pharmacies in the QIP (Quality Incentive Program) given the tremendous opportunity for community pharmacy to improve patient outcomes, experience and reduce costs.** The greatest opportunity to leverage community pharmacy in value-based care to improve health for Medicaid beneficiaries within the state is to develop direct opportunities for pharmacy to participate in the QIP. Program incentives should be realigned because relying on health plans to share bonuses or incentive payments with pharmacies is unrealistic and it creates administrative burden and complexity. It is more effective and efficient to align financial incentives directly with clinical care delivery and incentives by developing direct payment opportunities for pharmacies within the goals and mission of QIP. Specifically, based on a myriad of evidence, pharmacists are well positioned to impact many of the existing QIP measures including controlling high blood pressure, blood glucose, immunization coverage, tobacco cessation interventions, reducing readmissions, depression screening, health and wellness screenings, medication reconciliation, and more. By incentivizing pharmacies to provide more of the care they are well positioned to provide, given the accessibility and clinical expertise of pharmacists, other care providers across the continuum can hone-in on metrics and interventions that they are uniquely qualified to provide. Efforts to meaningfully promote community pharmacy delivery of care services within QIP offers patients more convenient options for care and better leverages pharmacists to deliver on value and quality to remove burden and strain on other providers.
5. **Ensure value-based initiatives include meaningful measures, including standardized pharmacy-level quality metrics.** DHCS plans to partner with stakeholders to develop a metric set "that prioritizes CMS Adult

[40] https://pqa.memberclicks.net/assets/library/PQA_Quality_Forum_Webinar_2019-10-03.pdf
[41] Doucette, William R, et al.; "Pharmacy performance while providing continuous medication monitoring."; *Journal of the American Pharmacists Association*; Volume 57,Issue 6, 692-697. https://www.japha.org/article/S1544-3191(17)30788-4/fulltext
[42] https://www.pharmacytoday.org/article/S1042-0991(21)00011-6/fulltext
[43] https://www.amcp.org/Resource-Center/managed-care-practice-issues/evolving-models-support-expanding-role-pharmacist
[44] Lewin Group. (September2019). Comprehensive End Stage Renal Disease Care (CEC) Model Performance Year 2 Annual Evaluation Report.

and Child Core Set measures, HEDIS measures, increased capacity for primary and specialty care services and other nationally vetted and endorsed measures, or measures in wide use across Medicare and Medicaid quality initiatives," many of which are likely impacted by medication adherence, management and safety. Many existing value-based initiatives include pharmacy-level quality measures, further indicating that community pharmacies can meaningfully impact quality and outcomes under value-based models.

6. **In the alternative to direct payment opportunities for pharmacy within QIP, require and incentivize participants in QIP to include community pharmacists as part of patient care teams, given community pharmacists' accessibility to patients and their ability to provide multiple interventions and patient-centered services.** Leveraging the range of services community pharmacists provide such as preventive services (including immunizations and screenings), chronic care management, and medication optimization and adherence, for example, can improve patient experience and outcomes and help to control costs. Further, coordination between hospitals and community pharmacists post-discharge and during transitions of care can improve continuity of care (e.g., through medication screening during inpatient admissions followed by discharge consultation from pharmacists)—which could be especially impactful under the QIP.[45]
7. **To promote such partnerships, the state should create a standard contract or collaborative practice agreement that Medicaid managed care plans or providers could use to partner with pharmacies under specific value-based initiatives.** This would remove some of the administrative burden related to partnership between MCOs and community pharmacies so that each entity may focus their efforts on initiatives that drive value and improve care for patients.

III. Clinical Pharmacy Care Services Should Not be Carved Out of Medicaid Managed Care

Importantly, as the state prepares to execute on the Governor's Executive Order to carve the dispensing of prescription medications out of managed care, the state should ensure that pharmacy clinical care services are maintained under managed care to preserve incentives for clinical pharmacy care. It is clear the Executive Order is focused solely on carving out dispensing of prescription drugs; however, the Cal-AIM proposal makes reference to the term "pharmacy services" as being carved out. If this term encompasses clinical pharmacy care services, it would undermine the goals of managed care to improve outcomes and control costs through leverage of pharmacy (see page 57 of proposal for mention of "pharmacy services"). Carving out clinical pharmacy services creates misaligned incentives for managed care plans to promote the uptake of pharmacy care to improve health.

Pharmacy services certainly extend beyond dispensing of a drug and include clinical interventions such as immunizations, chronic disease management, medication optimization, screenings (e.g. point-of-care testing), and more, in addition to pharmacist services already covered under the Medi-Cal benefit which including furnishing naloxone, furnishing self-administered contraception, initiating and administering immunizations, furnishing nicotine replacement therapy, and furnishing travel medications.

The state should work with stakeholders to ensure changes in the management of drugs does not adversely impact access to community-based pharmacy care services for beneficiaries. It is imperative that carving dispensing of prescription drugs out of managed care does not result in barriers in access to clinical pharmacy care services or impediments to care coordination across providers and settings. Patients, especially those who are vulnerable, must be able to maintain access to medications and the providers most able to ensure optimal medication use and adherence, as this improves health and helps control spending on prescription drugs as well as the underlying medical conditions for which the drugs are prescribed.

[45] Ensing, H. T., Koster, E. S., Dubero, D. J., Dooren, A. A. V., & Bouvy, M. L. (2019). Collaboration between hospital and community pharmacists to address drug-related problems: The HomeCoMe-program. Research in Social and Administrative Pharmacy, 15(3), 267–278. doi: 10.1016/j.sapharm.2018.05.001

NACDS Recommendations:

8. Clarify that the carve out of dispensing prescription medication based on the Governor's Executive Order in 2019 only applies to the dispensing function of prescription drugs and not clinical pharmacy care services. Carving out clinical pharmacy services creates misaligned incentives for managed care plans to promote the uptake of pharmacy care to improve health.

Conclusion. NACDS strongly believes that community pharmacies can support DHCS as it works to improve the health care system and outcomes for Medi-Cal beneficiaries while also ensuring the long-term fiscal and programmatic sustainability of the Medi-Cal program. Given the demonstrated impact of pharmacy care on outcomes, quality and costs, as well as the role pharmacists play as a key health care access point, community pharmacies are well positioned to improve care and health under initiatives outlined in the CalAIM proposal.

We appreciate the opportunity to offer these comments and recommendations to DHCS and welcome the opportunity to continue the dialogue and support your efforts to improve health across the state.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer National Association of Chain Drug Stores

SAN FRANCISCO COMMUNITY HEALTH CENTER

May 4, 2021

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 Demonstration Application and 1915(b) Waiver Proposals

Dear Director Lightbourne:

San Francisco Community Health Center (SFCHC) writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of the CalAIM Demonstration Application and 1915(b) Waiver Proposals (collectively, "Cal-AIM"). To the extent CalAIM incorporates Medi-Cal Rx into its framework, SFCHC urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

San Francisco Community Health Center is an FQHC that cares for Medi-Cal and uninsured patients in the city and county of San Francisco. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through contracts with 49 pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows SFCHC to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, SFCHC annually incurs a significant savings through participation in Medi-Cal managed care and the 340B Drug Discount Program. This savings allows SFCHC to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability, enabling us to provide the wraparound support required to ensure we provide the most culturally tailored services for our homeless, marginally housed patients as well as our communities struggling with substance use and mental illness.

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SAN FRANCISCO COMMUNITY HEALTH CENTER

These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care system, SFCHC patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[2] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx. SFCHC incorporates by reference the CHCAPA public comment letter into this letter. SFCHC fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, San Francisco Community Health Clinic urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable SFCHC and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. SFCHC looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Lance Toma
CEO

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

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COUNTY OF SANTA CLARA
Health System

May 6, 2021

Jacey Cooper
Medicaid Director and Chief Deputy Director of Health Care Programs
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Jacey,

The County of Santa Clara Health System (Health System) offers the following comments focused on outcomes, parity and financing in response to the California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 and 1915 (b) Waiver documents released by the State of California's Department of Health Care Services (DHCS). As stated in our previous comments, our Health System is committed to the health and well-being of the communities we serve and hopes to strengthen our partnership with DHCS to better serve them. Maintaining the momentum of the Whole Person Care (WPC), Global Payment Program (GPP) and the synergies developed through the relationship with the counties/public health systems can be enhanced through some modifications to the CalAIM proposal before submission to the Centers for Medicare and Medicaid Services (CMS).

Outcomes
Our Health System shares the overall goals of DHCS to improve quality outcomes, reduce health disparities and drive care delivery transformation. CalAIM's proposals address these goals but I offer these comments to modify and clarify how we can safeguard gains made by public healthcare systems through the past waivers to meet and oftentimes exceed what managed care plans are currently required to deliver. With that in mind, DHCS would be well served by requiring greater transparency from managed care plans on historical data so that we all commonly understand baselines and expectations for progress, including methodologies for reporting care outcomes and how each managed care plan has improved over time. This would include capturing and reporting specific data to show racial/ethnic and health outcomes by populations of focus. Requiring plans to meet minimal standards is not sufficient, as many public healthcare systems were required to meet improvements year after year. DHCS should further explain how managed care plans will be required to show continual progress in improving health outcomes, especially for those communities/populations bearing the disproportionate burden of the past, which impact their health today and into the future.

Equity and Parity
The Health System supports the continuation of the Safety Net Care Pool funding for the GPP and the addition of the Equity Sub-Pool. GPP has proven a valuable component to the Medi-Cal 2020 Waiver to expand primary care and provide more timely access to care. The COVID-19 pandemic and its disproportionate impacts on specific populations have made the strongest compelling case to sustain and maintain these efforts with sufficient funding support.

The pandemic's disproportionate impact on some communities demonstrates the value/ criticality of focusing attention, as well as the need for data and outcomes, on specific populations. The Equity Sub-Pool offers the opportunity to bring focus to addressing specific needs. Having the same equity focus throughout the CalAIM 1115 and 1915 (b) components would move our State forward and make progress in addressing health disparities and social determinants of health – important goals advanced through WPC. Translating the WPC goals and work into CalAIM's outcomes is important; continuous work to improve outcomes is necessary. We encourage DHCS to include language and flexibilities allowing public health systems to address historical and current conditions for all populations and requiring managed care plans to directly contract with lead entities and public providers. When adding the recommendation for requiring year over year improvement in outcomes for all populations, the Equity Sub-Pool and extension of equity goals across all CalAIM programs and services, then improvement becomes part of the design and requirements for all Medi-Cal enrollees.

Alignment of the Waivers, services and populations covered are of critical importance to achieve parity in improving the health and well-being of the populations Medi-Cal serves. Allowing flexibility so that enhanced care management (ECM) and GPP services can be provided consistently and for all enrollees makes for good public policy and would help providers focus on designing the care plan each patient needs, rather than having to consider the specific Medi-Cal program the patient is covered by and modeling care plans and care coordination in pieces.

While parity is required in statute, the reality is that the fragmented managed care marketplace has led to poor coordination of care and navigational challenges for the mentally ill and substance abusing populations. Much more time and effort will be required to design and build a Medi-Cal system to provide the individual patient what they need and not allow managed care plans to risk stratify populations and care delivery networks to avoid responsibilities and expect counties and public healthcare providers to fill the gaps without the necessary funding. The full spectrum of medical and behavioral health services should be made available for enrollees and barriers to accessing such services should be eliminated. Universal screening requirements for a wide range of needs should be built into CalAIM, beyond those required today. The Health System encourages DHCS to consider requiring managed care plans to expend at least 95% of their payment (consistent with actuarially sound limits) on services and programs for target populations, to ensure funds are used to serve populations and not on administrative or unnecessary costs. This would be another step in helping make parity a reality in California.

Services for mild to moderate behavioral health needs and intensive services for the seriously mentally ill can be provided through county systems. Requiring plans to contract with county and public health systems would bring a wide spectrum of services to enrollees through an integrated provider system. This would also maintain continuity of care and ensure benefits are not taken away from those enrolled in Medi-Cal. This would maintain what exists and is proven to work and would maintain the infrastructure and investment that counties, health systems, county behavioral health, DHCS, and CMS have supported.

A final recommendation related to equity would be consideration of the American Rescue Plan's (ARP) option to extend the Medi-Cal eligibility period for pregnant women to 12 months postpartum. The ARP makes this option available for five years, which would cover the term of CalAIM. This coverage would benefit pregnant women beyond those with a mental health condition. Senate Bill 65, if approved, would extend Medi-Cal

eligibility beyond the current 60 days postpartum by an additional 10 months, provided federal approvals are obtained and direct DHCS to seek a state plan amendment the first quarter of 2022. Including provisions in CalAIM could have this work begin sooner.

Financing

The inclusion of Providing Access and Transforming Health (PATH) Supports in CalAIM is a welcome addition to help with capacity building and infrastructure. The design should be specific in supporting existing WPC lead entities and providers in maintaining the current level of services as the covered populations expand. A sufficient level of funding for ECM and In Lieu of Services is needed to ensure all enrollees, including the residually uninsured, are able to access services equitably.

Requiring plans to contract with WPC lead entities and providers, as well as county behavioral health, would ensure consistency for current WPC enrollees as the State transitions to CalAIM. It would also help ensure capacity and service levels are maintained. COVID-19 has proven the value of county health systems and the reliance DHCS has on its existence. Contract requirements including sufficient funding for the services provided are components to ensuring public healthcare systems can continue to play our critical role for the State and Californians. Additional work to better integrate behavioral health funding, reduce fragmentation, improve quality, and break down the silos is necessary to put the Medi-Cal enrollee at the center and align services around their needs. As the 1915 (b) components are refined, this work could further our collective goals to improve service, care and outcomes.

In closing, the County of Santa Clara Health System remains committed to improving the health and well-being of the communities we serve; a few modifications to the CalAIM proposal would assist us in maintaining the current, broad spectrum of services.

As stated before, the County of Santa Clara Health System is ready, willing and able to pilot the Full Integration Plan right out of the gate and could partner with DHCS on learning what modifications would be needed to enact more broadly. Starting with the Full Integration Plan, we could also pilot the integration of the mental health and substance use disorder services and funding to provide valuable learnings to enable a smoother transition as those payment reforms are enacted. Our County already provides housing, connections with justice involved individuals and skilled nursing facility services and intends on further investments going forward. To partner with DHCS now, we could collaboratively design senior housing, housing for those unhoused and behavioral health support services into expansion plans.

Healthy regards,

[redacted]

René G. Santiago
Deputy County Executive and Director, County of Santa Clara Health System

Thank you for the ability to give feedback about CalAim. I truly hope that CalAim will help reduce the administrative burden placed on various staff providing these wonderful services. So many people, who have such a heart for helping clients, are so discouraged by the paperwork and the fact that sometimes the slightest mistake can get all of these services disallowed. Most people in the field of Mental Health and Substance Use Disorder just want to help people. I do understand the necessary paperwork for billing purposes, outcomes, etc., however, my hope is that CalAIM can mainstream the services and paperwork and allow the clients to get the help they need.

Thank you,

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May 4, 2021

Department of Health Care Services Director's Office
Jacey Cooper, Medicaid Director
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Delivered via email to: CalAIMWaiver@dhcs.ca.gov

Re: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Cooper,

Thank you for the opportunity to provide comments on the Department of Health Care Services' vision for the future Medi-Cal delivery system. The comments contained herein are directed at the aspirational behavioral health service delivery aspects of the 1115 and 1915(b) waiver proposals.

We support California's vision to revitalize behavioral health care through a person-centered, recovery-based services approach that offers individuals with behavioral health care needs an avenue to wellness and quality of life. We value our relationship with the Newsom Administration and look forward to the implementation of this revitalization effort.

About Beacon Health Options

Beacon Health Options (Beacon) is one of the largest and oldest organizations in the United States focused exclusively on providing administrative support services to behavioral health systems. Beacon currently manages services for more than 13 million Medicaid beneficiaries in 20 states. This includes more than 3.5 million Californians with Medi-Cal.

Beacon has direct contracts with State and County governments through which we are responsible for organizing services ranging from acute crisis, acute inpatient, intensive wrap-around programs for adults and children, Peer-run community recovery programs and more outpatient psychiatric and therapeutic mental health and substance use disorder services. As an Administrative Service Organization (ASO) dedicated to behavioral health, Beacon combines the ability to meet twenty-first century Medicaid Managed Care organizational capabilities with deep knowledge of recovery-based, person-centered service modalities.

CalAim and the proposed investments by the Newsom Administration recognize the critical importance of behavioral health within the Medi-Cal Program and its benefit-cost positivity for all Californians.

Regional Contracting

CalAim recognizes potential administrative gains that can be achieved if Counties join together to deliver behavioral health services under the 1915(b) specialty mental health and 1115 Drug Medi-Cal Organized Delivery System waivers. Several counties could contract together with an ASO through a Joint Powers Authority (JPA) to achieve compliance with Federal requirements

for Medicaid Managed Care, such as data and technology capabilities, credentialing and network adequacy. Based on Beacon's prior experience contracting with multiple California counties to provide an outpatient network for foster youth placed outside the county of origin and our current experience contracting with four Counties for various administrative services, we offer the following suggestions.

1. **A single contract.** The joint contract should start with DHCS and the JPA, which could then subcontract with an ASO for specific delegated activities. This would create uniform expectations and reporting requirements across all the counties. This standardization is important to reduce administrative burden and expense.

2. **Standardized eligibility process.** DHCS should provide to the JPA a standard HIPPAA compliant eligibility file to the JPA, as it does with the Medi-Cal Managed Care Plans. This is an important step to define the cohort for population health management and for streamlining administrative processes and reporting. Without an up-to-date eligibility file, a unique member record must be created manually in an electronic data system for each individual accessing services, thus preventing automation and population-level demographic analysis that includes individuals who may not have accessed services.

3. **Uniform oversight process**. Multiple counties working together should be subject to one joint oversight process, including one DHCS audit and External Quality Review Organization (EQRO) process. An ASO would support them in these oversight activities.

4. **Streamlined provider contracting**. DHCS should encourage regional provider contracting versus individual county contracts. This would reduce provider administrative burden and help to expand access.

The California Medical Services Program (CMSP) is a relevant example for how many counties can work together with ASO support to deliver health services. The ASO contracts, credentials and trains providers, processes treatment authorization requests, pays claims and provides customer support on behalf of thirty-five counties.

SMI/SED demonstration waiver opportunity

The CalAim proposal indicates interest in pursuing the Federal SMI/SED Demonstration Waiver that would allow Medicaid reimbursement for individuals between ages 21 and 64 receiving short-term services within institutions for mental disease (IMDs). Beacon encourages DHCS to use the list of milestones required by this Waiver as a framework of consistent statewide parameters upon which to continue building toward a high performing community-based system. CMS sets a high bar for system readiness. Making progress toward the defined milestones will result in a better behavioral health system for all Californians.

The SMI/SED Demonstration Waiver has the following goals:

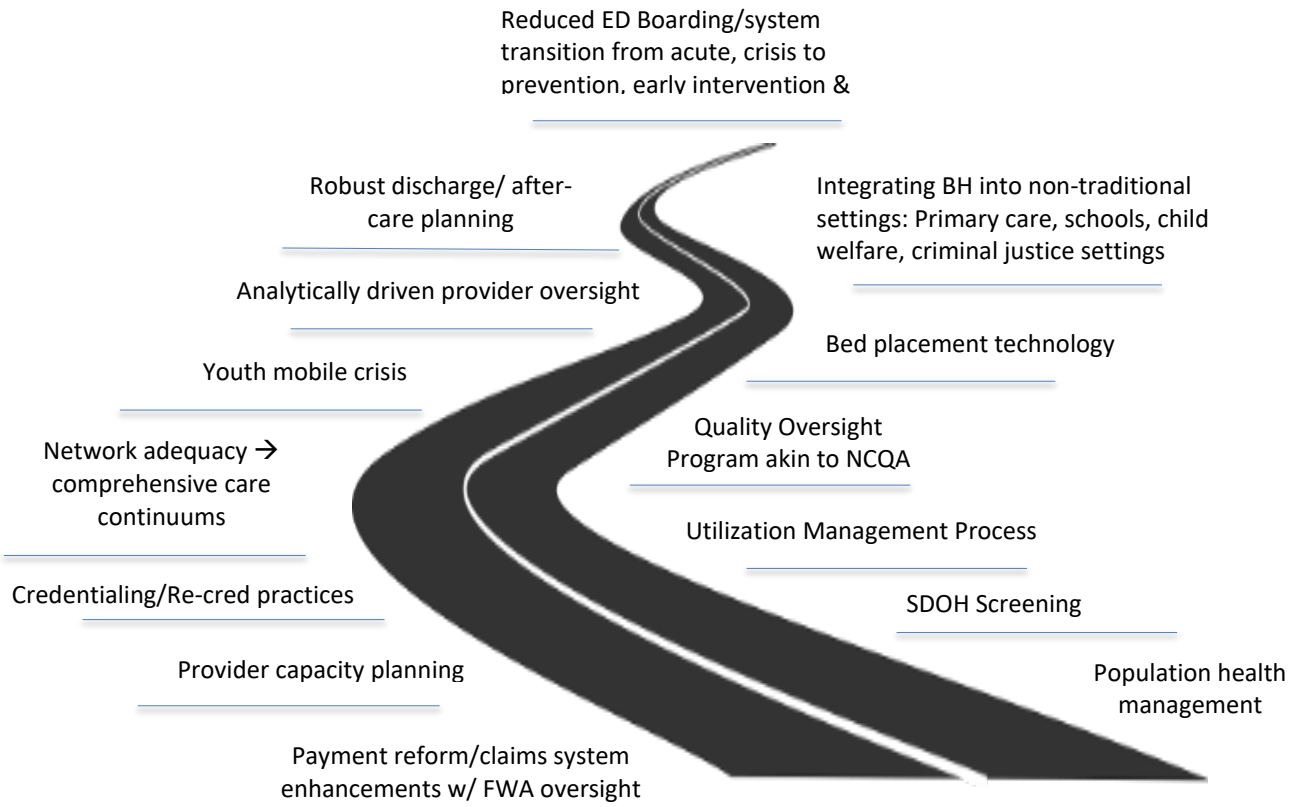
1. Reduced use and length of stay in emergency departments for individuals needing MH care;

2. Reduced preventable re-admissions to inpatient & residential treatment;

3. Improved availability of crisis services;

4. Improved access to community-based services for chronic conditions, including physical health and behavioral health integration; and
5. Improved care coordination, especially post-facility transition

Required Milestones for SMI/SED Demonstration Waiver Participation



California's Counties have been, and continue to be, the safety net for individuals who have experienced the most trauma and hardship, and who need the most support to achieve their fullest potential. For many counties, however, the challenges to operationalize the complex Medicaid Managed Care rules and obligations is incredibly challenging. The table below lists all the required milestones for this Demonstration Waiver. Next to each is an example of how an ASO, such as Beacon, can support counties in achieving the milestones. It is important to note that working with an ASO does not relinquish a county's role or authority to set the strategy and priorities for that particular county. The ASO is an additional tool or vehicle by which the county can achieve those goals.

Table 1: SMI/SED Demonstration Waiver Required Milestones

Milestone	Milestone Description	How an ASO can support achievement
1. UR Review	Use of a utilization review entity (e.g., a managed care organization or administrative service organization) to ensure beneficiaries have access to the appropriate levels and types of care and to provide oversight to ensure lengths of stay are limited to what is medically necessary and only those who have a clinical need to receive treatment in psychiatric hospitals and residential treatment settings are receiving treatment in those facilities.	Beacon is an ASO with decades of Medicaid utilization review experience in more than 20 different states. We focus on ensuring individuals get treatment in the least restrictive setting. Our broad experience brings best practices and context to each community's unique system of care. Providers should focus on providing clinical intervention and improving individual outcomes, not overburdened with utilization review processes. Our approach balances collecting core information to monitor and improve outcomes, analyze trends, and ensure program integrity. Our web portal gives providers a seamless and efficient experience, thus reducing the amount of time providers spend on the telephone and allowing them to focus on member care.
2. Level of Care Criteria	Implementation of a requirement that providers, plans, and utilization review entities use an evidence-based, publicly available patient assessment tool, preferably endorsed by a mental health provider association, e.g., LOCUS or CASII, xciv to help determine appropriate level of care and length of stay.	Authorization of services using evidence-based criteria leads to better member care. Beacon follows requirements from NCQA to use rigorous level of care placement tools for all medical necessity decision making. Beacon uses LOCUS and InterQual for the California market, depending on regulatory requirements.
3. Robust discharge planning and after-care coordination	Implementation of a process to ensure that psychiatric hospitals and residential treatment settings provide intensive pre-discharge, care coordination services to help transition beneficiaries out of these settings and into appropriate community-based outpatient services - as well as requirements that community-based providers participate in these transition	Beacon is experienced in working with facilities on after-care planning. We have an entire team dedicated to this function, sharing best practices across markets. We believe that discharge planning should start at the time of admission and incorporate that into our facility UR process.

Milestone	Milestone Description	How an ASO can support achievement
	efforts (e.g., by allowing initial services with a community-based provider while a beneficiary is still residing in these settings and/or by hiring peer support specialists to help beneficiaries make connections with available community-based providers, including, where applicable, plans for employment). Implementation of a requirement that psychiatric hospitals and residential treatment settings have protocols in place to ensure contact is made by the treatment setting with each discharged beneficiary within 72 hours of discharge and to ensure follow-up care is accessed by individuals after leaving those facilities by contacting the individuals directly and by contacting the community-based provider the person was referred to.	This team sets appointments for members, reminds members of their appointments and follows up with providers and members to ensure the appointment took place. If it was missed we identify barriers and work to overcome them. Effective network management also plays a role in after-care coordination. We execute contracts with providers to do home-based, follow-up care that supports individuals' successful recovery. We also hold providers accountable to performance standards in their contracts related to transition of care planning. We deliver providers a balanced score card that shows their performance compared to other providers with regards to how many of their patients need higher levels of care, 7-day follow up rates and readmission rates.
4. Joint Commission or CARF Accreditation	Participating hospitals and residential settings are licensed or otherwise authorized by the state to primarily provide treatment for mental illnesses and are accredited by a nationally recognized accreditation entity including the Joint Commission or the Commission on Accreditation of Rehabilitation Facilities (CARF) prior to receiving FFP for services provided to beneficiaries.	Beacon oversees accreditation processes and requirements as part of our standard credentialing processes.
5. Provider Capacity Planning	Annual assessments of the availability of mental health services throughout the state, particularly crisis stabilization services and updates on steps taken to increase availability.	Beacon is experienced at monitoring provider capacity, access and availability on an ongoing basis. We appreciate the differences between rural and urban areas with regards to available resources. Sample strategies to address capacity and timely access issues include: - Requiring providers to notify us when their program is not accepting new referrals.

Milestone	Milestone Description	How an ASO can support achievement
		- Working with providers to identify barriers and implement performance improvement initiatives. - Identifying additional levels of care and provider competency to expand capacity. - Requesting assistance from State and local NAMI chapters and other member/families/advocacy organizations to relay information related to waiting lists and delays. - Working with the regional mental health boards and community collaboratives to identify access-related issues. - Supporting peer-based programs to be successful.
6. Rigorous Credentialing and re-credentialing process	Participating psychiatric hospitals and residential treatment settings meet federal program integrity requirements, and the state has a process for conducting risk-based screening of all newly enrolling providers, as well as revalidating existing.	Beacon's credentialing procedures comply with NCQA standards. We have automated the process as much as possible through a collaboration with CAQH, a free web-based service that allows providers to upload their source materials in one place for all payers.
7. Supporting providers to address co-morbid physical health issues.	Implementation of a state requirement that participating psychiatric hospitals and residential treatment settings screen enrollees for co-morbid physical health conditions and SUDs and demonstrate the capacity to address co-morbid physical health conditions during short-term stays in these treatment settings (e.g., with on-site staff, telemedicine, and/or partnerships with local physical health providers).	Beacon's provider quality management team can work with facilities to develop checklists and protocols and then audit to ensure those protocols are followed. Further, in instances where Beacon contracts with the Medi-Cal managed care plan and has the medical and pharmacy data, we could run analytics that create a list of comorbidities based on historical claims data for all individuals admitted to inpatient psychiatric facilities and incorporate this into the UR review and discharge planning process. Beacon can contract with telehealth vendors or to provide screening for medical clearance or to address co-morbid physical health issues, thus

Milestone	Milestone Description	How an ASO can support achievement
		helping to avoid unnecessary visits to emergency rooms.
8. Integrating BH into non-traditional settings	Increasing integration of behavioral health care in non-specialty care settings, including schools and primary care practices, to improve identification of serious mental health conditions sooner and improve awareness of and linkages to specialty treatment providers.	An example of Beacon's experience at driving improvements of integrated care at the primary care level, is our practice transformation team in Colorado. Led by a primary care physician, the team works closely with large health facilities to apply Six Sigma strategies to improve BH integration and overall whole-person care. In California, Beacon is supporting one large Medi-Cal Managed Care Plan in implementing the Proposition 56 Behavioral Health Integration Innovation project. Our aim is to turn the work with providers into an informal learning collaborative, sharing best practices and building infrastructure necessary so providers can bill for integrated services via the Collaborative Care model. Beacon has experience reimbursing school-based services in California through our managed care plan partners. We are accustomed to coordinating with multiple community stakeholders to ensure the services match specific community needs and school cultures.
9. Finance	Commitment to a financing plan approved by CMS to be implemented by the end of the demonstration to increase availability of non-hospital, non-residential crisis stabilization services, including services made available through crisis call centers, mobile crisis units, coordinated community crisis response that involves law enforcement and other first responders, and observation/assessment centers as well as on-going community-based services, e.g., intensive outpatient services, assertive community treatment, services	With more than 30 years of experience paying claims for Medicaid-funded complex behavioral health services, Beacon is able to automate claims payment and funding for myriad funding streams and services. This enables us to run automated reports that reveal insights into utilization trends, provider performance and identify areas for focused intervention. We can build a claims processing hierarchy that reflects unique billing rules and maximizes all available funding via Medicaid, MHBG,

Milestone	Milestone Description	How an ASO can support achievement
	in integrated care settings such as the Certified Community Behavioral Health Clinic model described in Part I of this letter as well as consideration of a self-direction option for beneficiaries.	SAPG and state proviso funding, such as MHSA. Having more real-time data will support County-led strategies in rebalancing service costs away from inpatient and toward diversionary and outpatient services.
10. Fraud Waste and Abuse Oversight program	States must screen all newly enrolling providers and reevaluate existing providers pursuant to the rules in 42 CFR Part 455 Subparts B and E, ensure treatment providers have entered into Medicaid provider agreements pursuant to 42 CFR 431.107, and establish rigorous program integrity protocols to safeguard against fraudulent billing and other compliance issues.	Beacon has a FWA team and Special Investigation Unit (SIU) that monitors provider claims for fraud or potential inappropriate use. We use software that identifies potential issues and have established workflows for ensuring patient records substantiate billed services. We can move questionable providers to pre-payment review processes, thus avoiding the need, and often unsuccessful, method of post-service recovery.
11. Quality oversight process	Establishment of an oversight and auditing process that includes unannounced visits for ensuring participating psychiatric hospitals and residential treatment settings meet state licensure or certification requirements as well as a national accrediting entity's accreditation requirements.	Beacon operates a provider quality management program that varies across the country based on local market needs. Working with inpatient and residential settings to ensure contract compliance, including unannounced site visits, as well as collaboratively developing quality improvement targets are key features of this team's abilities. Depending on the regulatory requirements and expectations, Beacon can adjust our quality oversight process accordingly.
12. Research and evaluation	States will also be required to conduct independent and robust interim and final evaluations that will draw on the data collected for the milestones and performance measures, as well as other data and information needed to support the evaluation that will describe the effectiveness and impact of the	Beacon is capable of providing all data and reports needed to support a robust evaluation program, including monthly, quarterly and annual performance and utilization reports. Additionally, we have capability for client self-serving reporting whereby clients are able to extract data themselves to answer specific research questions or program needs.

Milestone	Milestone Description	How an ASO can support achievement
	demonstration using quantitative and qualitative outcomes and a cost analysis.	For some direct-to-state contracts, Beacon has experience partnering with academic institutions in designing and carrying out data analysis that provide important insights to state and county planners. In one state, for example, Beacon has a long-standing partnership with Yale University to analyze aspects of the publicly funded mental health and substance use disorder treatment systems.
13. Reducing ED Boarding: providing rapid access to psych consultations & peer support coordination programs	Implementation of strategies to prevent or decrease the lengths of stay in EDs among beneficiaries with SMI or SED (e.g., through the use of peers and psychiatric consultants in EDs to help with discharge and referral to treatment providers).	Transparency is a first, important step toward reducing ED boarding. In Washington State where Beacon manages the public crisis system in three regions, we monitor ED boarding and other indicators and publish a performance dashboard that is updated monthly to our website. This allows any community member to easily see how many individuals needed an inpatient bed but here not able to get one and for how long. It also shows the average time of response for the adult and youth crisis teams; what percent of responses occurred in the home or community versus ED or jail and the percent of callers into the crisis line that were diverted from needing more intensive services. Using this data, we work collaboratively with the community to set achievable, time-specific action goals to improve experience in the crisis system. This has included expanding youth mobile crisis, adding a crisis stabilization unit, ensuring availability of a sobering center and urgent outpatient service availability.

Milestone	Milestone Description	How an ASO can support achievement
14. Bed Tracking technology	Implementation of strategies to improve the state's capacity to track the availability of inpatient and crisis stabilization beds to help connect individuals in need with that level of care as soon as possible.	Beacon has extensive experience across the country using a variety of bed tracking and crisis dispatching technologies. We have developed strategic partnerships with what we believe is the best in class bed tracking and closed loop referral technology.
15. Interoperable data sharing	Implementation of strategies to develop and enhance interoperability and data sharing between physical, SUD, and mental health providers with the goal of enhancing care coordination so that disparate providers may better share clinical information to improve health outcomes for beneficiaries with SMI or SED.	Beacon can be an aggregator of data, including medical, pharmacy and behavioral health claims. Beacon can also participate in near real-time exchanges through application programming interfaces (APIs) with other company software or local health information exchanges to support care coordination.
16. SDOH Screening	Implementation of a process to assess the housing situation of individuals transitioning to the community from psychiatric hospitals and residential treatment settings and connect those who are homeless or have unsuitable or unstable housing with community providers that coordinate housing services where available.	Beacon has incorporated social driver of health screening into our care management workflows. We are able to track and report on the data collected and use that to guide treatment planning. Beacon also has a strategic relationship with Aunt Bertha, a referral library for SDOH resources, including food supports, housing and intimate partner violence needs.
17. Identifying rising risk	Implementation of strategies for identifying and engaging individuals, particularly adolescents and young adults, with serious mental health conditions, in treatment sooner including through supported employment and supported education programs.	Beacon has significant experience contracting for first episode psychosis programs around the country. We also can use claims data to identify youth with emerging needs using crisis services and ensure they are connected to ongoing treatment. Beacon is experienced at developing population health management profiles and interventions, as required by NCQA. For example, we are refining algorithms that help predict drivers of future behavioral health needs. One pilot

Milestone	Milestone Description	How an ASO can support achievement
		program takes an all-claims database and sorts individuals with co-morbid physical and behavioral health needs into four categories: 1) individuals with avoidable ED visits; 2) individual with preventable inpatient admissions; 2) high cost individuals; and 4) potential cost bloomers. Based on pharmacy and medical history, the software recommends specific interventions that are refined through knowledge gained about that individual's social drivers of health. We stand guarded to monitory any unintended biases in any algorithm that could perpetuate underlying disparities or inequities.
18. Evidence of availability of community-based services and alternatives to inpatient and residential services in each geographic region of the state (e.g., maps of provider availability and provider agreements).	Evidence of availability of community-based services and alternatives to inpatient and residential services in each geographic region of the state (e.g., maps of provider availability and provider agreements)	Beacon can produce GeoAccess maps that show compliance with State time and distance requirements. Furthermore, we are experienced at completing the DMHC's annual provider access and availability survey (PAAS) process.
19. ED use among Medicaid beneficiaries with SMI or SED and their lengths of stay in the ED;	ED use among Medicaid beneficiaries with SMI or SED and their lengths of stay in the ED.	Beacon is capable of doing data analysis from multiple claim sources. In many counties, Beacon has an existing contract with the Medicaid MCO. We can create reporting based on medical, behavioral and pharmacy claims to present a full 360-degree view of members' experience, including ED utilization and length of stay. In some markets we are accustomed to working with crisis teams on tracking ED

Milestone	Milestone Description	How an ASO can support achievement
		boarding while waiting for an inpatient facility. These are reported within 72 hours into a single repository that is then used for regional and statewide performance monitoring.
20. Readmissions to inpatient psychiatric or crisis residential settings;	Readmissions to inpatient psychiatric or crisis residential settings.	Beacon is capable of tracking all re-admission data and setting detailed intervention strategies to drive performance improvement.
21. Average lengths of stay in participating psychiatric hospitals and residential settings.	Average lengths of stay in participating psychiatric hospitals and residential settings.	Beacon can track ALOS through admission and claims data. We can track incurred but not reported (IBNR) claims expenses to inform financial planning. We monitor trends in facility performance, identifying outliers and developing specific interventions. This often includes developing safe, community-based discharge options, such as transitional residential care and supportive housing.
22. Medication reconciliation upon admission (Medicare Inpatient Psychiatric Facility (IPF) Reporting Requirement);	Medication reconciliation upon admission (Medicare Inpatient Psychiatric Facility (IPF) Reporting Requirement).	Beacon is experienced at working with facilities on this reporting measure.
23. SUD screening of beneficiaries admitted to psychiatric hospitals or residential treatment settings (Medicare IPF Reporting Requirement).	SUD screening of beneficiaries admitted to psychiatric hospitals or residential treatment settings (Medicare IPF Reporting Requirement).	Beacon is experienced at working with facilities on this measure and monitoring compliance. We do this today for Medicare Advantage membership in California.

Beacon looks forward to working with DHCS and County partners in developing regional models of behavioral health service delivery and the administrative infrastructure necessary to achieve the important goals of helping Californians live their lives to the fullest potential.

Please do not hesitate to reach out with any questions.

Sincerely,

Beacon Health Options of California

DAY OUT
Adult Day Health Care

Comments on the Proposed CalAIM #1115 Demonstration Application

By Aimee Mattson / May 6, 2021

As a director for a Community Based Adult Services (CBAS) program I am writing to express my appreciation for the opportunity to share some insights into the value of Section 1115 Demonstration Application. As beneficiaries expand into dual eligibility, programs like ours will not have the capacity to serve some who could most benefit from our program. We need to restructure what we do, how we define delivery of service, and take a close look at the budget that would be associated with this necessary industry growth. I am writing to share ideas on solutions that could deliver a quick increase in access to / and definition of; person-centered-care. The innovation and collaboration of community resources can provide a wealth of ideas and information, and I appreciate your taking the time to sincerely evaluate the benefit of allowing them to impact the next 5 - year waiver.

I, along with industry peers, supports the CDA proposal to use the renewal of 1115 waiver through CalAIM to update the current Medi-Cal CBAS model. We have learned a lot during this public health emergency, and there is a direct connection to using what we've learned to deliver ideas for change that aligns with the goals of the Master Plan for aging; that being, to increase access to community-based programs throughout the state.

During this public health emergency, we have stayed open, working creatively to create a TAS that would continue to serve our populations via tele-health. We have learned a lot, most importantly was discovering how we could use flexibility to create a tele-health service that truly delivered person centered results. In real-time this was the definition of "meeting people where they are" and bringing services "to them". I am humbled to say that our partnership with those we serve has been deeply changed by adding the flexibility of tele-health. We are more strongly connected, serving the participant as well as their support person(s) in meaningful ways. Staying close and continuing to serve has enriched us all. We have been creative and dedicated, with strong involvement from our entire inter-disciplinary team… and we are all the stronger for it.

An important area to review is how to expedite access for CBAS services critical to immediate care needs. During TAS we learned that the most vulnerable in our population could discharge from an acute setting, and there would be an immediate benefit to have been able to access our services. Our goal is to support their greater independence, which in this case would be physical and mental recovery and being connected to good care management. The usual process can be quite lengthy, taking several weeks to complete. If they were

1460 Merced Ave. Merced, CA. 95341 p: 209-388-9175 f: 209-388-9178

within criteria guidelines (perhaps 60 days post discharge) and with skilled needs, they should be automatically eligible for enrollment in a CBAS program.

Complex challenges face these vulnerable populations, not the least of which is the fact that this population is growing faster than we can support it under the current model. There is a marked increase for those struggling daily with homeless, or the fear of pending homelessness. We need to develop a plan to support high-needs and hard-to-reach populations. We would engage in the same "whole person care" approach, allowing the results to improve their health outcomes... and stabilize their role within their communities.

Currently most managed care programs are individually supported. Our targeted populations have multiple teams delivering care; the result is a high risk of service gap as these individuals struggle to manage the complex system all on their own.

Three high goals associated with these modifications are:

1. Manage individual risk through the application of person-centered care, including steps to include the mental / social detriments of health.
2. Reduce complexity in providing care / and increase flexibility for how we define it.
3. Improved outcomes for each area identified and reduce associated health disparities.

It feels important to be proactive in developing committed partnerships NOW with our Managed Care Organizations (MCO) to ensure that we position ourselves to meet the surging interest of dual eligible transition to Medi-Cal managed care. To help address that goal we would like to see CBAS transition back to a state plan by the end of the next 1115 waiver period.

Our targeted populations face strong vulnerabilities and having clear access to services that are defined with flexibility could greatly impact their need to seek institutionalized care / services.

Thank you again for considering these opinions. Standing in the trenches day after day I assure you, what we do makes a big difference... and now we look to you in shaping what that looks like in the bigger picture.

Respectfully submitted,

[redacted]

Aimee Jo Mattson / Director

DayOut ADHC - Merced

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

May 03, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding Removal of Pharmacy Services from Medi-Cal Managed Care in Conjunction with CalAIM Section 1915(b) Waiver Proposal

Dear Director Lightbourne:

The Community Health Center Alliance for Patient Access ("CHCAPA"), a non-profit organization composed of 31 federally-qualified health centers ("FQHCs") and support organizations, writes to object to the California Department of Health Care Service ("DHCS") proposal to carve pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of Medi-Cal managed care in connection with implementation of DHCS' California Advancing and Innovating Medi-Cal ("CalAIM"). The proposed removal of pharmacy benefits and services from Medi-Cal managed care is also known as "Medi-Cal Rx."[1]

Medi-Cal Rx is antithetical to the stated goals of CalAIM. Indeed, in the Background and Overview section of the Executive Summary, DHCS touts the benefits of Medi-Cal managed care as follows:

> Medi-Cal has significantly expanded and changed over the last ten years, most predominantly because of changes brought by the Affordable Care Act and various federal regulations as well as state-level statutory and policy changes. During this time, the DHCS has also undertaken many initiatives and embarked on innovative demonstration projects to improve the beneficiary experience. In particular, DHCS has increased the number of beneficiaries receiving the majority of their physical health care through Medi-Cal managed care plans. These plans are able to offer more complete care coordination and care management than is possible through a fee-for-service system. They can also provide a broader array of services aimed at stabilizing and supporting the lives of Medi-Cal beneficiaries. [Emphasis added.]

CHCAPA agrees that Medi-Cal managed care plans are able to offer more complete care coordination and care management than is possible through a fee-for-service ("FFS") system. Carving pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of managed care, and instead reimbursing these benefits or services on a FFS basis, increases,

[1] Specifically, page 18 of the CalAIM Executive Summary and Summary of Changes, Proposal 3.1, identifies as an element of "Managed Care Benefit Standardization" that benefits to be carved out include: "4/1/21: Pharmacy benefits or services by a pharmacy billed on a pharmacy claim." https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-Executive-Summary-02172021.pdf Medi-Cal Rx was not implemented on 4/1/21, and has not been implemented to date, with no implementation date yet announced to the public.

rather than decreases, system fragmentation and renders care coordination and care management more, rather than less, difficult.

Integrating pharmacy and medical services in managed care allows FQHCs to better serve patients. The FQHCs can serve as a one-stop-shop for all of their patients' medical needs, and integration facilitates the FQHCs' ability to assist patients in following their treatment plan, including pharmacy. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for historically underserved patients.

Additionally, providing pharmacy benefits and services in the context of Medi-Cal managed care enables FQHCs to effectively leverage discount drug pricing available through the 340B Drug Pricing Program. The savings available through participation in the 340B program allow FQHCs to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed on a FFS basis. As a result of the current managed care system, FQHC patients have better access to more services, as Congress intended in enacting the 340B program.[2]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[3] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede FQHCs' ability to provide critical services to patients. The proposed FFS reimbursement, compounded with the loss of 340B savings and COVID-19 financial losses, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of the Medi-Cal program and CalAIM, which is to improve access to healthcare and reduce health inequities.

Finally, federal Medicaid law prohibits states from waiving the FQHC reimbursement requirements described in 42 U.S.C. § 1396a(bb) under a 1915b waiver.[4] California's Medi-Cal program does not currently have a compliant manner of reimbursing FQHCs for Medi-Cal's share of the cost of providing pharmacy services outside of the managed care system.

On the dispensary side, DHCS has not implemented the requirements of Welfare & Inst. Code § 14132.01 relating to reimbursement of Medi-Cal drugs provided through a clinic dispensary and has made no attempt to ensure that the dispensing fee for FQHC pharmacies or

[2] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[3] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

[4] 42 U.S.C. § 1396n(b).

dispensaries reimbursed under the fee-for-service alternative payment methodology are not less than the specific FQHC site would receive under the PPS floor. Moreover, the Mercer study that supported the pharmacy fee-for-service dispensing fees completely failed to address the requirements of 42 U.S.C. § 1396a(bb)(6)(B).

In addition, Medi-Cal has failed to adopt a standard for avoiding duplicate discounts on drugs dispensed through contract pharmacies, as required under HRSA's 2010 Contract Pharmacy Guidance, thus the transition would eliminate use of contract pharmacies for fee-for-service claims.

As a result, if Medi-Cal Rx is approved as part of the 1915b waiver, FQHCs will no longer be able to dispense Medi-Cal covered drugs through clinics' dispensaries or contract pharmacies, and will not be reimbursed at their actual cost of providing the mandatory FQHC services benefit, in violation of 42 U.S.C. § 1396n(b),resulting in a backdoor waiver of the FQHC reimbursement and service requirements in violation of federal law

Please see the attached letter from CHCAPA to the Centers for Medicare and Medicaid Services ("CMS"), dated April 16 2021, for a full description of our substantive and procedural concerns regarding Medi-Cal Rx.

In conclusion, CHCAPA agrees with Secretary Becerra that FQHCs and DHCS should "work in partnership to provide individuals access to affordable healthcare, including prescription drugs." Therefore, CHCAPA urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration.

Thank you for your time and consideration. CHCAPA looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]
President

Encl.

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April 16, 2021

VIA OVERNIGHT DELIVERY

Teresa DeCaro, Acting Director
State Demonstrations Group,
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: Community Health Center Alliance for Patient Access Request that CMS Reject California's Removal of Pharmacy Services from Managed Care, as proposed in Attachment N to the State of California's Section 1115 Waiver Extension

Dear Director DeCaro:

As follow-up to my previous letter dated March 18, 2021, please see the enclosed letter from the Community Health Center Alliance for Patient Access ("CHCAPA"). CHCAPA's letter provides a comprehensive description of the serious flaws and consequences of the so-called "Medi-Cal Rx" initiative.

CHCAPA is an organization of 31 California Federally-qualified health centers and support organizations throughout California whose mission is to ensure access to care for underserved communities. The list of CHCAPA's affiliate members includes the following organizations:

Avenal Community Health Center

Clinicas de Salud del Pueblo

Community Health Centers of the Central Coast

Desert AIDS Project

Family Health Centers of San Diego

Gardner Family Health Network

Golden Valley Health Centers

HealthRIGHT 360

Hill Country Health & Wellness Center

Imperial Beach Community Clinic

La Maestra Family Clinic

MCHC Health Centers

Mission Area Health Associates

Omni Family Health

Open Door Community Health Centers

Ravenswood Family Health Network

San Francisco Community Health Center

San Ysidro Health

Shasta Community Health Center

South of Market Health Center

TrueCare

United Health Centers of the San Joaquin Valley

Vista Community Clinic

WellSpace Health

Central California Partnership for Health (Affiliate Support Organization)

Thank you for your consideration. Please direct any questions, follow-up discussion, or responses to me via email or phone.

Thank you,

[redacted]

Kathryn E. Doi
Partner

cc: Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Heather Ross, Project Officer, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Jacey Cooper, Chief Deputy Director, California Department of Health Care Services
Rob Bonta, California Attorney General
Darrel W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

April 16, 2021

VIA FEDERAL EXPRESS

Teresa DeCaro, Acting Director
State Demonstrations Group
Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: California's Removal of Pharmacy Services from Managed Care, as proposed in Attachment N to the State of California's Section 1115 Waiver[1]

Dear Director DeCaro:

The Community Health Center Alliance for Patient Access ("CHCAPA") writes to inform CMS of significant problems with the California Department of Health Care Service's ("DHCS") proposed Attachment N to its 1115(a) Medicaid Waiver, entitled "Medi-Cal 2020" (Project Number 11-W-00193/9). Specifically, CHCAPA has serious concerns about the proposed removal of pharmacy services from managed care, an initiative called "Medi-Cal Rx."

CHCAPA urges CMS to reject the Medi-Cal Rx proposal for four reasons. First, California's fee-for-service ("FFS") reimbursement method fails to adequately fund Federally-Qualified Health Centers ("FQHCs") at the level that federal law requires. Second, Medi-Cal Rx deprives FQHCs of the 340B Drug Pricing Program ("340B") savings that currently fund numerous whole-person care services for the most vulnerable Medi-Cal beneficiaries. Third, DHCS did not follow the legal process for amending the 1115 Waiver, and misled the public and CMS regarding Medi-Cal Rx's negative effects on providers and patients. Fourth, Medi-Cal Rx undermines Medicaid's central objective of providing health care to low-income patients and does not produce any significant savings.

Despite its implications for health care for over 11 million Medi-Cal beneficiaries, DHCS has not thoroughly considered how Medi-Cal Rx affects the Medi-Cal program, Medi-Cal beneficiaries, or overall Medi-Cal costs. At minimum, CMS should require an additional 30-day public comment period and for DHCS to provide a detailed analysis of how Medi-Cal Rx affects underserved beneficiaries and FQHCs. *See* 42 C.F.R. § 431.412(a)(2), (c)(3).

I. California's fee-for-service reimbursement method for Medi-Cal pharmacy services will not reimburse FQHCs at the level federal law requires.

Federal law requires California to reimburse FQHCs at 100 percent of their costs. *See* 42 U.S.C. § 1396a(bb); *Tulare Pediatric Health Care Ctr. v. Dep't of Health Care Svc's*, 41 Cal. App. 5th 163, 171 (2019).

[1] This letter provides the substantive information for CMS to consider as it evaluates Medi-Cal Rx as promised in the earlier letter from CHCAPA's counsel, dated March 18, 2021 (attached as **Exhibit A).**

Managed care is California's predominate Medi-Cal delivery system. Roughly 83 percent of Medi-Cal beneficiaries – over 11 million people – are enrolled in managed care[2]. About 70 percent of pharmacy services spending occurs in managed care.[3] As CMS knows, managed care plans negotiate directly with FQHCs to establish reimbursement rates for pharmacy services that generally reimburse FQHCS at 100 percent of their costs. Because managed care plans cover the vast majority of pharmacy claims, California and DHCS have not addressed deficiencies in the state's other delivery systems.

California did not design its non-managed care delivery systems to adequately reimburse FQHCs for their costs. First, by statute, California's FFS methodology only pays FQHCs their "actual acquisition cost for the drug," plus either a professional fee or dispensary fee. *See* Cal. Welf. & Inst. Code § 14105.46(d). The professional fee is capped at $10.05, or $13.20, depending on the pharmacy's annual claim volume. *Id.* § 14105.45(b)(1)(B). Similarly, the dispensary fee is set at $12 or $17 for certain take-home drugs. *Id.* § 14132.01(b)(2). However, these fee amounts did not account for FQHCs' costs when the State adopted them[4]. Additionally, DHCS has not created a billing mechanism for dispensing medication through a dispensary license. *See* Francisco Castillon Decl. ¶ 14 (attached as **Exhibit B**).

Second, California's prospective payment system ("PPS") rate is similarly flawed. The PPS method reimburses providers on a "per visit basis," but California excludes a patient's visit to a pharmacist as a reimbursable "visit." *See* Cal. Welf. & Inst. Code § 14132.100(g). Further, if an FQHC experiences a cost increase due to changes in its scope of services, it faces an automatic 20 percent reduction of the total new costs before the new PPS rate is set. *See* Dean Germano Decl. ¶ 19 (attached as **Exhibit C**).

In short, Medi-Cal Rx will replace California's managed care delivery system with undeveloped systems that do not comply with federal law. Therefore, CMS should reject Medi-Cal Rx.

II. Medi-Cal Rx undermines the 340B Program by depriving FQHCs of the savings they use to provide comprehensive care to underserved communities.

The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most.[5] Managed care currently generates necessary savings for FQHCs to do exactly that.

California FQHCs, including CHCAPA affiliates, leverage 340B savings to provide better care to their patients and communities. For example, Family Health Centers of San Diego uses its 340B savings to provide expanded vision services, substance abuse recovery programs, and mobile

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[2] *See* Medi-Cal Monthly Eligible Fast Facts, DHCS, February 2021, at p. 9 available at: https://www.dhcs.ca.gov/dataandstats/statistics/Documents/FastFacts-November2020.pdf

[3] "The 2019-20 Budget: Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care," California Legislative Analyst's Office, April 5, 2019, at p. 6. (hereinafter "LAO Carve-Out Report").

[4] *See* "Professional Dispensing Fee and Actual Acquisition Cost Analysis for Medi-Cal – Pharmacy Survey Report," Mercer Government Human Services Consulting, January 4, 2017, at p. 4.

[5] *See* H.R. Rep. No. 102-384, pt. 2, at 10.

health services to low-income patients. Ricardo Roman Decl. ¶ 13 (attached as **Exhibit D**). Shasta Community Health Center's 340B savings enable it to subsidize prescription costs for the poorest patients, some of whom will pay a maximum of $10 for their medication. Germano Decl. ¶ 2. The Desert AIDS Project uses its 340B savings to employ four infectious disease physicians and provide ongoing HIV and STD testing to combat the spread of HIV. David Brinkman Decl. ¶ 7 (attached as **Exhibit E**). These are just a few examples of how the managed care system enables FQHCs to use 340B savings the way Congress intended.

Nevertheless, DHCS seeks to deprive FQHCs of these 340B savings by moving all pharmacy services into an undeveloped FFS system. California's FFS model will not support the vital whole-person care programs upon which the most vulnerable FQHC patients rely. Instead, FQHCs will experience a "significant loss" in order for the State of California to gain an uncertain amount of savings for its general fund[6]. Without 340B savings, FQHCs will have to cut services to already underserved Medi-Cal patients. *See, e.g.*, Castillon Decl. ¶¶ 12-13.

Thus, Medi-Cal Rx causes a reduction in patient services, which DHCS neither mentioned nor even considered in its Extension Request.

III. CMS should neither excuse nor permit DHCS to obtain approval for Medi-Cal Rx through a flawed and misleading public process.

A. DHCS improperly submitted Medi-Cal Rx as a "technical" change contrary to federal law and the Special Terms and Conditions of California's 1115 Waiver.

Federal law and the Special Terms and Conditions of California's 1115 Waiver ("STCs") require that "substantial" changes to benefits, delivery systems, reimbursement methods, and other "comparable program elements" occur as amendments to the 1115 Waiver. 42 C.F.R. § 431.412(c); STC III, Section 7. Amendments require the State to follow specific public processes and to provide detailed information and analyses on the impact of the proposed change. STC III, Section 8. CMS has the authority to deny or delay approval of any amendment based on California's violation of the STCs. *Id.*

Medi-Cal Rx is undoubtedly a substantial change to the delivery and reimbursement of Medi-Cal pharmacy services. It completely removes the pharmacy benefit from the managed care delivery system, and places it into the FFS delivery system. The FFS system, in turn, has an entirely different reimbursement method that will underfund FQHCs, as discussed.

Moreover, Medi-Cal Rx will "fundamentally alter" how more than 11 million Medi-Cal beneficiaries receive treatment. *See* Kelvin Vu Decl. ¶ 8 (attached as **Exhibit F**). For example, doctors currently are able to access the availability of prescriptions and their patient's adherence to their treatment plan in real-time. *Id*. If a pharmacy does not have a prescription in stock, the doctor will know immediately and can adjust the order. *Id.* ¶ 5. As a result, the patient is more likely to get their medication and adhere to their treatment plan. *Id.* ¶¶ 5-8. But not under Medi-Cal Rx. Instead, Medi-Cal Rx removes the doctor's ability to coordinate with a pharmacy, and creates a new barrier for the patient to access the prescriptions they need. Vu Decl. ¶ 8; Paramvir Sidhu Decl. ¶¶ 5-9 (attached as **Exhibit G**).

[6] LAO Carve-Out Report, at p. 1.

Despite these substantial changes to Medi-Cal, DHCS submitted Medi-Cal Rx as a "technical" amendment. *See* Extension Request at p. 14. The only analysis DHCS provided was that Medi-Cal Rx would "reflect the transition of pharmacy benefits to the fee-for-service delivery system effective January 1, 2021." *Id.* This is a description, not an analysis. DHCS further described Medi-Cal Rx in the two short paragraphs, with no mention of the differences in delivery systems, the shortcomings of non-managed care reimbursement methods, the impact on 340B savings and the patient services they fund, or the real effects on patients and their doctors. *See id.*

CMS should treat Medi-Cal Rx as the substantial amendment that it is. CMS cannot allow DHCS to avoid its obligation to fully describe and understand Medi-Cal Rx. Accordingly, CMS should reject Medi-Cal Rx, or at the very least, require DHCS to provide additional information and more time for public input. *See* 42 C.F.R. § 431.412(a), (c).

B. DHCS has been implementing Medi-Cal Rx without CMS' approval.

Federal law and the STCs prohibit DHCS from implementing major changes to California's Waiver without CMS' approval. *See Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1017-18 (9th Cir. 2013); STCs III, Sections 7-8.

DHCS is not waiting for CMS to move forward with Medi-Cal Rx. For example, it has unilaterally set and changed two different "effective" dates that did not depend on CMS approval. *See* Extension Request at p. 14[7]. DHCS contracted with Magellan Medicaid Administration to create a Medi-Cal Rx customer service center. Providers have already had to register for secure Medi-Cal Rx portals and participated in Medi-Cal Rx trainings. The State of California created a supplemental payment pool in its state budget because of the losses FQHCs will suffer under Medi-Cal Rx. Germano Decl. ¶¶ 4-15. DHCS has begun to implement Medi-Cal Rx without CMS approval and without understanding its consequences.

DHCS' unapproved implementation of Medi-Cal Rx is already affecting providers. For example, Family Health Centers of San Diego has had to undergo a complete budget review anticipating the loss of 340B savings, and has dedicated significant staff time to enroll in Medi-Cal Rx provider portals and to track Medi-Cal Rx updates. Fran Butler-Cohen Decl. ¶ 9 (attached as **Exhibit H**). Providers have also had to register for and participate in several different trainings, answer readiness surveys, and provide claims information for calculating their professional dispending fee under FFS. *See, e.g.,* DHCS Medi-Cal Rx Monthly Bulletin (attached as **Exhibit I).** These efforts distract FQHCs from patient service, such as providing free testing and vaccines to combat the spread of COVID-19. *See id.* ¶¶ 6-8.

In sum, DHCS is violating federal law and the STCs by implementing Medi-Cal Rx without CMS' approval. CMS should not allow DHCS to do so, and should accordingly reject Medi-Cal Rx.

[7] *See also* Medi-Cal Rx Transition home page, available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx

C. DHCS prevented meaningful public input regarding Medi-Cal Rx through misleading public notices and a rushed public comment process.

States must allow for "meaningful public input" when submitting 1115 Waiver amendments or extension requests. 42 C.F.R. §§ 431.408(a)(1)(i), 431.412 (c)(2)(ii). This requires states to provide a "comprehensive description" discussing who will be impacted by the proposals, changes to the existing demonstration, and how the state received and considered public comments. *See* 42 C.F.R. §§ 431.408(a), 431.412(a), (c).

DHCS hindered "meaningful" public input regarding Medi-Cal Rx. Specifically, DHCS claimed that there was "no impact" to FQHCs in its Tribal Notice[8]. However, the state's Legislative Analyst's office explicitly stated that Medi-Cal Rx would directly affect FQHC funding and patient care coordination[9]. Also, DHCS held only two public hearings within 20 days of announcing the proposed Extension.

Although CMS waived some of the technical notice requirements, it certainly did not allow DHCS to falsely downplay the impact of the Extension Request and Medi-Cal Rx[10]. As the public was denied meaningful input into Medi-Cal Rx, CMS should not allow DHCS to implement it.

D. DHCS' Waiver Extension Request misled CMS by unfairly minimizing CHCAPA's legitimate and detailed objections to Medi-Cal Rx.

DHCS was obligated to provide CMS with a "report of the issues" raised in public comments and how it addressed them. 42 C.F.R. § 431.412(a)(viii), (c)(vii).

Yet DHCS did not provide an honest report of the public comments to CMS. In its Extension Request, DHCS misrepresented CHCAPA's extensive concerns in one sentence: "one commenter objected to the state's plan to carve-out the pharmacy benefit." Extension Request at p. 45. The "one commenter" was a collection of nearly 20 health centers across California that signed onto a CHCAPA-led comment letter. The "objection" was a detailed letter describing numerous problems with the FFS and PPS reimbursement methods and the overall disruption Medi-Cal Rx will cause. DHCS' characterization hid serious public concerns from CMS.

DHCS' response to CHCAPA's concerns was similarly sparse. In a single paragraph, DHCS claimed that it "must" move the pharmacy benefit out of managed care in order for pharmacy services to move from managed care. *See* Extension Request at p. 49. By contrast, DHCS provided detailed summaries and responses for comments that were generally or strongly supportive of its Extension proposals. *See* Extension Request at 44-49. DHCS cannot provide one-sided information in order to obtain CMS' approval of a flawed initiative.

[8] DHCS Tribal Notice of Proposed Change to Medi-Cal Program, July 22, 2020 at p. 2, available at: https://www.dhcs.ca.gov/Documents/1115-1915bWaiverTribalNotice7-22-20.pdf

[9] LAO Carve-Out Report, at pp. 1, 13-14

[10] *See* CMS Completeness Letter, dated Oct. 1, 2020

CMS cannot adequately evaluate Medi-Cal Rx based on the scant information DHCS provided regarding its scope and costs. At best, DHCS failed to provide accurate and sufficient information to CMS. Therefore, CMS should decline to approve Attachment N and Medi-Cal Rx until these important issues have been addressed.

IV. Medi-Cal Rx impedes Medicaid's primary objective by depriving beneficiaries of high-quality care, and is not likely produce the savings DHCS claims.

Any change to California's Medicaid Waiver must promote the objectives of Medicaid. *See* 42 U.S.C. § 1315(a). Medicaid's most fundamental objective is to provide comprehensive, high-quality medical care to people who would not have access to it otherwise. *See id.* § 1396-1.

Medi-Cal Rx directly undermines Medicaid's purpose in two ways. First, it will eliminate vital patient services for beneficiaries. Because of the COVID-19 pandemic, FQHCs in California are facing an estimated loss of $530 million dollars[11]. Medi-Cal Rx will exacerbate FQHCs' financial strain by shifting 340B savings to the state while underpaying FQHCs through FFS. These cuts will force FQHCs to eliminate key services for their patients, including transportation assistance, mobile health initiatives, and prescription subsidies. *See, e.g.*, Castillon Decl. ¶¶ 12-13; Germano Decl. ¶¶ 2, 16; Brinkman Decl. ¶ 9.

Second, Medi-Cal Rx will diminish the quality of care for the remaining FQHC services. It will disrupt Medi-Cal care coordination, severely undermining the whole-person care model that DHCS expects FQHCs to follow. *See* Vu Decl. ¶ 8; Sidhu Decl. ¶¶ 5-9. It will also disrupt important medical intervention programs that combat substance abuse and opioid addiction. *See* Vu Decl. ¶ 10. Medi-Cal Rx will therefore lead to fewer services and worse health outcomes during a pandemic that has claimed the lives of over 60,000 Californians.

Medi-Cal Rx will cause significant disruption without any real financial benefit to California. DHCS has not provided any thorough analysis to support its claim of savings, and actually excluded such claims from its final submission to CMS. *See* Extension Request at pp. 37, 49. In fact, an internal DHCS analysis shows that while Medi-Cal Rx would yield a net savings of $5.8 billion, the fee-for-service pharmacy costs would grow to about $5.65 billion[12]. By its own analysis, DHCS knows that Medi-Cal Rx *might* save the state a maximum of $400 million over an unknown period of time.

Studies by reputable entities also cast doubt on whether Medi-Cal Rx will yield significant state savings, if any. The Legislative Analyst's Office noted that even if there is some net savings, the amount is "highly uncertain"[13]. Further, an independent analysis found that moving pharmacy benefits into fee-for-service would actually result in a net *increase* of as much as $757 million to

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[11] *See* "Financial Impact of COVID-19 on California Federally Qualified Health Centers," California Health Care Foundation, available at: https://www.chcf.org/wp-content/uploads/2021/03/FinancialImpactCOVID19CaliforniaFQHCInfographic.pdf

[12] May 2020 Medi-Cal Local Assistance Estimate, DHCS, at PC page 107, available at: https://www.dhcs.ca.gov/dataandstats/reports/mcestimates/Documents/2020_May_Estimate/M2099-Medi-Cal-Local-Assistance-and-Appropriation-Estimate.pdf

[13] LAO Carve-Out Report, at pp. 1, 11-12

California's General Fund over five years[14]. Thus, any benefits of Medi-Cal Rx are limited and uncertain.

In sum, Medi-Cal Rx subverts – not promotes – Medicaid's core objective of providing low-income people with access to health care. CMS should therefore reject the proposal, especially during an ongoing pandemic when the health care system needs stability.

V. Conclusion

Medi-Cal Rx is an undeveloped proposal that directly undermines the purpose of Medicaid. Medi-Cal Rx will significantly disrupt patient care and create new barriers to access for the sake of speculative state savings. DHCS cannot upend an entire delivery system affecting over 11 million Medi-Cal beneficiaries under the label of a "technical" change to its Waiver. By providing insufficient and misleading information to the public and to CMS, DHCS violated federal law and its contract with CMS.

Accordingly, CHCAPA urges CMS to reject the Medi-Cal Rx proposal. At minimum, CMS should use its authority to treat Medi-Cal Rx as a substantive amendment and require DHCS to follow the formal amendment process specified in the Code of Federal Regulations and the Special Terms and Conditions of the Waiver.

Thank you for your time and consideration.

Sincerely,

[redacted]

President, CHCAPA

CC: Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Heather Ross, Project Officer, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Jacey Cooper, Chief Deputy Director, California Department of Health Care Services
Rob Bonta, California Attorney General
Darrel W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General

[14] Assessment of Medi-Cal Pharmacy Benefits Policy Options, The Menges Group, May 15, 2019 at p. 3, available at: https://www.themengesgroup.com/upload_file/assessment_of_medi-cal_pharmacy_benefits_policy_options.pdf.

Exhibit A
to letter dated 4/16/2021

KATHRYN E. DOI
PARTNER
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March 18, 2021

VIA FEDERAL EXPRESS

Judith Cash, Director
State Demonstrations Group
Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, MD 21244-1850

Re: Community Health Center Alliance for Patient Access ("CHCAPA") Request that CMS Pause Its Consideration to Proposed Attachment N to the State of California's Medi-Cal 2020 Section 1115 Waiver Demonstration to Allow for Comment

Dear Ms. Cash:

We represent the Community Health Center Alliance for Patient Access ("CHCAPA") and individual Federally-qualified health centers in federal court litigation challenging the State of California's implementation of the Medi-Cal Rx program to transition the pharmacy benefit from Medi-Cal managed care to fee-for-service reimbursement. (*Community Health Center Alliance for Patient Access, et al. v. Lightbourne, et al.*, United States District Court for the Eastern District of California, Case No. 2:30-cv-02171-JAM-KJN.)

On Tuesday, March 9, 2021, a hearing was held on the Defendants' (the California Department of Health Care Services and its Director Will Lightbourne) motion to dismiss and the Plaintiffs' motion for a preliminary injunction. At the hearing, Judge Mendez indicated on the record that he was granting the motion to dismiss with leave to amend the complaint because CMS has not yet acted on Attachment N to the State's 1115 Waiver. Attachment N was submitted to CMS by the State of California on December 24, 2020 and would result in the removal of the pharmacy benefit from the list of covered services under Medi-Cal managed care, thus effectuating the Medi-Cal Rx transition. During the hearing, the judge encouraged the Plaintiffs to raise with CMS the legal challenges to Medi-Cal Rx and Attachment N that Plaintiffs raised in the federal lawsuit. In the minutes of the proceeding, the judge ordered Plaintiffs to "wait to file an amended complaint until after CMS acts on the approval sought by Defendants."[1]

Consistent with the judge's recommendations, we are writing on behalf of the Plaintiffs to request that CMS pause its consideration of Attachment N to give us time to submit a

[1] Copies of the proposed Attachment N, the December 24, 2020 email message from the Department of Health Care Services ("DHCS") transmitting Attachment N to CMS, CMS' December 29, 2020 response to DHCS regarding the status of Attachment N, and the Court's March 9, 2021 minutes of proceeding are attached to this letter for your reference as **Exhibits A, B, C, and D**, respectively.

comprehensive letter outlining the reasons why approval of Attachment N and implementation of Medi-Cal Rx will result in a violation of the federal Medicaid and 340B laws. Since there is currently no Go Live date for the Medi-Cal Rx transition, we request that we be granted a minimum period of 45-days to submit our substantive comments.[2]

We also encourage CMS adopt an open and transparent process for its consideration of Attachment N to allow Plaintiffs and other stakeholders an opportunity to provide public input into CMS' decision-making process. The 1115 Waiver extension request and associated notices did not describe the Medi-Cal Rx transition, did not attach the proposed Attachment N and inaccurately stated there would be no impact on FQHCs, and therefore, there has been no opportunity for the public and stakeholders to weigh in on the impact of Medi-Cal Rx on patient care and the delivery system.

The proposed Attachment N will change the pharmacy delivery system for the roughly 8.8 million Medi-Cal beneficiaries who receive their health care through Medi-Cal managed care, a significant change for the beneficiaries, as well as the providers and health plans that are a part of their health care delivery system. To date, there has been no public examination of the consequences of removing the pharmacy benefit from managed care, including the resulting impact on coordination of care, oversight of pharmacy usage and patient compliance, or Medi-Cal's ability to deliver the whole person integrated care if the pharmacy benefit is carved out of managed care and delivered and administered by the State.

Such a sea change should not occur in a vacuum, but only after a public process that allows for identification of the key issues and allows for a careful review of the public policy and legal ramifications of such a major disruption to the health care delivery system for millions of low income Californians. To this end, because Attachment N substantially changes the original demonstration design and was not submitted as part of the original 1115 Waiver extension request, we request that CMS exercise its discretion to direct an additional 30-day public comment period pursuant to 42 C.F.R. 431.412(a)(2) and (c)(3).

We also request that CMS timely notify us of any action taken with respect to the State of California's request for approval of Attachment N so we might return to court as provided by the judge's order.

Your attention to this matter is greatly appreciated.

Very truly yours,

[redacted]

Kathryn E. Doi
Partner

KED:KQD
Encls.

[2] DHCS' announcement that the April 1, 2021 Go Live date for Medi-Cal Rx was being suspended with no new date announced, is attached as **Exhibit E**.

cc: (VIA U.S. MAIL)
Xavier Becerra, Secretary, Health and Human Services
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Will Lightbourne, Director, California Department of Health Care Services
Lindy Harrington, Deputy Director, California Department of Health Care Services
Darrell W. Spence, California Supervising Deputy Attorney General
Joshua Sondheimer, California Deputy Attorney General
Anthony White, President, CHCAPA

Exhibit A

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Acupuncture Services	Other Practitioners' Services and Acupuncture Services	Acupuncture services shall be limited to treatment performed to prevent, modify or alleviate the perception of severe, persistent chronic pain resulting from a generally recognized medical condition.	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Acute Administrative Days	Intermediate Care Facility Services	Acute administrative days are covered, when authorized by a Medi-Cal consultant subject to the acute inpatient facility has made appropriate and timely discharge planning, all other coverage has been utilized and the acute inpatient facility meets the requirements contained in the Manual of Criteria for Medi-Cal Authorization.	~~X[5]~~X[3,~~965~~]	~~X[5]~~X[3,~~965~~]	X	~~X[5]~~X[3]	~~X[5]~~X[3]	~~X[5]~~X[3]
Audiological Services	Audiology Services	Audiological services are covered when provided by persons who meet the appropriate requirements	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Behavioral Health Treatment (BHT)	Preventive Services- EPSDT	The provision of medically necessary BHT services to eligible Medi-Cal members under 21 years of age as required by the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) mandate and state plan.~~-~~	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~76~~]	~~X[10]~~X[~~7~~ ~~6~~]
Blood and Blood Derivatives	Blood and Blood Derivatives	A facility that collects, stores, and distributes human blood and blood derivatives. Covers certification of blood ordered by a physician or facility where transfusion is given.	X	X	X	X	X	X
California Children Services (CCS)	~~Service is not covered under the State Plan~~ EPSDT	California Children Services (CCS) means those services authorized by the CCS program for the diagnosis and treatment of the CCS eligible conditions of a specific Member.	~~X~~	~~X~~	X[9] ~~X[6]~~X[~~4~~]	~~X~~	~~X~~	~~X~~

Certified Family ~~nurse~~ Nurse ~~practitioner~~Practitioner	Certified Family Nurse Practitioners' Services	A certified family nurse practitioners who provide services within the scope of their practice.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Certified Pediatric Nurse Practitioner Services	Certified Pediatric Nurse Practitioner Services	Covers the care of mothers and newborns through the maternity cycle of pregnancy, labor, birth, and the immediate postpartum period, not to exceed six weeks; can also include primary care services.	X	X	X	X	X	X
Child Health and Disability Prevention (CHDP) Program	EPSDT	A preventive program that delivers periodic health assessments and provides care coordination to assist with medical appointment scheduling, transportation, and access to diagnostic and treatment services.	X	X	X[4]	X	X	X
Childhood Lead Poisoning Case Management (Provided by the Local County Health Departments)	EPSDT	A case of childhood lead poisoning (for purposes of initiating case management) as a child from birth up to 21 years of age with one venous blood lead level (BLL) equal to or greater than 20 µg/dL, or two BLLs equal to or greater than 15 µg/dL that must be at least 30 and no more than 600 calendar days apart, the first specimen is not required to be venous, but the second must be venous.	X	X	X	X	X	X
Chiropractic Services	Chiropractors' Services	Services provided by chiropractors, acting within the scope of their practice as authorized by California law, are covered, except that such services shall be limited to treatment of the spine by means of manual manipulation.	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Chronic Hemodialysis	Chronic Hemodialysis	Procedure used to treat kidney failure - covered only as an outpatient service. Blood is removed from the body through a vein and circulated through a machine that filters the waste products and excess fluids from the blood. The "cleaned" blood is then returned to the body. Chronic means this procedure is performed on a regular basis. Prior authorization required when provided by renal dialysis centers or community hemodialysis units.	X	X	X	X	X	X
Community Based Adult Services (CBAS)		CBAS Bundled services: An outpatient, facility based service program that delivers skilled nursing care, social services, therapies, personal care, family/caregiver training and support, meals and transportation to eligible Medi-Cal beneficiaries. CBAS Unbundled Services: Component parts of CBAS center services delivered outside of centers, under certain conditions, as specified in paragraph 95.	X	X	X	X	X	X
Comprehensive Perinatal Services	Extended Services for Pregnant Women-Pregnancy Related and Postpartum Services	Comprehensive perinatal services means obstetrical, psychosocial, nutrition, and health education services, and related case coordination provided by or under the personal supervision of a physician during pregnancy and 60 days following delivery.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Dental Services (Covered under ~~Denti~~Medi-Cal)		Professional services performed or provided by dentists including diagnosis and treatment of malposed human teeth, of disease or defects of the alveolar process, gums, jaws and associated structures; the use of drugs administered in-office, anesthetics and physical evaluation; consultations; home, office and institutional calls.						
Drug Medi-Cal Substance Abuse Services	Substance Abuse Treatment Services	Medically necessary substance abuse treatment to eligible beneficiaries.						
Durable Medical Equipment	DME	Assistive medical devices and supplies. Covered with a prescription; prior authorization is required.	**X**	**X**	**X**	**X**	**X**	**X**
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Services ~~and EPSDT Supplemental Services~~	EPSDT	EPSDT is the Medicaid program's benefit for children and adolescents, providing a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act. ~~Preliminary evaluation to help identify potential health issues.~~	**X**~~76~~	**X**~~67~~	**X**~~67~~	**X**~~67~~	**X**~~67~~	**X**~~67~~
~~Erectile~~ Sexual Dysfunction Drugs		FDA-approved drugs that are~~may~~ be prescribed for~~if a~~ male or female sexual dysfunction are non-benefits of the program.~~patient experiences an inability or difficulty getting or keeping an erection as a result of a physical problem.~~						

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Expanded Alpha-Fetoprotein Testing (Administered by the Genetic Disease Branch of DHCS)		A simple blood test recommended for all pregnant women to detect if they are carrying a fetus with certain genetic abnormalities such as open neural tube defects, Down Syndrome, chromosomal abnormalities, and defects in the abdominal wall of the fetus.						
Eyeglasses, Contact Lenses, Low Vision Aids, Prosthetic Eyes and Other Eye Appliances	Eyeglasses, Contact Lenses, Low Vision Aids, Prosthetic Eyes, and Other Eye Appliances	Eye appliances are covered on the written prescription of a physician or optometrist.	X[8]	X[8]	X[8]	X[8]	X[8]	X[8]
Federally Qualified Health Centers (FQHC) (Medi-Cal covered services only)	FQHC	Services described in 42 U.S.C. Section 1396d(a)(2)(C) furnished by ~~An~~ an entity defined in ~~Section 1905 of the Social Security Act (~~42 ~~United States Code~~ U.S.C. Section 1396d(l)(2)(B)).	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Health Home Program Services	Health Home Program Services	The community based care management entity assigns care managers, such as nurses or other trained professionals, to help members who have chronic conditions find the right health care or other services in their communities. Health Home Program services: Comprehensive Care Management; Care Coordination; Health Promotion; Comprehensive Transitional Care; Individual and Family Supports; and Referral to Community/Social Supports; are defined in the CMS- approved Health Home Program SPAs, and include any subsequent amendments to the CMS-approved Health Home Program SPAs.	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]	X[44] X[87]
Hearing Aids	Hearing Aids	Hearing aids are covered only when supplied by a hearing aid dispenser on prescription of an otolaryngologist, or the attending physician where there is no otolaryngologist available in the community, plus an audiological evaluation including a hearing aid evaluation which must be performed by or under the supervision of the above physician or by a licensed audiologist.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Home and Community-Based Waiver Services (Does not include EPSDT Services)		Home and community-based waiver services shall be provided and reimbursed as Medi-Cal covered benefits only: (1) For the duration of the applicable federally approved waiver, (2) To the extent the services are set forth in the applicable waiver approved by the HHS; and (3) To the extent the Department can claim and be reimbursed federal funds for these services.						
Home Health Agency Services	Home Health Services-Home Health Agency	Home health agency services are covered as specified below when prescribed by a physician and provided at the home of the beneficiary in accordance with a written treatment plan which the physician reviews every 60 days.	X	X	X	X	X	X
Home Health Aide Services	Home Health Services-Home Health Aide	Covers skilled nursing or other professional services in the residence including part-time and intermittent skilled nursing services, home health aide services, physical therapy, occupational therapy, or speech therapy and audiology services, and medical social services by a social worker.	X	X	X	X	X	X
Hospice Care	Hospice Care	Covers services limited to individuals who have been certified as terminally ill in accordance with Title 42, CFR Part 418, Subpart B, and who directly or through their representative volunteer to receive such benefits in lieu of other care as specified.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Hospital Outpatient Department Services and Organized Outpatient Clinic Services	Clinic Services and Hospital Outpatient Department Services and Organized Outpatient Clinic Services	A scheduled administrative arrangement enabling outpatients to receive the attention of a healthcare provider. Provides the opportunity for consultation, investigation and minor treatment.	X	X	X	X	X	X
Human Immunodeficiency Virus and AIDS drugs ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021		Human Immunodeficiency Virus and AIDS drugs that are listed in the Medi-Cal Provider Manual			X[5]			

Hysterectomy	Inpatient Hospital Services	Except for previously sterile women, a nonemergency hysterectomy may be covered only if: (1) The person who secures the authorization to perform the hysterectomy has informed the individual and the individual's representatives, if any, orally and in writing, that the hysterectomy will render the individual permanently sterile, (2) The individual and the individual's representative, if any, has signed a written acknowledgment of the receipt of the information in and (3) The individual has been informed of the rights to consultation by a second physician. An emergency hysterectomy may be covered only if the physician certifies on the claim form or an attachment that the hysterectomy was performed because of a life-threatening emergency situation in which the physician determined that prior acknowledgement was not possible and includes a description of the nature of the emergency.	X	X	X	X	X	X
Service	**State Plan Service Category**	**Definition**	**Covered in GMC**	**Covered in 2-Plan**	**COHS**	**Regional**	**Imperial**	**San Benito**
Indian Health Services (Medi-Cal covered services only)		Indian means any person who is eligible under federal law and regulations (25 U.S.C. Sections 1603c, 1679b, and 1680c) and covers health services provided directly by the United States Department of Health and Human Services, Indian Health Service, or by a tribal or an urban Indian health program funded by the Indian Health Service to provide health services to eligible individuals either directly or by contract.	X	X	X	X	X	X

~~In-Home Medical Care Waiver Services and Nursing Facility Waiver Services~~	-	~~In-home medical care waiver services and nursing facility waiver services are covered when prescribed by a physician and provided at the beneficiary's place of residence in accordance with a written treatment plan indicating the need for in- home medical care waiver services or nursing facility waiver services and in accordance with a written agreement between the Department and the provider of service.~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~
Inpatient Hospital Services	Inpatient Hospital Services	Covers delivery services and hospitalization for newborns; emergency services without prior authorization; and any hospitalization deemed medically necessary with prior authorization.	X	X	X	X	X	X
Intermediate Care Facility Services for the Developmentally Disabled	Intermediate Care Facility Services for the Developmentally Disabled	Intermediate care facility services for the developmentally disabled are covered subject to prior authorization by the Department. Authorizations may be granted for up to six months. The authorization request shall be initiated by the facility. The attending physician shall sign the authorization request and shall certify to the Department that the beneficiary requires this level of care.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Intermediate Care Facility Services for the Developmentally Disabled Habilitative	Intermediate Care Facility Services for the Developmentally Disabled Habilitative	Intermediate care facility services for the developmentally disabled habilitative (ICF-DDH) are covered subject to prior authorization by the Department of Health Services for the ICF-DDH level of care. Authorizations may be granted for up to six months. Requests for prior authorization of admission to an ICF-DDH or for continuation of services shall be initiated by the facility on forms designated by the Department. Certification documentation required by the Department of Developmental Services must be completed by regional center personnel and submitted with the Treatment Authorization Request form. The attending physician shall sign the Treatment Authorization Request form and shall certify to the Department that the beneficiary requires this level of care.	X[5] X[3]	X[5] X[3]	X	X[5] X[3]	X[5] X[3]	X[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Intermediate Care Facility Services for the Developmentally Disabled-Nursing.		Intermediate care facility services for the developmentally disabled-nursing (ICF/ID-N) are covered subject to prior authorization by the Department for the ICF/ ID-N level of care. Authorizations may be granted for up to six months. Requests for prior authorization of admission to an ICF/ID-N or for continuation of services shall be initiated by the facility on Certification for Special Treatment Program Services forms (HS 231). Certification documentation required by the Department of Developmental Services shall be completed by regional center personnel and submitted with the Treatment Authorization Request form. The attending physician shall sign the Treatment Authorization Request form and shall certify to the Department that the beneficiary requires this level of care.	X[5] X[3]	X[5] X[3]	X	X[5] X[3]	X[5] X[3]	X[5] X[3]
Intermediate Care Services	Intermediate Care Facility Services	Intermediate care services are covered only after prior authorization has been obtained from the designated Medi-Cal consultant for the district where the facility is located. The authorization request shall be initiated by the facility. The attending physician shall sign the authorization request and shall certify to the Department that the beneficiary requires this level of care.	X[5] X[3,965]	X[5] X[3,965]	X	X[5] X[3]	X[5] X[3]	X[5] X[3]
Laboratory, Radiological and Radioisotope Services	Laboratory, X- Ray and Laboratory, Radiological and Radioisotope Services	Covers exams, tests, and therapeutic services ordered by a licensed practitioner.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Licensed Midwife Services	Other Practitioners' Services and Licensed Midwife Services	The following services shall be covered as licensed midwife services under the Medi-Cal Program when provided by a licensed midwife supervised by a licensed physician and surgeon: (1) Attendance at cases of normal childbirth and (2) The provision of prenatal, intrapartum, and postpartum care, including family planning care, for the mother, and immediate care for the newborn.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Local Educational Agency (LEA) Services	Local Education Agency Medi- Cal Billing Option Program Services	LEA health and mental health evaluation and health and mental health education services, which include any or all of the following: (A) Nutritional assessment and nutrition education, consisting of assessments and non-classroom nutrition education delivered to the LEA eligible beneficiary based on the outcome of the nutritional health assessment (diet, feeding, laboratory values, and growth), (B) Vision assessment, consisting of examination of visual acuity at the far point conducted by means of the Snellen Test, (C) Hearing assessment, consisting of testing for auditory impairment using at-risk criteria and appropriate screening techniques as defined in Title 17, California Code of Regulations, Sections 2951(c), (D) Developmental assessment, consisting of examination of the developmental level by review of developmental achievement in comparison with expected norms for age and background, (E) Assessment of psychosocial status, consisting of appraisal of cognitive, emotional, social, and behavioral functioning and self-concept through tests, interviews, and behavioral evaluations and (F) Health education and anticipatory guidance appropriate to age and health status, consisting of non- classroom health education and anticipatory guidance based on age and developmentally appropriate health education.						

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Long Term Care (LTC)		Care in a facility for longer than the month of admission plus one month. Medically necessary care in a facility covered under managed care health plan contracts	~~X~~[5]~~X~~[3,~~9~~65]	~~X~~[5]~~X~~[3,~~596~~]	X[53]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]
Medical Supplies ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. ~~Does not include incontinence creams and washes~~	X	X	X	X	X	X
Medical Supplies (effective April 1, 2021 onward)	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. Does not include medical supplies carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including medical supplies described in the Medi-Cal Rx All Plan Letter (APL 20-020). [1] ~~Medically necessary supplies when prescribed by a licensed practitioner.~~	X	X	X	X	X	X
Medical & Non-Medical (NMT) Transportation Services	Transportation-Medical & Non-Medical ~~(NMT)~~Transportation (NMT) Services	Covers ambulance, litter van and wheelchair van medical transportation services are covered when the beneficiary's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically contraindicated, and transportation is required for the purpose of obtaining needed medical care. NMT is transportation by private or public vehicle for	X	X	X	X	X	X

[1] https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2020/APL20-020.pdf

		beneficiary~~'s~~sies ~~people~~ who do not have another way to get to their appointment.						
Multipurpose Senior Services Program (MSSP)		MSSP sites provide social and health care management for frail elderly clients who are certifiable for placement in a nursing facility but who wish to remain in the community.	X[9]X[65]	X[9]X[65]	X[9]X[65]			
Nurse Anesthetist Services	Other Practitioners' Services and Nurse Anesthetist Services	Covers anesthesiology services performed by a nurse anesthetist within the scope of his or her licensure.	X	X	X	X	X	X
Nurse Midwife Services	Nurse-Midwife Services	An advanced practice registered nurse who has specialized education and training in both Nursing and Midwifery, is trained in obstetrics, works under the supervision of an obstetrician, and provides care for mothers and newborns through the maternity cycle of pregnancy, labor, birth, and the immediate postpartum period, not to exceed six weeks.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Optometry Services	Optometrists' Services	Covers eye examinations and prescriptions for corrective lenses. ~~Further services are not covered.~~	X	X	X	X	X	X
Outpatient Mental Health	Outpatient Mental Health	Services provided by licensed health care professionals acting within the scope of their license for adults and children diagnosed with a mental condition as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) resulting in mild to moderate distress or impairment of mental, emotional, or behavioral functioning. Services include: • Individual and group mental health evaluation and treatment (psychotherapy) • Psychological testing when clinically indicated to evaluate a mental health condition • Outpatient Services for the purpose of monitoring drug therapy • Outpatient laboratory, ~~drugs,~~ supplies and supplements • Screening and Brief Intervention (SBI) • Psychiatric consultation for medication management	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Organized Outpatient Clinic Services	Clinic Services and Organized Outpatient Clinic Services	In-home medical care waiver services and nursing facility waiver services are covered when prescribed by a physician and provided at the beneficiary's place of residence in accordance with a written treatment plan indicating the need for in- home medical care waiver services or nursing facility waiver services and in accordance with a written agreement between the Department and the provider of service.	X	X	X	X	X	X
Outpatient Heroin Detoxification Services	Outpatient Heroin Detoxification Services	Can cover of a number of medications and treatments, allowing for day-to-day functionality for a person choosing to not admit as an inpatient. Routine elective heroin detoxification services are covered, subject to prior authorization, only as an outpatient service. Outpatient services are limited to a maximum period of 21 days. Inpatient hospital services shall be limited to patients with serious medical complications of addiction or to patients with associated medical problems which require inpatient treatment.						
Part D Drugs		Drug benefits for full-benefit dual eligible beneficiaries who are eligible for drug benefits under Part D of Title XVIII of the Social Security Act.						
Pediatric Subacute Care Services	Nursing Facility Services and Pediatric Subacute Services (NF)	Pediatric Subacute care services are a type of skilled nursing facility service which is provided by a subacute care unit.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Personal Care Services	Personal Care Services	Covers services which may be provided only to a categorically needy beneficiary who has a chronic, disabling condition that causes functional impairment that is expected to last at least 12 consecutive months or that is expected to result in death within 12 months and who is unable to remain safely at home without the services.	~~X~~[9] X[65, ~~14~~]	~~X~~[9] X[65, ~~14~~]	~~X~~[9] X[65, ~~14~~]			
Pharmaceutical Services and Prescribed Drugs ~~(effective Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Pharmaceutical Services and Prescribed Drugs	Covers medications including prescription and nonprescription and total parenteral and enteral nutrition supplied by licensed physician.	X	X	X	X	X	X
Pharmaceutical Services and Prescribed Drugs (effective Apr 1, 2021 onward)	Pharmaceutical Services and Prescribed Drugs	Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and enteral nutrition supplied by licensed physician. Does not include pharmacy benefits carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including covered outpatient drugs, physician administered drugs (PADs), medical supplies, and enteral/parenteral nutritional products as described in the Medi-Cal Rx All Plan Letter (APL 20-020). ~~Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and~~	X	X	X	X	X	X

		~~enteral nutrition supplied by licensed physician.~~						
Physician Services	Physician Services	Covers primary care, outpatient services, and services rendered during a stay in a hospital or nursing facility for medically necessary services. Can cover limited mental health services when rendered by a physician, and limited allergy treatments.	X	X	X	X	X	X
Podiatry Services	Other Practitioners' Services and Podiatrists' Services	Office visits are covered if medically necessary. All other outpatient services are subject to the same prior authorization procedures that govern physicians, and are limited to medical and surgical services necessary to treat disorders of the feet, ankles, or tendons that insert into the foot, secondary to or complicating chronic medical diseases, or which significantly impair the ability to walk. Services rendered on an emergency basis are exempt from prior authorization.	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]
Preventive Services	Preventive Services	All preventive services articulated in the state plan.	X	X	X	X	X	X

Attachment N
Capitated Benefits Provided in Managed Care
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Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Prosthetic and Orthotic Appliances	Prosthetic and ~~Orthodic~~ Orthotic Appliances	All prosthetic and orthotic appliances necessary for the restoration of function or replacement of body parts as prescribed by a licensed physician, podiatrist or dentist, within the scope of their license, are covered when provided by a prosthetist, orthotist or the licensed practitioner, respectively	X	X	X	X	X	X
~~Psychology,~~ Physical Therapy and ~~,~~ Occupational Therapy~~,~~ ~~Speech Pathology and Audiological Services~~	~~Psychology Listed as Other Practitioners' Services and Psychology,~~ Physical Therapy and~~,~~ Occupational Therapy~~, Speech Pathology, and Audiology Services~~	~~Psychology, P~~physical therapy and~~,~~ occupational therapy ~~, speech pathology and audiological services~~ are covered when provided by persons who meet the appropriate requirements	X[1,1,2*]	X[1,1,2]	X[1,1,2*]	X[1,1,2]	X[1,1,2]	X[1,1,2]
~~Psychotherapeutic drugs~~	~~Services not covered under the State Plan~~	~~Psychotherapeutic drugs that are listed in the Medi-Cal Provider Manual~~	~~X~~	~~X~~	~~X[8]~~	~~X~~	~~X~~	~~X~~
Rehabilitation Center Outpatient Services	Rehabilitative Services	A facility providing therapy and training for rehabilitation on an outpatient basis. The center may offer occupational therapy, physical therapy, vocational training, and special training.	X	X	X	X	X	X
Rehabilitation Center Services	Rehabilitative Services	A facility which provides an integrated multidisciplinary program of restorative services designed to upgrade or maintain the physical functioning of patients.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Renal Homotransplantation	Organ Transplant Services	Renal homotransplantation is covered only when performed in a hospital which meets the standards established by the Department for renal homotransplantation centers.	X	X	X	X	X	X
~~Requirements Applicable to EPSDT Supplemental Services.~~	~~EPSDT~~	~~Early and Periodic Screening, Diagnosis and Treatment: for beneficiaries under 21 years of age; includes case management and supplemental nursing services; also covered by CCS for CCS services, and Mental Health services.~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~	~~X~~
Respiratory Care Services	Respiratory Care Services	A provider trained and licensed for respiratory care to provide therapy, management, rehabilitation, diagnostic evaluation, and care of patients with deficiencies and abnormalities affecting the pulmonary system and aspects of cardiopulmonary and other systems.	X	X	X	X	X	X
Rural Health Clinic Services	Rural Health Clinic Services	Services described in 42 U.S.C. Section 1396d(a)(2)(B) furnished by a rural health clinic as defined in 42 U.S.C. Section 1396d(l)(1)~~Covers primary care services by a physician or a non-physician medical practitioner, as well as any supplies incident to these services; home nursing services; and any other outpatient services, supplies, and e~~Equipment and drugs~~~~.	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~	X[8] ~~X~~
Scope of Sign Language Interpreter Services	Sign Language Interpreter Services	Sign language interpreter services may be utilized for medically necessary health care services	X	X	X	X	X	X
Services provided in a State or Federal Hospital		California state hospitals provide inpatient treatment services for Californians with serious mental illnesses. Federal hospitals provide services for certain populations, such as the military, for which the federal government is responsible.						

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Short-Doyle Mental Health Medi-Cal Program Services	Short-Doyle Program	Community mental health services provided by Short-Doyle Medi-Cal providers to Medi-Cal beneficiaries are covered by the Medi-Cal program.						
Skilled Nursing Facility Services~~,~~	Nursing Facility Services and Skilled Nursing Facility Services	A skilled nursing facility is any institution, place, building, or agency which is licensed as a SNF by DHCS or is a distinct part or unit of a hospital, (except that the distinct part of a hospital does not need to be licensed as a SNF) and has been certified by DHCS for participation as a SNF in the Medi-Cal program.	~~X~~[5] X[3,~~965~~]	~~X~~[5] X[3,~~965~~]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
~~Special~~ Private Duty Nursing	~~Private Duty Nursing Services~~EPSDT	Private duty nursing is the planning of care and care of clients by nurses, whether a registered nurse or licensed practical nurse.	X[~~67~~]	X[~~67~~]	X[~~67~~]	X[~~67~~]	X[~~67~~]	X ~~X[76]~~
Specialty Mental ~~H~~health ~~S~~services		Rehabilitative services, which includes mental health services, medication support services, day treatment intensive, day rehabilitation, crisis intervention, crisis stabilization, adult residential treatment services, crisis residential services, and psychiatric health facility services.						
Specialized Rehabilitative Services in Skilled Nursing Facilities and Intermediate Care Facilities	Special Rehabilitative Services	Specialized rehabilitative services shall be covered. Such service shall include the medically necessary continuation of treatment services initiated in the hospital or short term intensive therapy expected to produce recovery of function leading to either (1) a sustained higher level of self care and discharge to home or (2) a lower level of care. Specialized rehabilitation service shall be covered.	~~X~~[5] X[3]	~~X~~[5] X[3]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]

Speech Pathology	Speech Pathology	Speech pathology services are covered when provided by persons who meet the appropriate requirements	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
State Supported Services		State funded abortion services that are provided through a secondary contract.	X	X	X	X	X	X

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Subacute Care Services	Nursing Facility Services and Skilled Subacute Care Services SNF	Subacute care services are a type of skilled nursing facility service, which is provided by a subacute care unit.	~~X~~[5] X[3,~~965~~]	~~X~~[5] X[3,~~965~~]	X	~~X~~[5] X[3]	~~X~~[5] X[3]	~~X~~[5] X[3]
Swing Bed Services	Inpatient Hospital Services	Swing bed services is additional inpatient care services for those who qualify and need additional care before returning home.	X	X	X	X	X	X
~~Targeted Case Management Services Program~~	~~Targeted Case Management~~	~~Persons who are eligible to receive targeted case management services shall consist of the following Medi-Cal beneficiary groups: high risk, persons who have language or other comprehension barriers and persons who are 18 years of age and older.~~						
Targeted Case Management and Services~~.~~	Targeted Case Management	Persons who are eligible to receive targeted case management services shall consist of the following Medi-Cal beneficiary groups: high risk, persons who have language or other comprehension barriers and persons who are 18 years of age and older. Targeted case management services shall include at least one of the following service components: A documented assessment identifying the beneficiary's needs, development of a comprehensive, written, individual service plan, implementation of the service plan includes linkage and consultation with and referral to providers of service, assistance with accessing the services identified in the service plan, crisis assistance planning to coordinate and arrange immediate service or treatment needed in those situations that appear to be emergent in nature or which require immediate attention or resolution in order to avoid, eliminate or						

		reduce a crisis situation for a specific beneficiary, periodic review of the beneficiary's progress toward achieving the service outcomes identified in the service plan to determine whether current services should be continued, modified or discontinued.						

Attachment N
Capitated Benefits Provided in Managed Care
(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Transitional Inpatient Care Services	Nursing Facility and Transitional Inpatient Care Services	Focus on transition of care from outpatient to inpatient. Inpatient care coordinators, along with providers from varying settings along the care continuum, should provide a safe and quality transition.	X	X	X	X	X	X
Tuberculosis (TB) Related Services	TB Related Services	Covers TB care and treatment in compliance with the guidelines recommended by American Thoracic Society and the Centers for Disease Control and Prevention.						

[1] ~~Chiropractic~~Optional benefits~~-Optional benefits~~ coverage is limited to only beneficiaries in "Exempt Groups": 1) beneficiaries under 21 years of age for services rendered pursuant to EPSDT program; 2) beneficiaries residing in a SNF (Nursing Facilities Level A and Level B, including subacute care facilities; 3) beneficiaries who are pregnant; 4) CCS beneficiaries; 5) beneficiaries enrolled in the PACE; and 6) beneficiaries who receive services at an FQHC (including Tribal) or RHC.~~.~~ Services include: Chiropractic Services, Audiologist and Audiology Services, and Speech Pathology.

[2] Services provided by primary care physicians; psychiatrists; psychologists; licensed clinical social workers; or other specialty mental health provider. Solano County for Partnership Health plan (COHS) covers specialty mental health, and Kaiser GMC covers inpatient, outpatient, and specialty mental health services.

~~[3] Fabrication of optical lenses only covered by CenCal Health.~~

~~[4] Not covered by CenCalCovered by CenCal as of 7/1/2016~~

~~[5]~~ [3] Only covered for the month of admission and the following month.

~~[6]~~ [4] Not covered by Gold Coast Health Plan.

Covered by CenCal Health, Central California Alliance for Health, and Health Plan of San Mateo (effective July 1, 2018). Covered by Partnership HealthPlan of California (effective January 1, 2019) and CalOptima (effective ~~January~~ July 1, 2019).

~~[7] [5] Only covered in Health Plan of San Mateo and CalOptima.~~

~~[8] Only covered in Health Plan of San Mateo~~

~~[9]~~ [6][5] Services covered under managed care only in MLTSS Eligible Beneficiary Authorized Counties: ~~Alameda,~~ Los Angeles, Orange, Riverside, San Bernardino, San Diego, San Mateo, and Santa Clara~~, and Riverside~~. IHSS benefits are not part of this covered service.

~~[10]~~ [7][6] Benefit coverage is limited to only beneficiaries under 21 years of age for services rendered pursuant to EPSDT ~~program~~requirements.

~~[11]~~ [8][7] Health Home Program (HHP) service coverage is limited to only those beneficiaries specified in the HHP State Plan Amendments (SPAs), including any subsequent amendments to the CMS-approved HHP SPAs. HHP services will be provided only through the Medi-Cal managed care delivery system to beneficiaries enrolled in managed care. Individuals receiving benefits through the fee-for-service (FFS) delivery system who meet HHP eligibility criteria, and who wish to receive HHP services, must instead enroll in an MCP to receive all services, including HHP services. HHP services will not be provided through a FFS delivery system. The HHP-specific provisions of the Medi-Cal 2020 demonstration freedom of choice waiver, and managed care delivery system implementation Medicaid authority, are in effect for any CMS-approved HHP SPAs - including SPA requirements specific to eligible populations, geographic limitation approved providers, and any other SPA requirements, including any subsequent amendments to the CMS - approved HHP SPAs – for the duration of the Medi-Cal 2020 demonstration.

[8]The fabrication of eyeglasses lenses are carved out statewide to FFS Medi-Cal contracted optical laboratories, **except specialty lenses, including lenses that exceed contract lab ranges.**

[9]California Children Services covered in COHS counties with the exception of Ventura County (Gold Coast Health Plan)

Exhibit B

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FW: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

[redacted]

Attachment N Updates ...
119 KB

Attachment N Updates ...
104 KB

Show all 2 attachments (223 KB) Download all

[redacted]

From: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>
Sent: Thursday, December 24, 2020 10:17 AM
To: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>
Cc: Young, Cheryl (CMS/CMCS) <Cheryl.Young@cms.hhs.gov>; Zolynas, Brian (CMS/CMCS) <Brian.Zolynas@cms.hhs.gov>; Cooper, Jacey@DHCS <Jacey.Cooper@dhcs.ca.gov>; Toyama, Aaron@DHCS <Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good Morning,

DHCS formally submits the attached updated Attachment N as a technical amendment request to the California Medi-Cal 2020 Demonstration Special Terms and Conditions (STCs).

Changes to Capitated Benefits Provided in Managed Care (Attachment N), an attachment to the California Medi-Cal 2020 Demonstration STCs, stem from recent legislative or administrative changes in Medi-Cal benefit policy including but not limited to the California State Auditor's assessment of the efficacy of preventive care services for children, the State's Medi-Cal Rx initiative, and the restoration of optional benefits as a result of SB 78 and AB 678. These changes are proposed to be effective on January 1, 2021, in conjunction with the State's request to extend the Medi-Cal 2020 Demonstration for 12 months, which is currently under CMS review.

Changes to Attachment N include:

- Clarification of capitated benefits categorized under the Early and Periodic Screening, Diagnostic and Treatment entitlement.

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- In-Home Medical Care Waiver Services was removed.
- Other services updated for clarification include: hysterectomy within all managed care model types and non-emergency medical transportation.
- Updates were made to previously optional benefits, such as fabrication of lenses and the provision of podiatry services with prior authorization.
- Alameda county was removed from the list of Coordinated Care Initiative (CCI) counties.
- Updates to service definitions for dental and outpatient mental health and outpatient rehabilitative services, Federally Qualified Health Care Centers (FQHCs), and Rural Health Clinics.
- Footnotes were appropriately updated to reflect all changes.

Please let us know if CMS has any questions on this amendment request. Thank you, and happy holidays!

Amanda Font
California Department of Health Care Services
Director's Office

Exhibit C

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FW: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

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[redacted]

From: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>
Sent: Tuesday, December 29, 2020 3:35 AM
To: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>
Cc: Young, Cheryl (CMS/CMCS) <Cheryl.Young@cms.hhs.gov>; Zolynas, Brian (CMS/CMCS) <Brian.Zolynas@cms.hhs.gov>; Cooper, Jacey@DHCS <Jacey.Cooper@dhcs.ca.gov>; Toyama, Aaron@DHCS <Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: RE: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good morning Amanda,
Thank you for the information. CMS will review the attachment. I would like to let the state know that CMS will not be incorporating this attachment into the STCs for the temporary extension request for December 31, 2020, but we are going to review the information to be updated to the STCs with the other updates to the CA STCs within the state's original extension request. CMS understands that the pharmacy update is not to happen until April 1, 2021 and we are working to make sure this attachment will be incorporated before that time.

If you have additional questions, please reach out to Julian Taylor and myself to discuss.
Thank you
Heather Ross

From: Font, Amanda@DHCS <Amanda.Font@dhcs.ca.gov>
Sent: Thursday, December 24, 2020 1:17 PM
To: Ross, Heather V. (CMS/CMCS) <Heather.Ross@cms.hhs.gov>; Nawara, Lorraine (CMS/CMCS) <Lorraine.Nawara1@cms.hhs.gov>; Taylor, Julian (CMS/CMCS) <Julian.Taylor@cms.hhs.gov>

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<Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good Morning,

DHCS formally submits the attached updated Attachment N as a technical amendment request to the California Medi-Cal 2020 Demonstration Special Terms and Conditions (STCs).

Changes to Capitated Benefits Provided in Managed Care (Attachment N), an attachment to the California Medi-Cal 2020 Demonstration STCs, stem from recent legislative or administrative changes in Medi-Cal benefit policy including but not limited to the California State Auditor's assessment of the efficacy of preventive care services for children, the State's Medi-Cal Rx initiative, and the restoration of optional benefits as a result of SB 78 and AB 678. These changes are proposed to be effective on January 1, 2021, in conjunction with the State's request to extend the Medi-Cal 2020 Demonstration for 12 months, which is currently under CMS review.

Changes to Attachment N include:

- Clarification of capitated benefits categorized under the Early and Periodic Screening, Diagnostic and Treatment entitlement.
- Clarification of specific drug and medical supplies categories both prior to, and after, the April 1, 2021 implementation of Medi-Cal Rx, to make necessary updates associated with Medi-Cal Rx initiative.
- In-Home Medical Care Waiver Services was removed.
- Other services updated for clarification include: hysterectomy within all managed care model types and non-emergency medical transportation.
- Updates were made to previously optional benefits, such as fabrication of lenses and the provision of podiatry services with prior authorization.
- Alameda county was removed from the list of Coordinated Care Initiative (CCI) counties.
- Updates to service definitions for dental and outpatient mental health and outpatient rehabilitative services, Federally Qualified Health Care Centers (FQHCs), and Rural Health Clinics.
- Footnotes were appropriately updated to reflect all changes.

Please let us know if CMS has any questions on this amendment request. Thank you, and happy holidays!

Amanda Font
California Department of Health Care Services
Director's Office

Exhibit D

Christopher M. House

From: caed_cmecf_helpdesk@caed.uscourts.gov
Sent: Tuesday, March 9, 2021 4:14 PM
To: CourtMail@caed.uscourts.dcn
Subject: [EXTERNAL] Activity in Case 2:20-cv-02171-JAM-KJN Community Health Center Alliance for Patient Access et al v. Lightbourne et al Order on Motion to Dismiss.

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U.S. District Court

Eastern District of California - Live System

Notice of Electronic Filing

The following transaction was entered on 3/9/2021 at 4:13 PM PST and filed on 3/9/2021
Case Name: Community Health Center Alliance for Patient Access et al v. Lightbourne et al
Case Number: 2:20-cv-02171-JAM-KJN
Filer:
Document Number: 37(No document attached)

Docket Text:
MINUTES for proceedings held via video conference before District Judge John A. Mendez: MOTION HEARING re Plaintiffs' pending [22] Motion for Preliminary Injunction and Defendants' pending [23] Motion to Dismiss held on 3/9/2021. A. Stroud, R. Boyle and K. Doi appeared via video for the plaintiffs. J. Sondheimer appeared via video for the defendants. The Court and Counsel discussed Plaintiffs' pending Motion for Preliminary Injunction and Defendants' pending Motion to Dismiss. After arguments, for the reasons stated on the record, the Court GRANTED Defendants' [23] Motion to Dismiss without prejudice and ORDERED Plaintiffs wait to file an amended complaint until after CMS acts on the approval sought by Defendants. Court Reporter: J. Coulthard. [TEXT ONLY ENTRY] (Michel, G.)

2:20-cv-02171-JAM-KJN Notice has been electronically mailed to:

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2:20-cv-02171-JAM-KJN Electronically filed documents must be served conventionally by the filer to:

Exhibit E

From: DHCS Communications <DHCSCommunications@DHCS.CA.GOV>
Sent: Wednesday, February 17, 2021 5:12 PM
To: DHCSSTAKEHOLDERS@MAILLIST.DHS.CA.GOV
Subject: [EXTERNAL] Important Update on Medi-Cal Rx

Dear Stakeholders,

The Department of Health Care Services (DHCS) is delaying the planned Go Live date of April 1, 2021, for Medi-Cal Rx because of the need to review new conflict avoidance protocols submitted by Magellan Health, the project's contracted vendor.

In January 2021, Centene Corporation announced that it plans to acquire Magellan. Centene operates – through subsidiaries – managed care plans and pharmacies that participate in Medi-Cal. This transaction was unexpected and requires additional time for exploration of acceptable conflict avoidance protocols to ensure that there will be acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal beneficiaries, and to protect other proprietary information.

Medi-Cal Rx remains of utmost importance to the State of California as a tool to standardize the Medi-Cal pharmacy benefit statewide under one delivery system. It will improve access to pharmacy services with a network that includes approximately 94 percent of the state's pharmacies. Medi-Cal Rx will also apply statewide utilization management protocols to all outpatient drugs, standardizing the experience for all Medi-Cal beneficiaries and providers. Medi-Cal Rx will also strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers, helping to reduce pharmaceutical costs.

DHCS anticipates providing further information in May.

If you have any questions, please feel free to direct them to the Medi-Cal Rx Project Team at RxCarveOut@dhcs.ca.gov.

Thank you,
DHCS

From: Medi-Cal Rx Education and Outreach Team <postmaster@dhcs.ca.gov>
Sent: Wednesday, February 17, 2021 5:53 PM
To: Kathryn E. Doi
Subject: [EXTERNAL] Medi-Cal Rx News: Important Update on Medi-Cal Rx

MCRxSS Announcement

The Important Update on Medi-Cal Rx alert posted to the Medi-Cal Rx Web Portal on 2/17/2021.

If the above link does not take you to the alert, then simply copy and paste the following link into your browser to access the Bulletins and News page: https://medi-calrx.dhcs.ca.gov/provider/pharmacy-news.

***Please note: Internet Explorer is no longer a supported web browser. Please utilize Chrome, Microsoft Edge, or another supported web browser when clicking on links for the Medi-Cal Rx Web Portal.

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Important Update on Medi-Cal Rx

February 17, 2021

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DHCS anticipates providing further information in May. Please note that DHCS will be working to update and/or remove, as applicable, provider guidance and associated Medi-Cal Rx provider bulletins/Newsflash articles in the coming weeks to reflect this change.

Exhibit B
to letter dated 4/16/2021

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Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF FRANCISCO CASTILLON IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Francisco Castillon, declare as follows:

1. I am the Chief Executive Officer ("CEO") at Omni Family Health ("OFH") and have held this role since May 2011. As CEO, I am responsible for overseeing the organization of thirty-five (35) health centers and four (4) pharmacies. In addition, I have

oversight of OFH's 340B Program. I have reviewed the data relevant to impact of the Medi-Cal Rx Transition on OFH in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. OFH is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act that meets all requirements in Section 330 of the Public Health Service Act. OFH has been in business since 1978 and operates health centers in Kern, Fresno, Tulare, and Kings Counties.

3. OFH provides pharmaceutical services through four licensed pharmacies and two clinic dispensaries, as well as through eighty (80) 340B contract pharmacies.

4. In order to comply with applicable State and Federal law relating to the 340B program OFH has registered each of our FQHC sites that dispenses drugs to Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B drugs to our Medi-Cal patients.

5. In 2019 our cost of providing pharmacy services, including the cost of pharmaceuticals, through in-house pharmacies, contract pharmacies and our clinic dispensary license was $7,085,757.00

6. Approximately seventy percent of the patients utilizing our pharmacy services were Medi-Cal beneficiaries, thus Medi-Cal's share of the total cost was approximately $4,960,029.90.

7. OFH carved its pharmacy services costs out of our Medi-Cal prospective payment rate as to our in-house and contract pharmacy services, and is currently reimbursed for these services under the fee schedules applicable to California's Alternative Payment Methodology ("APM"). As a practical matter, this means that we are reimbursed by Medi-Cal managed care plans at a negotiated rate under the APM.

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8. OFH does not dispense 340B drugs (or any drugs) to Medi-Cal beneficiaries who are reimbursed by Medi-Cal's fee-for-service system through contract pharmacies.

9. OFH's in-house pharmacies dispense an extremely limited volume of drugs to Medi-Cal fee-for-service beneficiaries since the majority of our Medi-Cal patients are enrolled in managed care plans. Medicaid managed care plans, under non-discrimination provisions of State and Federal law, are prohibited from paying FQHCs less than they pay to other health care providers furnishing similar services.

10. Fee-for-service reimbursement paid to 340B Covered Entities, including OFH, is limited to the "actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee" of either $10.05 or $13.20, depending on the pharmacy's dispensing volume. This has not had a significant negative impact on OFH to-date, since we have had few prescriptions reimbursed under this methodology.

11. Under this fee-for-service reimbursement methodology, however, the cost of the drug must be determined by the FQHC on a claim-by-claim basis, which would eliminate the benefit intended for the 340B program (allowing us to stretch scarce federal resources through the gap between generally applicable reimbursement and the special discount accorded 340B covered entities), but it would significantly increase our administrative and facility costs associated with dispensing these drugs, since we would no longer be able to fill Medi-Cal prescriptions through low-cost contract pharmacies.

12. If the Medi-Cal Rx Transition became effective on April 1, 2021, approximately seventy percent of our prescriptions would be filled through Medi-Cal's 340B-specific fee-for-service reimbursement schedule. This will require changes to our current operations, which may include discontinuing home delivery of drugs to those unable to come to the clinic for health reasons or due to a lack of transportation. Additionally, we would need to discontinue stocking of more expensive medications.

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13. If the Medi-Cal Rx Transition became effective, there is a risk that we will have to close the two pharmacies that are carved into our PPS rate, since we are not reimbursed for the cost of these drugs except through a historical assessment of costs that has not kept up with the changes in drug prices, and since we are not reimbursed for pharmacy visits on a per-visit basis. These two pharmacies serve agricultural, rural areas, in which many of our patients are undocumented, and for whom filling prescriptions through our health center is the sole available option. Many of our patients have no access to a pharmacy within a 30-minute drive. We are currently able to fill their prescriptions for the uninsured on a sliding fee scale, consistent with the "open door" requirements applicable to health centers. If we are unable to continue providing pharmaceutical services to these patients at our current level, there will be a severe impact on the quality of care we are able to provide. Our most vulnerable patients will not be able to receive required medications from us, and unless they are able to find another source of care, will likely discontinue taking medications. This would particularly impact patients with diabetes, heart conditions, and patients receiving treatment for opioid addiction through our Medication Assistant Therapy ("MAT") program. Many of our migrant farmworker patients are working in the field all day. They cannot just pop into a local pharmacy, particularly if ours is forced to close.

14. California law requires FQHCs that are reimbursed for pharmaceutical services outside of their PPS rate to be reimbursed for drugs dispensed to Medi-Cal beneficiaries through a dispensary in accordance with Welfare & Inst. Code § 14132.01. With the exception of Medi-Cal beneficiaries enrolled in the Family Planning Access Care and Treatment Program ("Family PACT"), there is currently no billing system in place that would permit us to be reimbursed under this statute.

15. Additionally, our reimbursement for Family PACT drugs has at no time been assessed by DHCS to ensure that it fully covers our cost of providing such services.

16. According to the Uniform Data System ("UDS") report that OFH submitted to the federal Health Resources and Services Administration ("HRSA") for 2019, OFH

provided primary care services to 131,449 unduplicated patients, and had 588,936 patient visits (encounters). The distribution of OFH patients as a percentage of poverty guidelines is 62,160 patients (47.29%) at 100 percent and below the federal poverty level; 10,102 patients (7.69%) at 101 to 150 percent of the federal poverty level; 4,009 patients (3.05%) at 151 to 200 percent of the federal poverty level; 2,433 patients (1.85%) at over 200 percent of the federal poverty level; and 52,745 patients (40.13%) whose percent of the federal poverty level is unknown.

17. OFH also reported the following with respect to the special populations served by our clinics: Migrant/Seasonal = 41,735 patients, Homeless patients = 647, and Veterans = 163.

18. The UDS report also captured OFH's demographic makeup, the largest categories consist of the following: Hispanic/Latino = 52,573 and White Non-Hispanic/Latino = 27,644, followed by African American = 5,582.

19. As reported on our UDS report, with respect to OFH visits involving patients with two or more diseases/diagnoses, the most common diseases/diagnoses involved were: Diabetes Mellitus = 37,494 visits, Overweight and Obesity = 48,295, Hypertension = 52,168, and Heart Disease = 4,747. In addition, the most common visits provided for mental health conditions and substance disorders were: anxiety disorder/PTSD = 37,001, depression and mood disorders = 39,324, and other mental disorders (excluding drug or alcohol dependence) = 22,011.

20. OFH's participation in the 340B Drug Pricing Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as OFH's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population. OFH passes the 340B savings on to its patients by providing uninsured patients of OFH making less than 200 percent of the federal poverty limit a sliding scale discount on all services including significant discounts for medication at OFH's in-house pharmacy. In addition to providing access to

affordable medications for low-income uninsured patients through our sliding scale discount and other prescription savings programs, OFH's 340B savings are reinvested into the cost of providing services that the Medi-Cal program does not include in OFH's prospective payment system per-visit rate, such as having in-house outreach staff, case managers, care coordinators, referral staff, call center staff, pharmacy technicians, and other ancillary support that enhance services provided by the primary care team.

21. OFH's current 340B prescription drug program includes five (5) onsite and eighty (80) contract pharmacy sites. From January 1, 2020 through September 30, 2020, OFH's in-house pharmacies filled 228,791 prescriptions, 26,861 of which were prescriptions filled for uninsured patients. OFH's 80 contract pharmacies filled nearly 10,000 prescriptions, of which over 10 percent were dispensed for uninsured patients.

22. OFH's 2019 UDS report also identified two key payer groups who made up over 80 percent of the overall payer mix:

Medi-Cal Managed Care (MCO)	93,214 patients (71%)
Uninsured	13,821 patients (11%)
Total	**107,035 patients (82%)**

23. In 2019, OFH recognized an estimated net 340B income (reimbursement minus drug costs and program overhead) of $4,200,000 (over 70% of total) from filling Medi-Cal managed care (MCO) patient prescriptions. This net 340B benefit was and continues to be used for "stretching scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" not typically covered by Medi-Cal managed care (MCO) including the following. Our fifth pharmacy having opened only recently, the numbers presented represent the totals from 4 pharmacies.

24. Five in-house pharmacies ensure access to affordable prescription drugs through:

- Free home delivery and delivery options for patients residing in rural areas without local pharmacy access.

- Opening new locations to expand access to services and outreach to new patients, including clinic and pharmacy onsite services.
- Ensuring adequate resource funding for clinic programs and onsite pharmacies that have demonstrated nationally having a significant positive impact on emergency room utilization, improved coordination of care, and improved outcomes for such chronic conditions as asthma and diabetes.

25. OFH estimates 340B savings generated from our pharmacies through the 340B Drug Pricing Program account for about 20 percent of our direct patient care staffing expenses.

26. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes the prescriptions affordable for all patients, including the uninsured. In addition, the savings retained by OFH are utilized to serve even more patients and to increase comprehensive services at no cost to the taxpayer. Because of this action taken by California's Governor to eliminate 340B savings, patient services and programs such as having a call center, referral center, case management, onsite pharmacies, pharmacy technicians, care coordinators, and in-house behavioral services, and dental services are at risk of being significantly reduced or eliminated. This, in turn, puts our patients at risk for increased access to care issues, as well as health problems that increase health care costs to the entire primary care medical home health care system. In addition to the loss of services, higher costs, poorer patient outcomes, and loss of employee positions, losing contract pharmacy 340B savings would negatively affect strategic plans for a much needed facility expansion aimed at increasing our ability to serve more of the uninsured is frightening and will be devastating to the health outcomes of our patients.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 19th day of December 2020, in Sacramento, California.

Francisco Castillon

Exhibit C
to letter dated 4/16/2021

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Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF C. DEAN GERMANO IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, C. Dean Germano, declare as follows:

1. I am the Chief Executive Officer ("CEO") of Shasta Community Health Center ("SCHC") and have been in this position since 1992. I am a past Board President of the California Primary Care Association ("CPCA") and am currently Board Emeritus

with CPCA. I am also a past Chair of the Shasta County Public Health Advisory Board, and past-Chair and current member of Golden Umbrella and Senior Nutrition Centers (Dignity Health Affiliates) Advisory Board in Redding, California. I am also past Chair and current member of the Health Alliance of Northern California ("HANC"), an organization that represents Federally Qualified Health Centers ("FQHCs") in the Shasta region, working with hospitals and medical groups to create positive community health systems changes in our region. Beginning in 2006, I was selected to the Board of The California Endowment (the "Endowment"), a $3+ billion statewide healthcare foundation dedicated to improving the health and well-being of all Californians. In 2012, I served as Vice-Chair of the Board of the Endowment, and then served as its Chair until my nine-year term ended in 2015. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. As CEO of SCHC, I am responsible for overseeing care to 40,000 unduplicated patients, providing over 130,000 visits a year in a multi-specialty type practice that includes mental health and dental. Over 92% of SCHC's patients live below 200% of the federal poverty line. I also have oversight of our 340B Program. For many years, the savings that SCHC has retained through the discounted drug purchase prices available through the 340B program has been used to benefit our patients through such things as the passing of the 340B price to our uninsured and underinsured patients, allowing us to charge many sliding fee patients no more than $10 for prescriptions at our contract pharmacies, and providing services such as transportation assistance, covering a significant portion of lab costs for sliding fee patients, and covering patient education services and gap funding for departments that are not profitable, such as telemedicine. In 2019, SCHC's 340B Medi-Cal savings totaled $1.79 million. The Medi-Cal transition to managed care would result in a loss of these savings and would force SCHC to make cuts to these programs that will have a negative impact on patient care and service to our community.

3. Following the Governor's announcement of the pharmacy transition in January 7, 2019, , the California Primary Care Association ("CPCA") began to advocate with the Department of Health Care Services (the "Department") to address the revenue impact that FQHCs were going to experience as a result of the pharmacy transition. I was familiar with these efforts through my participation with CPCA as an emeritus board member and through my active participation in various CPCA committees and meetings.

4. The Department ultimately agreed to support legislation that would establish a "supplemental payment pool" ("SPP"), which is intended to compensate community health centers who will lose Medi-Cal managed care 340B savings if the State transitions the pharmaceutical benefit away from managed care plans and into fee for service.

5. In connection with establishing the SPP, in the fall of 2019, the Department and CPCA asked community health centers to report their projected loss of 340B savings to the State. According to CPCA, 109 community health centers submitted data to the State and 91 submitted data to CPCA and the State. The total amount of lost savings reported by the community health centers that responded to the data request was $105 million. CPCA staff and the CPCA board also appointed a "Solutions Team" to work with the Department regarding implementation of the SPP. I was one of the people appointed to the Solutions Team.

6. The Governor's January 2020 budget included the SPP for non-hospital based clinics in the sum of $105 million ($52.5 million in State funds; $52.5 million in presumed federal matching funds). In February 2020, CPCA staff and the Solutions Team met with Department leadership regarding implementation of the SPP.

7. In March, COVID-19 hit and the Department's focus shifted to addressing the pandemic. CPCA and others urged the Newsom Administration to delay the pharmacy transition given the challenges that were already facing FQHCs, which were on the front line of the pandemic serving the low income communities that were

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disproportionately impacted by the pandemic. The Administration did not agree to a delay.

8. In May, analysts predicted a $54 billion state budget deficit due to COVID-19. Dozens of programs and services were proposed to be cut in the Governor's May Revise budget, including the $105 million SPP.

9. Ultimately, the SPP was adopted in the Budget Trailer Bill, and codified as California Welfare & Institutions Code § 14105.467, which became effective on June 29, 2020. This legislation requires the Department to "establish, Implement, and maintain a supplemental payment pool for nonhospital 340B community clinics, subject to an appropriation by the Legislature." Qualifying FQHCs are to receive fee-for-service-based supplemental payments from a fixed-amount payment pool to compensate them for their loss of 340B program revenue.

10. Section 14105.467(b) further provides: "Beginning January 1, 2021, and any subsequent fiscal year to the extent funds are appropriated by the Legislature for the purpose described in this section, the department shall make available fee-for-service-based supplemental payments from a fixed-amount payment pool to qualifying nonhospital 340B community clinics in accordance with this section and any terms of federal approval ...."

11. Section 14105.467 also requires the Department to establish a stakeholder process that "shall be utilized to develop and implement the methodology for distribution of supplemental pool payments to qualifying nonhospital 340B community clinics." Section 14105.467 further requires the Department to conduct at least three meetings with stakeholders and to finalize the methodology for distribution no later than October 1, 2020.

12. Two stakeholder meetings were held in August and September 2020. Some of the Department's articulated goals/requirements for the process included:

(a) The federal government (the Centers for Medicare and Medicaid Services, or CMS) would approve the federal matching funds.

(b) The purpose of the SPP is to mitigate the impact of the pharmacy transition on community health centers.

(c) The SPP would be simple to administer.

(d) The SPP will be renewed annually.

(e) The SPP will be equitably distributed among the FQHCs losing the benefit of the 340B savings as long as the proposed distribution is acceptable to CMS.

13. Unfortunately, accomplishing these goals has been more challenging than anticipated and the October 1, 2020 statutory deadline for finalizing the methodology for distribution is now long past and the methodology for distribution of the SPP is not finalized today, as 2020 comes to a close.

14. In addition, CPCA has been told by the Department that the Department will be submitting a State Plan Amendment ("SPA") to authorize the SPP. To date, based on the information posted on the Department's website relating to proposed or pending SPAs, no proposed SPA has been submitted relating to the SPP, nor has any other federal approval been requested or obtained for the SPP.

15. Some of the challenges with the SPP concept that have surfaced are:

(a) Not all FQHCs who will suffer a loss of 340B savings submitted data in response to the 2019 request of CPCA and the Department, such that the $105 million that was to fund the SPP for the current fiscal year will not fully compensate all FQHCs who are participating in the 340B program for the loss of the 340B revenue.

(b) The allocation methodology under discussion would allow FQHCs that did not submit data regarding the loss in 340B savings in response to the 2019 call for data to participate in the SPP, such that FQHCs that did submit data will not be fully reimbursed in the amount reported and FQHCs that did not submit data will receive a share of the SPP.

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(c) We have been advised that CMS is requiring that all FQHCs be eligible to participate in the SPP, not just FQHCs that submitted survey data in 2019, and not just FQHCs that will be losing 340B savings. In addition, the proposal is for FQHCs to submit claims for supplemental payments based on submission of *medical claims*, not *pharmacy claims*, such that FQHCs that did not even participate in the 340B program will share in the SPP, and resulting in a further reduction of supplemental payments to the FQHCs that will be losing revenue due to the pharmacy transition. Moreover, FQHCs with high average pharmacy costs but fewer visits would receive less than the amount of their loss in 340B savings and FQHCs with relatively low average pharmacy costs but a high visit count would receive more than the amount of their loss in 340B savings. The only way to prevent this result would be for FQHCs to agree to a redistribution of payments they receive from the Medi-Cal program in order to fulfill the purpose of the SPP, which was to compensate FQHCs who participate in the 340B program for lost savings. This would require an enormous administrative burden and the nearly full cooperation of the health centers, including those who would claim a windfall from this methodology at the expense of those who will otherwise incur real losses as a result of these changes.

16. For the foregoing reasons, by all appearances, the SPP will not be a short- or long-term viable solution to address the significant financial impact that the pharmacy transition will have on FQHCs like SCHC.

17. Shasta County, where SCHC is located, has been hard hit by COVID-19. SCHC is at the heart of the battle against the COVID-19 pandemic in Shasta County. As the largest community clinic organization serving the area, SCHCs services are provided in an already disadvantaged community and one hit hardest by the pandemic. As evidenced by the positivity rates seen at SCHC, health center patients carry more COVID-19 burden than the general population. Since the onset of the pandemic in

March 2020, SCHC has performed 1,883 COVID-19 PCR tests with a 6% overall test positivity rate. SCHC has also performed over 3,231 COVID point-of-care tests (same day results) with an overall positivity rate of 11.7%. These results are taken from the start of the pandemic in March 2020 to December 22, 2020. In the last weeks of November and into December 2020, SCHCs test positivity rate fluctuated between 12 and 17.5% for both types of COVID testing. Thus, SCHC, and FQHCs like ours, are at ground zero of the COVID-19 pandemic. Eliminating the savings we realize through the current 340B structure would be devastating to our ability to continue to care for a population with such high test positivity rates. As we near 2021, the drain on SCHC has become even more grave. With high levels of virus in the community, our providers and support staff are becoming positive at higher rates. The staffing shortage that creates along with the dual struggle of increased demand for testing while trying to first vaccinate our own staff and then the high-risk populations we care for put SCHC at particular disadvantage.

18. If the pharmacy transition is allowed to move forward on April 1, 2021, SCHC will need to implement an Immediate reduction of the amount of prescription drugs we could subsidize for our sliding fee patients. In addition, we would likely cut telemedicine services, which would have a large impact on access to specialists in our largely rural area. Patients, some of whom have little or no transportation, would be forced to travel several hours to access these services, and, as a result of the revenue impact, we would also likely have to cut back transportation assistance. Access to affordable medications and to services such as telemedicine sub-specialty care would be a major set-back in our mostly rural underserved region. The loss of patient education services, that is not typically covered by anyone except maybe through grants, would be a major loss. As a major provider of care for the medically underserved in this region, the loss of access capacity would be felt throughout of community. About a third of our county is low income and we care for about 70% of the low income population, what happens to our programs and services is deeply felt.

19. Over the years, SCHC has submitted change-in-scope-of-services requests ("CSOSRs") to DHCS in connection with changes in the scope of SCHC's services that increased costs and constituted grounds for an adjustment to SCHC's prospective payment system rates. In connection with each of these CSOSRs, at the end of the audit process, DHCS applied the 80% adjustment factor to reduce the increase in SCHC's actual and reasonable costs by 20% before adding the adjusted increase to SCHC's PPS rates.

20. In my capacity as CEO of SCHC I am also a member of the Board of Directors of Partnership Health Plan of California ("PHP"), a non-profit community based health care organization that contracts with the State to administer Medi-Cal benefits through local care providers, as the Shasta County Community Health Center Representative. In this role, I am familiar with the contract that the State has with Medi-Cal managed care plans like PHP to manage the care of the Medi-Cal beneficiaries who receive their health care through Medi-Cal managed care. One of the most critical elements of the agreement between the State and a Medi-Cal managed care plan is the range of capitated benefits that will be provided to Medi-Cal beneficiaries under the plan, which is reflected in Attachment N to California's 1115 Waiver. The State pays the managed care plan a capitated rate per patient to manage and coordinate the covered services that are listed on the list of capitated benefits, and the managed care plan is responsible for contracting with downstream providers to provide those services. Thus, a change to the list of capitated benefits provided in managed care is a major substantive change that has a ripple effect from the State to the managed care plans to the providers of health care services to the Medi-Cal beneficiaries who receive those services. Such a change is not a "technical" change because it has a real and substantive impact up and

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down the chain relating to the provision of services, including the benefits available to the Medi-Cal beneficiaries who will receive those services.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of December, 2020, in Redding, California.

[redacted]

Exhibit D
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF RICARDO ROMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Ricardo Roman, declare as follows:

1. I am the Chief Financial Officer ("CFO") at Family Health Centers of San Diego ("FHCSD") and have held this role since September 2010. As CFO, I report directly to the Chief Executive Officer ("CEO") and am responsible for leading and

overseeing all financial aspects of FHCSD, including accounting, financial reporting, budgeting, and other financial matters. In addition, I am responsible for the oversight of our 340B program. I have reviewed the data and associated outcomes relevant to the impact of the Medi-Cal Rx Transition on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives federal grant funding under Section 330 of the Public Health Service Act. FHCSD meets all current statutory requirements under Section 330 of the Public Health Service Act. FHCSD has served the medically underserved communities of San Diego County since 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health Center, the flagship clinic of FHCSD. FHCSD has since transformed into the tenth largest health center in the country (47 service delivery sites), providing care to over 149,000 patients each year, of whom 90 percent are low income (under 200% of Federal Poverty Level) and 31 percent are uninsured. FHCSD serves all patients regardless of their ability to pay.

3. FHCSD provides pharmaceutical services primarily through one hundred and eighty one (181) 340B contract pharmacies.

4. In order to comply with applicable State and Federal law relating to the 340B program, FHCSD has registered each of our FQHC sites that dispenses drugs to Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B drugs to our Medi-Cal fee-for-service patients.

5. FHCSD does not dispense 340B drugs (or any drugs) to Medi-Cal beneficiaries who are reimbursed by Medi-Cal's fee-for-service system through contract pharmacies. We exclude the dispensing of 340B drugs to Medi-Cal fee-for-service beneficiaries, in part because the reimbursement does not cover our cost of dispensing drugs under the fee-for-service reimbursement methodology, under which we would be

paid at "actual acquisition cost" plus a $10.05 or $13.20 dispensing fee.

6. FHCSD's in-house pharmacies dispense an extremely limited volume of drugs to Medi-Cal fee-for-service beneficiaries since the majority of our Medi-Cal patients are enrolled in managed care plans. Medicaid managed care plans, under non-discrimination provisions of State and Federal law, are prohibited from paying FQHCs less than they pay to other health care providers furnishing similar services.

7. Fee-for-service reimbursement paid to 340B Covered Entities, including FHCSD, is limited to the "actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee" of either $10.05 or $13.20, depending on the pharmacy's dispensing volume. This has not had a significant negative impact on FHCSD to-date, since we have had few prescriptions reimbursed under this methodology.

8. If the Medi-Cal Rx Transition becomes effective on April 1, 2021, we would entirely discontinue dispensing drugs to Medi-Cal beneficiaries through our contract pharmacies, and we would need to identify additional funds to subsidize our existing pharmacy facility and drug costs.

9. According to the most recent FHCSD Uniform Data System (UDS) report submitted to the federal Health Resources & Services Administration (HRSA) for 2019, FHCSD conducted clinic visits with the following distribution of services for the 149,244 unduplicated FQHC patient population.

Clinical Service	Number of Patients	Percent of Patients	Number of Visits	Percent of Visits
Medical (Primary Care)	126,178	84.54%	457,021	50.73%
Dental	24,344	16.31%	70,816	7.86%
Mental Health	18,819	12.61%	110,624	12.28%
Substance Abuse	1,504	1.01%	18,046	2.00%
Other Professional Services	28,844	19.33%	121,286	13.46%

Vision	13,149	8.81%	16,120	1.79%
Enabling Services	28,560	19.14%	107,022	11.88%
Total	**N/A**	**N/A**	**900,935**	**100.00%**

Note: Total number and percent of patients is not applicable since individual patients may have received more than one visit across the seven categories of patient visits or encounters.

10. The distribution of FHCSD patients as a percentage of federal poverty guidelines in 2019 was 109,876 (73.62%) at or below 100 percent of the federal poverty guideline and 134,225 (89.94%) at or below 200 percent of the federal poverty guideline. Please note: the percent of patients at or below 100 percent of the federal poverty guideline, is included in the value for the patients at or below 200 percent of the federal poverty guideline.

11. In 2019, FHCSD's payer mix included the following key groupings:

- Medicaid/CHIP 87,330 patients (58.51%)
- None/Uninsured 46,966 patients (31.47%)
- Medicare 8,159 patients (5.47%)
- Other Third-Party Payers 5,688 patients (3.81%)
- Dually Eligible 1,101 patients (.74%)

12. Other population and/or patient important demographic and clinical management-related indicators reported in the 2019 FHCSD filed UDS report included:

Indicator	Number of Patients	Percent of Patients
Special Populations		
Homeless	26,859	18.00%
School-Based	9,131	6.12%
Veterans	1,841	1.23%
Agricultural	1,214	.81%
Age		
Children (<18 years)	36,659	24.56%
Adults (18 to 64 years)	102,429	68.63%
Adults (65 and over)	10,156	6.80%

Race		
Asian	9,506	6.37%
Native Hawaiian/Other Pacific Islander	1,090	.73%
Black/African American	13,331	8.93%
American Indian/Alaska Native	839	.56%
White	91,968	61.62%
More than 1 Race	6,249	4.19%
Race Unreported/Refused	26,261	17.60%
Ethnicity		
Hispanic/Latino	81,076	54.33%
Non-Hispanic	56,032	37.54%
Ethnicity Unreported/Refused	12,136	8.13%
Medical Conditions		
Hypertension	23,482	15.73%
Diabetes	13,015	8.72%
Asthma	7,025	4.71%
Symptomatic/Asymptomatic HIV	1,361	.91%
Prenatal Care Patients		
Number of Patients	3,650	100.00%
Number of Patients who Delivered	2,017	55.26%
Chronic Disease Management		
Use of Appropriate Meds for Asthma	1,127	93.70%
Statin Therapy for Prevention & Treatment of Cardiovascular Disease	13,663	78.70%
Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	2,245	89.67%
Controlling High Blood Pressure	21,886	69.74%
Diabetes: Controlling Hemoglobin A1c	12,656	64.08%
% of Patients Seen for Follow-up within 90 days of first ever HIV diagnosis	46	86.96%

13. The purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." FHCSD's participation in the 340B program allows the organization to stretch scarce resources to meet the needs of the medically underserved residents of San Diego County. This includes the most vulnerable high-risk populations (*e.g.*, uninsured, underinsured, elderly, and disabled patients). Under federal law, regulation, and program guidance, grantee programs are expected to reinvest their 340B net savings directly back into services provided to their patient populations. From July 1, 2018 to June 30, 2019, FHCSD's 340B onsite pharmacy and contract pharmacy

programs recognized total gross revenues from the Medi-Cal managed care ("MCO") patient population of $13,329,936 with a net program savings (gross revenues less program and drug replenishments costs) of $5,113,166. FHCSD utilized these net 340B savings to fund the following services and programs in circumstances where health reimbursements do not keep up with the costs.

- Affordable Patient Medication & Pharmacy Programs
- HIV and Hep C Patient Screening and Care Management
- Expanded Patient Vision Services
- Increased Access to Mobile Medical & Mental Health Services
- Expanded Older Adult Patient Services
- Critical Workforce Development Initiatives
- Expanded Clinical Patient Services
- Patient Weight Management Program
- Expanded Patient Health Education
- Urgent Care Services
- Patient Clinical Care Coordination/Patient Case Management
- Expanded Patient Specialty Services
- Patient Quality Improvement Staff and Programs
- Clinical Computer Upgrades
- Clinical Infrastructure Upgrades
- Patient Substance Abuse and MAT Programs
- Clinical Lab and Point of Care Testing Upgrades
- Expanded Podiatry Services
- Patient Security Control
- PHI Security and Server Upgrades

14. Under HRSA regulation and grantee scope of service requirements and guidance, FQHCs utilize their 340B net savings to:

- Provide uninsured patients with access to prescription drugs paid for by the health center;
- Subsidize care for the patient population with incomes below 200 percent of federal poverty guidelines who participate in FHCSD's sliding-scale payment programs; and
- Subsidize care not covered under Medi-Cal or other key payers (e.g., Medicare, California Children's Services, etc.).

15. FHCSD's MCO patient population accounts for approximately 71 percent of the 340B savings achieved through FHCSD's onsite pharmacy and contract pharmacy programs. From July 1, 2020 to June 30, 2021 (annualized), the FHCSD 340B pharmacy programs are anticipated to generate gross revenues of $39,107,192 with net program savings (gross revenues minus program and drug replenishment costs) of $17,256,644. This is based on estimates of filling 709,156 prescriptions (annualized) or 59,096 pharmacy claims per month. The estimated loss in net 340B benefits due to the Medi-Cal pharmacy program transition will be $12,164,687 (71 percent of total net 340B Program savings). These lost savings will have a negative impact on access, targeted patient clinical disease state programs, and enabling services for the most vulnerable patients. As a result, an unnecessary adverse impact will occur in such important quality and cost related indicators including: unnecessary emergency room/urgent care utilization, increased hospital admissions, increases in diabetes complications rates, lower health screening rates, and lower improvement of disease management outcomes.

16. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes prescription drugs affordable for all FQHC patients, including the uninsured and underinsured. In addition, the savings retained by FHCSD allow it to continue to serve more patients and to increase comprehensive services at no cost to the taxpayer. Because of the action taken by California's Governor to eliminate 340B savings, patient services and programs described above are at risk of being reduced significantly or

eliminated entirely. Patients will see longer wait times for appointments and decreased access to key support services such as patient-centered care coordination. Additionally, there will be an impact to the ratio of provider and clinic support staff to patients, resulting in negative patient outcomes. The Medi-Cal program and entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (e.g., diabetes, congestive heart failure), and decreased ability to provide such services as diabetes patient support, medication therapy management, and expanded access to primary care, mental health, and substance abuse treatment. Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and diabetes support will be impacted severely. The effect of this pharmacy transition is a major threat to the sustainability of California's primary care safety net program.

17. FHCSD is also at the heart of the battle against the COVID-19 pandemic in San Diego County. As the largest community clinic organization serving the area, FHCSD's clinics are located in already disadvantaged communities and those hardest hit by the pandemic. As evidenced by the positivity rates seen at FHCSD, health center patients carry more COVID-19 burden than the general population. Since the pandemic onset, FHCSD has performed 35,213 COVID-19 PCR tests with a 16.9% overall test positivity rate. Despite that high positivity over many months, each week in November and December 2020, our test positivity continued to climb to a current rate of 28.5%, more than double California's current test positivity rate of 12.2%. In short, FHCSD and FQHCs across the state are at ground zero of the COVID-19 pandemic. Eliminating the savings realized through the current 340B structure would be devastating to our ability to continue to care for a population with such high test positivity rates. As we near 2021, the drain on FHCSD resources has made it increasingly difficult to maintain quality healthcare for the communities we serve. With high levels of virus in the community, our

providers and support staff are also testing positive at higher rates than the County average. The resulting personnel shortage and dual struggle of increased demand for testing while trying first to vaccinate our staff and then the high-risk populations we care for are placing an unprecedented burden on our health care delivery system.

18. Over the years, FHCSD has submitted change-in-scope-of-services requests ("CSOSRs") to DHCS in connection with changes in the scope of FHCSD's services that increased costs and constituted grounds for an adjustment to FHCSD's prospective payment system rates. In connection with each of these CSOSRs, at the end of the audit process, DHCS applied the 80% adjustment factor to reduce the increase in FHCSD's actual and reasonable costs by 20% before adding the adjusted increase to FHCSD's PPS rates.

19. FHCSD has other concerns about the CSOSR process, as well. For example, as part of the CSOSR process, a health center with multiple sites is required to submit a home office cost report in addition to a cost report for each site that is seeking a change to its rate based on a change in the scope of its services. 340B drug costs associated with a health center's contract pharmacy arrangements are not included in the reimbursable costs of the health center because the contract pharmacy (such as a Walgreen's or CVS or corner drug store) incurs all of the costs associated with managing and dispensing the drugs, with the exception of the payment for the replenishment of the drugs, which is paid for by the health center. In connection with an FHCSD CSOSR that is currently under consideration by DHCS, DHCS is proposing to treat FHCSD's 340B drug costs as a non-reimbursable cost center and to allocate an amount of FHCSD's total overhead costs to the non-reimbursable cost center based on the proportion of overall costs represented by the "costs" of the 340B drugs. This proposed adjustment to the home office cost report will result in lower rates for the sites that are undergoing the CSOSR because a disproportionate amount of home office costs will be allocated to the 340B drug costs and away from sites that actually use and benefit from the costs

associated with FHCSD's home office. This is just one example of a variety of adjustments made by DHCS to a health center's CSOSR that result in the lowering of the adjustment to the health center's PPS rate in addition to the 20% haircut, also in violation of federal law.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22nd day of December 2020, in San Diego, California.

[redacted]

Ricardo Roman

Exhibit E
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES.

Defendants.

Case No. 2:20-CV-02171-JAM-KJN

DECLARATION OF DAVID BRINKMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, David Brinkman, declare as follows:

1. I am the Chief Executive Officer ("CEO") at Desert AIDS Project ("DAP") and have held this role since 2006. As CEO, I am responsible for overseeing the Federally Qualified Health Center ("FQHC") and our 340B Program. I have reviewed the data and associated outcomes relevant to the impact of the Medi-Cal Rx Transition on

DAP in connection with the preparation of this declaration. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of the plaintiffs' motion for a preliminary injunction.

2. DAP was founded in 1984 by a group of community volunteers in the face of the AIDS crisis. Since that time, DAP has been named one of the "Top 20 HIV/AIDS Charities" and has expanded its mission to other disenfranchised members of the Coachella Valley community. Today, DAP is a FQHC that serves over 7,000 active clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS. The majority of DAP's clients are low-income, with more than 75 percent of the immediate population living under 200 percent of the Federal Poverty Level. DAP receives federal grant funding under Section 330 of the Public Health Service Act. DAP meets all current statutory requirements under Section 330 of the Public Health Service Act. DAP also is a 340B-eligible Ryan White Part A (RWI) grantee provider organization.

3. According to the most recent DAP Uniform Data System ("UDS") report submitted to the federal Health Resources and Services Administration ("HRSA") for 2019, DAP conducted clinic visits with the following distribution of services for the 7,487 unduplicated FQHC patient population.

Clinical Service	* Number of Patients	* Percent of Patients	Number of Visits	Percent of Visits
Medical (Primary Care)	5,359	49.05%	19,247	47.29%
Dental	1,031	9.44%	5,275	12.96%
Mental Health	888	8.13%	5,492	13.49%
Substance Abuse Disorder	23	0.21%	130	0.32%
Enabling Services	3,624	33.17%	10,554	25.93%
Total	**10,925**	**N/A**	**40,698**	**100.00%**

* Total percent of patients is not applicable since individual patients may have received more than one visit across the four categories of patient visits or encounters.

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4. The distribution of DAP patients as a percentage of federal poverty guidelines in 2019 was 3,992 (53.32%) at or below 100 percent of the federal poverty guideline and 5,830 (77.87%) at or below 200 percent of the federal poverty guideline. Please note: the percent of patients at or below 100 percent of the federal poverty guideline, is included in the value for the patients at or below 200 percent of the federal poverty guideline.

5. In 2019, DAP's payer mix included the following key groupings:

- Medicaid 2,019 patients (26.97%)
- Other Public & Private Insurance 1,181 patients (15.77%)
- None/Uninsured/Sliding Scale 3,245 patients (43.34%)
- Medicare 731 patients (9.76%)
- Dually Eligible 311 patients (4.15%)

6. Other population and/or important patient demographic and clinical management-related indicators reported in the 2019 DAP filed UDS report included:

Indicator	Number of Patients	Percent of Patients
Special Populations		
Homeless	11	0.15%
Lesbian or Gay	5,070	67.72%
Transgender	406	5.42%
Veterans	362	4.84%
Other	1,638	21.88%
Age		
Children (<18 years)	6	0.08%
Adults (18 to 64 years)	6,101	81.49%
Adults (65 and over)	1,380	18.43%
Race & Ethnicity		
Racial and/or Ethnic Minority	1,147	15.32%
Hispanic/Latino	1,689	22.56%
Non-Hispanic White	4,478	59.81%
Asian	173	2.31%
Medical Conditions		
Hypertension	1,542	20.60%
Diabetes	506	6.76%
Sexually transmitted infections	1,067	14.25%

Asthma	252	3.37%
Symptomatic/Asymptomatic HIV	2,186	29.20%

7. The purpose of the 340B Program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." DAP's participation in the 340B Program allows the organization to stretch scarce resources to meet the needs of the medically underserved residents of the Coachella Valley and surrounding communities. This includes the most vulnerable high-risk populations (e.g., uninsured, underinsured, HIV/AIDS patients). Specifically, as a Ryan White/ HIV/ FQHC provider, DAP's population is heavily weighted (over 33%) with Ryan White clients. DAP also is a Hepatitis Center of Excellence that provides medication therapy to a number of patients diagnosed with Hepatitis C. Under federal law, regulation, and program guidance, grantee programs are expected to reinvest 340B net savings directly back into services provided to the organization's patient populations. In 2018 and 2019, DAP's Medi-Cal 340B claims from 340B contract pharmacies were estimated to be 10,300 and 9,300 respectively. DAP's Medi-Cal 340B contract pharmacy program recognized a net program savings (gross revenues less program and drug replenishments costs) of approximately $3,200,000 and $3,050,000 in 2018 and 2019, respectively. DAP utilized these net 340B funds to:

- Continue HIV and STD testing services aimed at stopping the spread of the HIV epidemic;
- Continue providing timely access to primary care, mental health, substance abuse, and prescription drug outpatient services for its patient population;
- Provide Medication Assistance for patients who could not afford medications otherwise;
- Pay for DAP's four Infectious Disease Physicians; and

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- Increase services (dental, housing, community health, STI clinic, and various vocational programs).

Under HRSA regulation and grantee scope of service requirements and guidance, FQHCs utilize their 340B net savings to:

- Provide uninsured patients with access to prescription drugs paid for by the health center;
- Subsidize care for the patient population with incomes below 200 percent of federal poverty guidelines who participate in DAP's sliding-scale payment programs; and
- Subsidize care not covered under Medi-Cal or other key payers.

8. DAP's 340B Program utilizing contract pharmacy has continued to grow significantly. In 2020 (based on YTD reporting), the DAP 340B contract pharmacy program is anticipated to generate gross revenues of $27,600,000 with net program savings (gross revenues minus program and drug replenishment costs) of $11,932,123. The estimated loss in net 340B benefits due to the Medi-Cal pharmacy program transition will be $3,000,000 (approximately 30 percent of total net 340B Program savings).

9. The 340B Drug Pricing Program requires drug manufacturers to provide discounted pharmaceuticals to health centers and other covered entities – which makes prescription drugs affordable for all FQHC patients, including the uninsured and underinsured. In addition, the savings retained by DAP allows it to continue to serve more patients and to increase comprehensive services at no cost to the taxpayer. Because of the action taken by California's Governor to eliminate 340B savings, patient services and programs described above are at risk of being reduced significantly or eliminated entirely. DAP's anticipated impact of eliminating $3,000,000 in funding would put 30-40 jobs at risk in DAP's community health, client support services, and HIV/STD testing programs. Furthermore, patients will see longer wait times for appointments and decreased access to key support services such as patient-centered care coordination. Additionally, there will be an impact to the ratio of provider and clinic support staff to

patients, resulting in negative patient outcomes. The Medi-Cal program and the entire FQHC medical home/patient-centered care coordination model will have increased costs due to higher emergency room utilization, increased hospitalizations due to complications from chronic diseases (*e.g.*, HIV, Hepatitis, congestive heart failure), and decreased ability to provide such services as medication therapy management, and expanded access to primary care, mental health, and substance abuse treatment. Strategic planning involving sustaining necessary resources to support important clinic functions that require more resources, such as outreach, education, care coordination, and STD testing will be impacted severely. The effect of this pharmacy transition is a major threat to the sustainability of California's primary care safety net program.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16th day of December 2020, in Palm Springs, California.

[redacted]

David Brinkman

Exhibit F
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF DR. KELVIN VU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Dr. Kelvin Vu, declare as follows:

1. I am currently a family physician at Open Door Community Health Centers ("Open Door"), where I have worked for the last ten years. I also currently serve as Chief Medical Officer at Open Door. I received my medical training from Western University and completed my Family Medicine Residency at the University of California, Davis

Medical Center, where I also served as Chief Resident in my final year. As a family physician, I regularly interact with patients, prescribe medications, and ensure my patients are receiving their medications and following the treatment regimens. As the Chief Medical Officer, I also receive reports from the other physicians about the provision of services to their patients, including concerns about challenges and suggestions for improving services. The majority of Open Door's patients are Medi-Cal beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a Preliminary Injunction.

2. Open Door is a Federally Qualified Health Center that receives federal grant funds under Section 330 of the Public Health Services Act. Open Door is committed to providing excellent health care and health education to medically underserved patients in the Humboldt and Del Norte Counties, two rural counties in the far northwest region of Northern California along the coast. Open Door currently operates twelve community health centers across both counties, serving more than 55,000 patients each year while employing nearly 700 members of the community.

3. Humboldt and Del Norte Counties are predominately rural, and tend to rank near the bottom for health outcomes among California counties. Like many rural areas, our patients struggle with widespread problems of poverty, opioid use disorder, lack of health education, lack of reliable housing and transportation, and numerous other socio-economic barriers to health care that directly affect their well-being in the short and the long term. As a physician who has worked in this community for ten years, I am well-aware that these socio-economic problems often cause my patients to forego necessary medical treatments in order to focus on other urgent aspects of their lives, such as going to work to support their families, or using their limited incomes to buy food or pay rent instead of paying for their prescribed medications.

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4. Open Door is committed to meeting our patients where they need us to be. To that end, we operate under a patient-centered medical home model ("Medical Home") that allows us to coordinate an individual patient's care across specialties so that we treat the whole person, rather than individual symptoms. As their Medical Home, Open Door proudly serves as a one-stop-shop for all of our patients' medical needs, as well as their unique needs for accessing transportation assistance, housing, and food. The Medical Home also helps patients follow their medical treatment plans because they do not need to go to multiple facilities – all of their providers are in one place, which greatly improves the patients' overall health outcomes.

5. The Medical Home includes coordination with pharmacy services and the MCP member services team. The ability for me as a prescribing physician to work directly with the MCP and case managers greatly improves my patients' ability to access necessary treatments. For example, if I prescribe a Lidocaine patch – a non-opioid chronic pain treatment – I will have access to real-time information regarding what the cost will be to the patient, when and if the patient is able to pick up the patch, or if the patch is not covered by the patient's plan. If the Lidocaine patch is not available for some reason, I am able to find out immediately and make same-day adjustments to the treatment plan so that my patient's needs are met. This is just one concrete example of how the pharmacy benefit's inclusion in managed care facilitates medical services for both doctors and patients, leading to better care and outcomes for the most vulnerable, medically underserved people in California.

6. The inclusion of the pharmacy benefit in managed care also enables me to tailor my treatment plan to the patient's needs. With the pharmacy and medical benefits linked, the current managed care model allows me to see and track if my patients are getting their prescriptions, taking them on schedule, re-filling them as prescribed, and returning for medical follow-ups on time. This information is critical to creating a treatment plan for my patients, tracking their progress and condition, and scheduling necessary follow-up appointments.

7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative will transfer the pharmacy benefit out of managed care and into a fee-for-service model. This will directly undermine Open Door's Medical Home model and my ability to treat my patients effectively. For example, disconnecting pharmacy services from medical services will require our patients to take multiple trips to receive their care and their medication. For most of my patients, this is not simply one more errand in their day – it is an insurmountable barrier because they do not have access to reliable transportation to make multiple trips, or they cannot take additional time from work during the day, or they need to be home to take care of children or other family members.

8. Additionally, Medi-Cal Rx will fundamentally alter the way I and other Medi-Cal providers at FQHCs will be able to treat our patients. For example, I will no longer have access to real-time information as to the availability of medications or my patients' adherence to the treatment plan. Using the example of the Lidocaine patch discussed above, under the Medi-Cal Rx fee-for-service model, I would prescribe the patch and my patient would have to make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it in stock or the pharmacist needs prior authorization, I will no longer be notified as part of managed care and will not necessarily be advised that my patient was unable to pick up their prescription. Because of the type of patients I work with and the challenges they face in making multiple trips to different healthcare providers, there is a high likelihood that my patient would forego the treatment altogether. I would not discover the problem until months later in a follow-up visit with my patient, at which point their condition and pain has worsened because they could not access the treatment I prescribed.

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9. It is also my understanding that Medi-Cal Rx will also change Open Door's and other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount program. I am gravely concerned that the proposed fee-for-service reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the cost of providing necessary pharmacy services to my patients.

10. In addition, the savings and reimbursement Open Door receives from the 340B program go directly to providing additional, much-need services for our patients that are not otherwise reimbursed by Medi-Cal. One key example is Open Door's Medication Assistance ("MAT") Program. MAT provides access to the medication buprenorphine, also known as Suboxone, which is scientifically proven to help patients struggling with opioid use disorder to overcome and manage their addiction. The drug is very expensive, so without 340B pricing, our patients would not be able to receive it at all. Additionally, MAT includes support groups that help patients maintain sobriety, which requires efforts from case managers and member services staff. However, these counseling services are not reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue and savings. Without services like our MAT Program, Open Door's patients will be denied access to a highly effective treatment option that can help them get away from opiates and improve their overall lifestyle.

11. Based on my experience as a family physician at an FQHC, I believe that Medi-Cal Rx will create additional barriers to healthcare services that my patients are already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well as how those patients access their Medi-Cal benefits. I am greatly concerned that removing the pharmacy benefit from managed care will directly prevent Open Door's ability to serve as the one-stop-shop Medical Home that our patients depend on to treat their unique and varied needs. Additionally, the loss of 340B revenue will force Open Door to cut off critical resources for patients who are struggling with opioid use disorder and other chronic conditions.

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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 2 day of February, 2021, in Arcata, California.

DR. KELVIN VU

Exhibit G
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

Judge: Hon. John A. Mendez
Date: March 9, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Dr. Paramvir Sidhu, declare as follows:

1. I am currently a family physician at Family Health Care Network ("FHCN"), where I have worked for the last ten years. I also currently serve as Chief Clinical Officer at Family Health Care Network. I received my medical training in India and completed my residency in family medicine at the Riverside Community Medical Center, Riverside,

California. As a family physician, I regularly interact with patients, prescribe medications, and ensure my patients are receiving their medications and following the treatment regimens. As the Chief Clinical Officer, I also receive reports from the other physicians about the provision of services to their patients, including concerns about challenges and suggestions for improving services. The majority of FHCN patients are Medi-Cal beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). Although FHCN is not a named plaintiff in this action, it is an affiliate of the Community Health Center Alliance for Patient Access. I have personal knowledge of the facts set forth herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a Preliminary Injunction.

2. FHCN is a Federally Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Services Act. FHCN is committed to providing excellent health care and health education to medically underserved patients in the Tulare, Kings and Fresno Counties, three rural counties in the San Joaquin Valley of Central California. FHCN currently operates forty-one (41) community health centers across these counties, serving more than 221,000 patients each year while employing nearly 1,500 members of the community.

3. The patients we serve from Tulare, Kings and Fresno counties are predominately from rural communities, and tend to rank near the bottom for health outcomes among California counties. Our patients struggle with widespread problems of poverty, lack of health education, lack of reliable housing and transportation, and numerous other socio-economic barriers to health care that directly affect their well-being in the short and the long term. A large majority of our patients are Seasonal and Migrant farmworkers who suffer from severe health care disparities. As a physician who has worked in this community for ten years, I am well aware that these socio-economic problems often cause my patients to forego necessary medical care in order to focus on other urgent aspects of their lives. These patients have to choose between utilizing their

limited resources to either buy food or pay rent to support their families, or pay for their prescribed medications.

4. FHCN is committed to meeting our patient's needs and provide access to quality medical care to everyone. We are Joint Commission Accredited clinics and we operate under a patient-centric medical home model ("Medical Home") that allows us to coordinate an individual patient's care across specialties so that we treat the whole person, rather than individual symptoms. As their Medical Home, FHCN proudly serves as a one-stop-shop for all of our patients' medical needs, as well as their unique needs for accessing transportation assistance, housing, and food and connect the patients with resources in the communities. The Medical Home also helps patients follow their medical treatment plans because they do not need to go to multiple facilities – all of their providers are in one place, which greatly improves the patients' overall health outcomes.

5. A part of the Medical Home also includes pharmaceutical services for our patients. Having pharmacies in our health centers and medications under the 340B program allows me as a prescribing physician to work directly with the pharmacists and greatly improve my patients' ability to access necessary treatments. For example, if I prescribe Insulin– a lifesaving treatment for diabetes – I will have access to real-time information as to when and if the patient is able to pick up the medication at a very affordable price. If the Insulin is not available for some reason or not covered by the patient's plan, the pharmacist is able to call and inform me and provide alternatives to the medication. This allows me to make same-day adjustments to the treatment plan and patient leaves the visit with medications. Relatedly, our in-house pharmacists have access to a patient's Electronic Health Record, allowing them to track prescription dosages and types, which enhances patient safety. For example, our pharmacist can see and verify the weight of a pediatric patient who is prescribed antibiotics for an infection, verify the dosage calculation, and consult with me prior to the patient leaving the health center. Another example would be the pharmacist reviewing the medical record and noting additional medications or supplements listed in the patient's medication

list that could have contraindications when taken with the prescribed medication. Again, this can be discussed with me before the patient leaves the health center. These are just a few concrete examples of how the pharmacy benefit's inclusion in managed care facilitates medical services for both doctors and patients, leading to better care and outcomes for the most vulnerable, medically underserved people in California.

6. The inclusion of the pharmacy benefit in managed care also enables me to tailor my treatment plan to the patient's needs. First, with the pharmacy and medical benefits linked, the current managed care model allows me to see if my patients are getting their prescriptions, taking them on schedule, re-filling them as prescribed, and returning for medical follow-ups on time. This information is critical to creating a treatment plan for my patients, tracking their progress and condition, and scheduling necessary follow-up appointments. Second, the 340B savings allow us to operate a robust in-house pharmacy program, including a Director of Pharmacy who sits on our Medical Director Team. This coordination allows us to create a formulary for our pharmacy specific to the clinical needs of our patient population and at the lowest acquisition price possible, benefiting our patients both clinically and financially. Without the 340B program, this cross-collaboration and comprehensive care management will not be possible, as the dramatic cuts that would need to be made to our in-house pharmacies would no longer allow us to have a Director of Pharmacy, and pharmacists would no longer be able to dedicate time to comprehensive care management.

7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative will transfer the pharmacy benefit out of managed care and into a fee-for-service model. This will directly undermine FHCN's Medical Home model and my ability to treat my patients effectively. For example, disconnecting pharmacy services from medical services will require our patients to take multiple trips to receive their care and their medication. For most of my patients, this is not simply one more errand in their day – it is an insurmountable barrier because they don't have access to reliable transportation to make multiple trips, or they cannot take additional time from work during the day, or they

need to be home to take care of children or other family members.

8. It is also my understanding that Medi-Cal Rx will also change FHCN's and other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount program. I am gravely concerned that the proposed fee-for-service reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the cost of providing necessary pharmacy services to my patients. It will also impact our ability to provide other benefits that are significant to our patients. For instance, we currently have an extensive patient transportation program that provides door-to-door service from a patient's home to the health center, which we would need to be scaled back or eliminated if we no longer received revenue from the 340B program. Additionally, we will have to increase the nominal fee offered to uninsured patients on our pharmacy sliding fee scale, which will increase the costs for patients who cannot afford higher out-of-pocket expenses for medical care. Such a change could result in uninsured patients forgoing prescriptions, leading to worse health outcomes.

9. Medi-Cal Rx will also fundamentally alter the way I and other Medi-Cal providers at FQHCs will be able to treat our patients. For example, FHCN has a Diabetic clinic where the goal is to provide coordinated diabetic care to patients. This includes the patient getting education about diabetes from health educators, necessary screenings and immunizations, and behavioral-health counseling. These services are in addition to medical care and treatment the physicians provide during the same (single) visit for the patient. Using the example of the Insulin discussed above, under the Medi-Cal Rx fee-for-service model, I would have to prescribe the Insulin and my patient would have to make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it in stock, the cost is too high, or the pharmacist needs prior authorization, I will not be notified immediately that my patient was unable to pick up their prescription. Because of the type of patients I work with and the challenges they face in making multiple trips to different healthcare providers, there is a high likelihood that my patient would forego the treatment altogether. I would not discover the problem until months later in a follow-up

visit with my patient, at which point their condition has worsened and severe complications developed because they could not access the treatment I prescribed, or the supportive Diabetic clinic services. The result for that patient is deteriorated clinical outcomes and, most likely, costly trips to the emergency room paid for by the Medi-Cal program for a Medi-Cal beneficiary.

10. In addition, the savings and reimbursement FHCN receives from the 340B program go directly to providing additional, much-need services for our patients that are not otherwise reimbursed by Medi-Cal. One key example is FHCN's Medication Assistance Program ("MAT"). MAT provides access to the medication buprenorphine, also known as Suboxone, which is scientifically proven to help patients struggling with opioid addiction to overcome and manage their addiction. The drug is very expensive, so without 340B pricing, our patients would not be able to receive it at all. Additionally, the MAT clinic includes counseling that help patients maintain sobriety, which requires efforts from Behavioral Health and member services staff. However, some of these ancillary services provided in the MAT clinic as well as the above mentioned Diabetic clinic are not reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue and savings. Without programs like MAT, FHCN's patients will be denied access to a highly effective treatment option that can help them get away from opiates and improve their overall lifestyle.

11. Based on my experience as a family physician at an FQHC, I believe that Medi-Cal Rx will create additional barriers to healthcare services that my patients are already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well as how those patients access their Medi-Cal benefits. I am greatly concerned that removing the pharmacy benefit from managed care will directly interfere with FHCN's ability to serve as the one-stop-shop Medical Home that our patients depend on to treat their unique and varied needs. Additionally, the loss of 340B revenue will force FHCN to cut off critical resources for patients who are struggling with opioid addiction and other chronic conditions like Diabetes.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 5 day of February, 2021, in Visalia, California.

[redacted]

DR. PARAMVIR SIDHU

Exhibit H
to letter dated 4/16/2021

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Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF FRAN BUTLER-COHEN IN OPPOSITION TO MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Judge: Hon. John A. Mendez
Date: February 23, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Fran Butler-Cohen, declare:

1. I am the Chief Executive Officer ("CEO") at Family Health Centers San Diego ("FHCSD") and have held this role since 1986. I have reviewed the data and associated outcomes relevant to the impact of Medi-Cal Rx on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth

herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives federal grant funding under Section 330 of the Public Health Services Act. FHCSD has served the medically underserved communities of San Diego County since 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's flagship clinic. FHCSD has since transformed into the tenth largest health center in the country, providing care to over 149,000 patients each year, of whom 90 percent are low income and 31 percent are uninsured. FHCSD serves all patients regardless of their ability to pay.

3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020, FHCSD has provided free COVID-19 testing to as many patients as the staff can manage. During this time, demand for FHCSD services has skyrocketed. To try to meet our patients' testing needs, FHCSD has purchased additional lab equipment and increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid testing and notification systems to quickly identify patients with COVID-19 and reduce community spread. Additionally, we have set up a separate obstetrics clinic for mothers who have tested positive for COVID-19. These steps have proven necessary, since, among the patients we serve, the COVID positivity rate in the second week of January 2021 was 35 percent, more than double the average statewide rate for the same time period.

4. In an effort to take care of patients and to avoid sending them to hospitals – which currently cannot handle an additional influx of patients – FHCSD has also ramped up its ability to care for the sickest, non-emergent patients. Instead, we have started Monoclonal Antibody administration for the sickest, non-emergent patients at one of our clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as soon as possible.

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5. Despite the heroic efforts of our health care workers – who have shouldered the burden of coming to work every day risking their own health and the health of their families – FHCSD staff is stretched beyond its limits and is struggling to continue. We currently have seventy (70) members of our team out of work due to COVID, which hurts FHCSD's ability to meet patients' needs and county demands. We have started an emergency child care program to keep our workers on the job when they have no other childcare options. We have also started an Employee Food Pantry Program so that employees who have lost income can feed their families.

6. Now, with the development of a COVID-19 vaccine, San Diego County is asking FHCSD to submit information regarding how many vaccinations we could administer to the general public, which requires me and the FHCSD staff to study guidance from the Centers for Disease Control and the Department of Defense to implement massive public vaccination events, in addition to juggling the current emergency needs of our patients and community.

7. Simultaneously, FHCSD is still required to commit time to fielding government audits and meet with the State and Managed Care Organizations on metric performance. In addition, FHCSD is currently in the beginning stages of a random federal 340B audit that has already taken several hundred hours of staff time in preparation and document submission. At the same time, the Health Resources and Services Administration is requesting capital funding grantees submit previously unrequired data and qualitative information to help them design future grant programs, Moreover, FHCSD has had to make significant modifications to contract pharmacy arrangements to ensure our patients receive affordable medications due to the attack on the 340B program by pharmaceutical manufacturers. All of this comes against the backdrop of the State of California awarding a contract valued at approximately $80 million annually to a for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by Centene, a publicly traded NYSE corporation worth $76 billion for $2.2 billion dollars to

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facilitate the state in their plan that will remove hundreds of millions of dollars from the state's health care safety-net.

8. It is unconscionable that during this time of perpetual crisis, when our staff and other healthcare workers have sacrificed so much to serve the communities that need them most, FHCSD and other FQHCs are required to prepare and plan for Medi-Cal Rx, which will result in drastic funding reductions due to changes in reimbursement. Additionally, the loss of 340B funding that helps stretch our resources to expand healthcare access will further reduce staff and desperately needed health services.

9. Although the "effective" date of Medi-Cal Rx has been moved to April 1, 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring health centers to adjust our conduct in a number of ways. Examples of some of the activities FHCSD has had to undertake in anticipation of the "go live" date for Medi-Cal Rx include:

- A complete budget review and assessment of programs currently funded through 340B savings, including the potential for lay-offs, elimination of support programs, and reduction in hours and types of services provided to our patients.
- Meetings with vendors that currently support in-house pharmacy operations to ensure systems remain compliant following full implementation.
- Subscribe to and dedicate staff time to monitor, review and bring forward issues noted in regular updates from the Medi-Cal Rx Subscription Service
- Secure Provider Portal access and enroll approximately 250 prescribing providers into the provider portal, necessitating hundreds of hours of administrative staff time.

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- Review all medication and pharmacy related policies and protocols across the organization to align with new systems and ensure compliance.
- Educate providers about the transition from the MCO formulary to using drugs on the FFS formulary.
- Educate providers on the new Prior Authorization (PA) systems as drugs prescribed that are therapeutic substitutions for more commonly prescribed drugs not found on the CDL, including any step therapy or pre-requisite therapies.
- Educate clinic directors, billing staff and other administrative personnel as to the new systems, how to use them and how to trouble shoot difficulties for patients and providers.
- Review how FHCSD payor mix will change given the pharmacy transition and evaluate whether it's beneficial for FHCSD and our patients to maintain current contract pharmacy relationships or cancel them.

10. The state and local governments still expect FHCSD to maintain the same quality of care and to serve more patients in more ways while implementing Medi-Cal Rx, which will squeeze FHCSD's resources at precisely the wrong time. Without the 100 percent reimbursement rate guaranteed by federal Medicaid law and the 340B savings FHCSD relies on, we simply will not be able to provide the same level of care for the patients we have worked tirelessly to serve. I fear that the healthcare workers and

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patients who have suffered the most throughout the COVID-19 emergency will also bear the burden of the Medi-Cal Rx initiative's consequences.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 20th day of January, 2021, at San Diego, California.

[redacted]

FRAN BUTLER-COHEN

Exhibit I
to letter dated 4/16/2021

Medi-Cal Rx Monthly Bulletin

April 1, 2021

The monthly bulletin consists of alerts, bulletins and notices posted to the Medi-Cal Rx Web Portal within the previous month.

Contents

1. Changes to the Contract Drugs List Effective April 1, 2021

The below changes have been made to the Contract Drugs List effective April 1, 2021.

For more information, see the Contract Drugs List on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Asenapine	FDA-approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Cabotegravir/Rilpivirine	Added to CDL with a restriction.	April 1, 2021
Exenatide	Extended release injectable suspension vial obsolete. Removed from CDL.	April 1, 2021
Leuprolide Acetate	Injection and powder for injection removed from CDL. Labeler restriction updated to 00074 only.	April 1, 2021

Drug Name	Description	Effective Date
Lurasidone Hydrochloride	FDA approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Morphine Sulfate/Naltrexone	Drug obsolete. Removed from CDL.	April 1, 2021
Nevirapine	Labeler restriction (00597) added to liquid only.	April 1, 2021
Propranolol	Additional liquid strength (1.28 mg/ml) added to CDL with a restriction.	April 1, 2021
Relugolix	Added to CDL with a restriction.	April 1, 2021
Sodium Zirconium Cyclosilicate	Added to CDL with labeler code restriction.	April 1, 2021

2. Updates to the List of Covered Enteral Nutrition Products

Effective for dates of service on or after March 1, 2021, the List of Covered Enteral Nutrition Products has been updated on the Medi-Cal Rx Web Portal. Effective for dates of service on or after April 1, 2021, products deleted from the List of Covered Enteral Nutrition Products will no longer be reimbursable, even with an approved prior authorization. The Maximum Acquisition Cost (MAC) for these products is no longer guaranteed.

3. Medi-Cal Provider Training Schedule

The transition of all administrative services related to Medi-Cal pharmacy benefits billed on pharmacy claims from the existing intermediaries, Medi-Cal Fee-for-Service (FFS) or Managed Care Plan (MCP) providers, will transition to the new Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (MMA).

This article serves as a guide to outline the trainings planned for March 2021 until the Medi-Cal Rx implementation that will assist pharmacy providers, prescribers, and their staff as they transition to Medi-Cal Rx.

User Administration Console Training

All Medi-Cal Rx pharmacy providers, prescribers, and their staff will need to complete registration in order to access the secure areas of the Medi-Cal Rx Web Portal. Access to the secured Medi-Cal Rx Provider Portal starts with registration via the User Administration Console (UAC) application.

Training Information:

To assist pharmacy providers, prescribers, and their staff with UAC registration, there are job aids and computer-based trainings (CBTs) available to walk users through the registration process. Those materials are as follows:

- UAC Quick Start Guide
- UAC Tutorial #1: Start Registration Process
- UAC Tutorial #1 Supplement: Alternate Address Instructions
- UAC Tutorial #2: Complete Registration
- UAC Tutorial #4: Granting Access for Yourself and Staff

If you run into any issues or have any questions about the UAC registration process, feel free to attend an office hours session with one of our Pharmacy Representatives (PSRs) who can assist with the process.

To register for a UAC office hours session, please email the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of Office Hours session

As of April 1, 2021 UAC Office Hours Sessions will be offered on an as-needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Saba LMS Training

Saba is the one-stop shop for Education and Outreach information for Medi-Cal Rx pharmacy providers and prescribers. Topics to be covered during the Saba training sessions include how to view the Education and Outreach events calendar, how to register to attend an event or take an online course, and how to complete evaluations of training effectiveness.

Training Information:

Training for Saba includes a job aid with step-by-step instructions:

Medi-Cal Rx Saba℠ Provider Job Aid

In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via Hewlett Packard Enterprise (HPE) MyRoom™. To register to attend a live webinar, please email Medi-Cal Rx Education and Outreach at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of training session

Before enrolling in a Saba training session, providers will need to confirm in their email if they have completed the following tasks:

- Registered successfully for UAC
- Received a PIN letter and completed UAC registration
- Registered as the Delegated Administrator or have been created as a user by the Delegated Administrator
- Have added or been granted access to the Saba application

As of April 1, 2021, Saba Training Sessions will be offered on an as needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Medi-Cal Rx Transition and Resources and Web Portal Training

This training is intended to give pharmacy providers and prescribers an overview of the Medi-Cal Rx Transition and the resources that are available on the Medi-Cal Rx Web Portal. Topics that will be covered in this training include the following:

- Medi-Cal Rx background and high-level changes affecting pharmacy providers and prescribers
- Point-of-Sale (POS) Technical and Operational Readiness
- Web Claims Submission and overview of the Finance Portal

Training Information:

Training will be available via job aids and live webinars coming April 2021.

Training sessions for Medi Cal Rx Transition and Resources and Web Portal will be offered via a series of videos and job aids with step-by-step instructions. In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via HPE MyRoom™. To register to attend a live webinar, please refer to the Saba Training Calendar for specific dates and times.

Pharmacy providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to the Saba application.

Medi-Cal Rx Transition and Resources and Web Portal Training Sessions (April 2021)	
Dates	**Times**
April 2021	Please refer to the Saba Training Calendar for specific dates and times.

Prior Authorization Training

A Prior Authorization (PA), previously known as a Treatment Authorization Request (TAR), requires providers to obtain approval before rendering certain services such as prescriptions.

This training will be intended for pharmacy providers and prescribers that plan to use the new Medi-Cal Rx Secured Portal to submit PAs.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available, live webinar training will be available via Saba. Providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and PA applications.

Web Claims Submission Training

This training will give providers an overview of the new Medi-Cal Rx Web Claims Submission system. Providers currently using a POS system to process prescription claims can still continue to submit web claims via this channel.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available live webinar trainings will be available via Saba. Pharmacy providers and prescribers and their staff that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and Medi-Cal Rx Web Claims Submission applications.

4. Prescriber Phone Campaign

Pharmacy Service Representatives (PSRs) will begin reaching out by phone to introduce the new Medi-Cal Rx Web Portal and available resources and functionality. This outreach to prescribers will accomplish the following:

- Provide guidance on how to start registration for the Secured Provider Portal.
- Inform prescribers of currently available training and resources for Medi-Cal Rx.

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure Web Portal registration in order to access Education and Outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba, and providers will have the ability to enroll in web-based, instructor-led, or computer-based training.

To access Saba, providers need to utilize the User Administration Console (UAC) application. Click the **Medi-Cal Rx Training** hyperlink on the Education & Outreach page of the Medi-Cal Rx Web Portal or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration.

To register for an Office Hours session, please email MediCalRxEducationOutreach@magellanhealth.com and include the following information:

1. Name of Individual
2. Provider Name
3. National Provider Identifier (NPI)
4. Phone Number
5. Email Address
6. Preferred Date and Time of Office Hours Session

5. Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey

How do you and your peers currently conduct business for Medi-Cal pharmacy services? We'd love to hear from you! The results of the Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey will be used to tailor training offerings for Medi-Cal Rx to ensure you are prepared for the upcoming transition. The information you provide is confidential and will be used only for future training.

6. Pharmacy Provider Self-Attestation Period Begins April 2021

Although currently delayed, Medi-Cal pharmacy benefits will eventually be transitioned to and thereafter administered through the Fee-for-Service (FFS) delivery system for all Medi-Cal beneficiaries (generally referred to as "Medi-Cal Rx"). The Department of Health Care Services (DHCS) has partnered with Magellan Medicaid Administration, Inc. (MMA) to provide a wide variety of administrative services and support for Medi-Cal Rx.

MMA has contracted with Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to administer the annual pharmacy provider self-attestation survey for professional dispensing fee reimbursement. The objective of the next self-attestation survey is to assign professional dispensing fee rates for Medi-Cal-enrolled pharmacies beginning July 1, 2021 and ending June 30, 2022.

DHCS, through Mercer, will be initiating the provider self-attestation process in April 2021 for the 2020 calendar year reporting period for those pharmacy providers seeking the higher of two professional dispensing fee rates determined by annual prescription volume. Key changes to the self-attestation process include the following:

- The provider self-attestation period for the calendar year 2020 reporting period will run from April 1 through April 30, 2021 (in previous years, the survey period was January 15 through the end of February).
- Mercer, on behalf of MMA and DHCS, will administer the provider self-attestation survey with options for online submission or an email submission of a Microsoft® Excel®-formatted template.
- In addition to the standard online submission, pharmacies will have an additional survey submission option that will allow a bulk submission for multiple locations. The new template will allow a corporate office for chain-affiliated stores under common ownership to submit multiple stores in one self-attestation survey file.

As in previous years, newly approved FFS pharmacy providers that are notified of their Medi-Cal enrollment approval after the attestation period closes will automatically receive the higher dispensing fee. However, those same providers will have to attest for subsequent reporting periods in order to continue to be eligible for the higher dispensing fee in subsequent fiscal years.

Pharmacy providers may refer to the updated Pharmacy Provider Self-Attestation FAQs for more information.

DHCS reminds the Medi-Cal pharmacy FFS provider community to closely monitor upcoming Medi-Cal pharmacy bulletins for additional information regarding future updates by signing up via the Medi-Cal Rx Subscription Service.

For updates on Medi-Cal Rx, please visit the Medi-Cal Rx Web Portal and the DHCS Medi-Cal Rx Transition website. In addition, DHCS encourages stakeholders to review the Medi-Cal Rx Frequently Asked Questions (FAQ) document, which continues to be updated as the project advances.

7. Portal Registration

What is Medi-Cal Rx and When Does it Happen?

Medi-Cal Rx is the name the Department of Health Care Services (DHCS) has given to the collective pharmacy benefits and services that will be administered through the Fee-for-Service (FFS) delivery system by its contracted vendor, Magellan Medicaid Administration, Inc. (MMA). Medi-Cal Rx will include all pharmacy services billed as a pharmacy claim, including but not limited to outpatient drugs (prescription and over the counter), Physician-Administered Drugs, enteral nutrition products, and medical supplies.

DHCS is delaying the planned Go-Live date of April 1, 2021, for Medi-Cal Rx. For more information, please see the Important Update on Medi-Cal Rx alert dated February 17, 2021.

What Should I Do Now?

Start by visiting the new Medi-Cal Rx Web Portal to review general information about the transition and to access registration and training for the Web Portal. This website serves as a platform to educate and communicate on Medi-Cal Rx resources, tools, and information. To stay informed, sign up for the Medi-Cal Rx Subscription Service (MCRxSS). Similarly, closely monitor Medi-Cal Rx news and bulletins for additional information regarding any future updates.

Next, register for the secure Medi-Cal Rx Provider Portal. Providers will need to complete registration for the User Administration Console (UAC) application. UAC is a registration tool that controls and manages a user's access to the secure section of the Medi-Cal Rx Web Portal and associated applications.

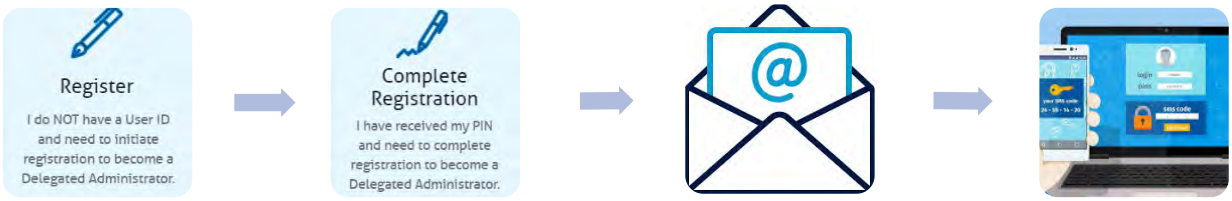
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- Prior Authorization System
- Secure Chat and Messaging Features
- Beneficiary Eligibility Lookup
- Web and Batch Claims Submission
- Education & Outreach Calendar and Training Registration

Refer to the UAC Quick Start Guide (PDF) and the information below for assistance with registering for UAC.

UAC Registration

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure web portal registration in order to access education and outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba and providers will have the ability to enroll in web-based, instructor-led, or computer-based training. To access Saba, providers need to utilize the UAC application. Click the hyperlink under **Medi-Cal Rx Training** on the Education & Outreach page of the Medi-Cal Rx Web Portal, or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration. To register for an Office Hours session, please email MediCalRxEducationOutreach@MagellanHealth.com and include the following information in your email: name of individual, provider name, National Provider Identifier (NPI), phone number, email address, and preferred date and time of Office Hours session.



To register, visit https://uac.magellanrx.com.

- Click **Register**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering as many IDs as necessary
- Click **Submit**

You will receive a letter with a PIN number.

- Return to the UAC website
- Click **Complete Registration**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering and validating all necessary IDs
- Click **Submit**

You will receive an email with an activation link (check spam or junk folder).

- Click activation link
- Confirmation screen appears indicating *You Have Been Successfully Added*
- Click on link in confirmation screen directing you to UAC application
- Here you can assign access and create accounts

Assign access/privileges and organizations.

- The first time you log into UAC, set up multifactor authentication
- Continue with sections 2.0, 3.0, and 4.0 in the Medi-Cal Rx UAC Quick Start Guide located at https://medi-calrx.dhcs.ca.gov/home/education

Christopher M. House

From: UPS <pkginfo@ups.com>
Sent: Monday, April 19, 2021 7:22 AM
To: Christopher M. House
Subject: [EXTERNAL] UPS Delivery Notification, Tracking Number 1ZA47F260198305886

Hello, your package has been delivered.

Delivery Date: Monday, 04/19/2021
Delivery Time: 10:20 AM
Left At: DOCK
Signed by: ANDRE

HANSON BRIDGETT LLP

Tracking Number:	1ZA47F260198305886
Ship To:	CENTER FOR MEDICAID & CHIP SERVICES 7500 SECURITY BOULEVARD, MAIL STOP S2-25-26 BALTIMORE, MD 212441850 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	2.0 LBS
Reference Number:	37366.3
Reference Number:	FHCSD / CHCAPA
Reference Number:	KATHRYN DOI

Download the UPS mobile app

CHC
Community Health Centers

May 5, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Community Health Centers of the Central Coast, Inc (CHCCC) writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, CHCCC urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

CHCCC is an FQHC that cares for Medi-Cal and uninsured patients in San Luis Obispo and Santa Barbara Counties. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through 1 in-house and 75 contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows CHCCC to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, CHCCC annually saves an estimated net savings of $8,382,552 in 2020 through participation in Medi-Cal managed care (the 340B Drug Discount Program). The savings allow CHCCC to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy

on a FFS basis. As a result of the current managed care system, CHCCC patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[2] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which CHCCC incorporates by reference into this letter. CHCCC fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, CHCCC urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable CHCCC and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. CHCCC looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Ronald E. Castle, CEO
Community Health Centers of the Central Coast, Inc

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

HEALTH CENTER PARTNERS
of Southern California

May 6, 2021

Will Lightbourne, Director
Department of Health Care Services
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413
Submitted via email to CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on CalAIM Section 1115 & 1915(b) Waivers

Dear Director Lightbourne:

On behalf of Health Center Partners of Southern California, representing 17 member organizations, including 12 Federally Qualified Health Centers, 4 Indian Health Centers, and Planned Parenthood of the Pacific Southwest, I would like to thank you for the opportunity to offer comment on the CalAIM Section 1115 & 1915(b) Waiver documents released by DHCS on April 6, 2021. Members of this regional primary care association operate over 160 practice sites across five counties, serve 917,000 patients with 3.9 million patient visits annually, and generate $2.2 billion in economic impact to the region and $1.4 billion in savings to Medicaid.

I appreciate the hard work and vision you have expressed for Medi-Cal in California through the California Advancing and Innovating Medi-Cal (CalAIM) initiative as well as your diligence and attention to ensure that stakeholder engagement remains a key part of that process. I look forward to continuing to work with you to support and implement a reformed health delivery system that addresses social determinants of health among our most vulnerable populations and returns all to equity in health, with a focus on whole person care.

Overall Comments on CalAIM Section 1115 & 1915(b) Waivers

I commend the administration's commitment to implementing CalAIM, an initiative that will lead to broad delivery system, program, and payment reforms across Medi-Cal. I see many positive changes in the proposal. **However, I do have concerns and recommendations, and I would like to share them below for your review and consideration. Specifically, in the paragraphs below, I detail the following:**

- DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.
- DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- DHCS must ensure community providers, including community health centers and FQHCs, are eligible for support under Providing Access and Transforming Health (PATH).
- DHCS must ensure the public has adequate opportunity to review and comment on all policy changes.
- DHCS must continue to pursue and provide data sharing and integration across all sectors of care including the social services.

I applaud DHCS for detailing a vision for large-scale transformation of the Medi-Cal delivery system. However, I am concerned the scale of transformation, and the ambitious timeline, may pose challenges in practice. I am concerned small community-based Drug Medi-Cal providers may not have the data sharing and claim processing infrastructure to transition to an integrated and more aligned Medi-Cal Managed Care (MCMC) system.

In addition, the CalAIM Waiver proposals outline significant integration and alignment of Medi-Cal services for beneficiaries through Medi-Cal Managed Care (MCMC) plans. The increased responsibility placed on MCMC plans will require a heightened level of oversight and accountability. **I encourage DHCS to share information with stakeholders on how it will increase oversight and transparency during and beyond the implementation of these Waivers.**

I thank you for your continued work on this important initiative and look forward to working with the Department on CalAIM implementation.

Comments

DHCS must continue to delay the transition of pharmacy benefits into FFS and consider removing the pharmacy transition from its waiver proposal.

- I am aware of the time and investment the state committed to the design and vision of Medi-Cal Rx. However, providers and health plans have systems in place today to ensure pharmacy access for Medi-Cal beneficiaries. Delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine an already strained delivery systems and further confuse and worry Medi-Cal beneficiaries.
- **I ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic.**
- Eliminating 340B savings would jeopardize patient access to critical supports like oral health, optometry, behavioral health, transportation services, health education, and cause in-house pharmacies to close. Taken collectively, such eliminations would raise costs. From the inception of Governor Newsom's Medi-Cal Rx program in 2019, Health Center Partners joined with community health centers across California to voice considerable concern with the proposed transition. At a time when access is needed most and when community health centers are stretched from a year of new financial burdens and operational challenges, community health centers need a guarantee that Medi-Cal Rx transition will not undermine their financial stability.
- **I recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.**

DHCS needs to clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.

- The CalAIM proposal will ensure beneficiaries receive the care they need no matter how they enter the system or where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which can often be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. I applaud the administration's proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal, which will ensure providers' ability to render necessary medical

services to patients. However, questions remain as to how providers can comply with and bill for these services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan.

- **I ask DHCS to provide clarification on how non-contracted providers can provide medically necessary services prior to an assessment.**

DHCS must apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.

- The CalAIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although I recognize a statewide need to enhance access to both sets of services in a coordinated manner, I see several issues that need to be addressed to ensure counties are prepared to adequately meet the demand for services and so patients and families may be assured they are receiving the highest quality of care.
- **I am concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs is consolidated**. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, the Medi-Cal Managed Care External Quality Review Technical Report, dated July 1, 2017–June 30, 2018, indicated several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care.
- **While I agree the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure oversight, transparency, adequacy, and access to timely and quality SMH/SUD services**.

DHCS must ensure community providers, including community health centers and FQHCs, are eligible for support under Providing Access and Transforming Health (PATH).

- I am pleased to see the inclusion of Enhanced Care Management (ECM) and In-Lieu-of-Services (ILOS) in the CalAIM proposal as well as the administration's commitment to ensure adequate funding be allocated for the development of these services in this year's budget. Providing Access and Transforming Health (PATH) funding will help provide the necessary support to transition from county-based Whole Person Care services to ECM ILOS. This support is also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care, and allow ECM and ILOS providers to continue to move toward delivery system reform, addressing inequities by race and ethnicity for patients who are historically underserved and experience poor health outcomes.
- **To ensure successful implementation of these elements, it is important community-based organizations, including community health centers, have the tools and resources needed to work together and build capacity, including payments for new staffing and infrastructure.**

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DHCS must ensure the public has adequate opportunity to review and comment on all policy changes.

- While I appreciate the opportunities to comment on the 1115 and 1915(b) waivers and expect DHCS will release other policy changes for public comment in the future, I would like to underscore the importance of gathering and incorporating stakeholder input into all final policies. This includes an opportunity to provide input on any assessment tools that will be selected for use. Assessment tools must be rapidly deployed in the care setting and integrated into provider electronic health record systems.
- California needs to get this right to build effective workflows between primary care and specialty providers, including specialty mental health. This is important because the responsibility exists at the local level to best serve the needs of beneficiaries. Too much can be left to interpretation, especially when one partner or system of care is under stress due to capacity or other constraints.
- **A thoughtful approach will require input from all stakeholders. I encourage DHCS to work with stakeholders to design clear guidance in implementing these assessment and referral processes. Specifically, I request extensive public comment and engagement on the following items noted in the proposal:**
    - The new Individual Risk Assessment (IRA) tool which DHCS plans to implement, in an adult and a pediatric version, for risk stratification - replacing several existing tools including the Staying Healthy Assessment (SHA) tool where providers were previously afforded the opportunity to contribute input.
    - A standardized screening tool for county mental health plans (MHPs) and Medi-Cal managed care (MCMC) plans to use to guide beneficiaries toward the delivery system that is most likely to meet their needs.
    - A standardized transition tool for MHPs and MCMC plans to use when a beneficiary's condition changes, and therefore as a result better served in another delivery system.
    - A process for facilitated referral and linkage from county correctional institution release to county MHPs, Drug Medi-Cal, DMC-ODS, and MCMC plans when the inmate was receiving behavioral health services while incarcerated, to allow for continuation of behavioral health treatment in the community.

DHCS must continue to pursue and provide data sharing and integration across all systems of care including social services.

- A major component of new success in Medi-Cal will stem from everyone's ability to capture and share data across systems. I am very excited to see DHCS' plan in the **CalAIM Data Exchange Roadmap,** with identification of data use cases, that define information system requirements and data sharing activities necessary to enable ECM and ILOS and facilitate care coordination between physical, behavioral, and social service providers.
- Tackling legal, regulatory, infrastructure, and care coordination issues that have plagued the industry for years and prevented real care coordination is now being addressed substantially. A heavy lift: but you should be commended for the move in this direction. I look forward to active participation in this process and finding resolution strategies that work for all providers and beneficiaries.
- I realize the Cal AIM Data Exchange Roadmap does not need CMS approval, and therefore is not included in the waiver, but it is an important component toward future success, so it is worth mentioning in this comment letter. This is an ambitious approach to driving data exchange at every level of the delivery system.

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- My only concern is this work will take years, and providers will not have the support and infrastructure necessary as the state rolls out major CalAIM and related initiatives. Most struggle with the systems they have in place today, lacking the underlying infrastructure to support expanded work and effort, which will diminish the possibility of success.
- **I recommend DHCS keep CalAIM Data Exchange Roadmap efforts at the forefront of their efforts and as a top priority with stakeholder engagement.**

Additional Comments on the CalAIM 1115 & 1915(b) Waivers

Section 3.4 - Low Income Pregnant Women

- I would like to thank the state in continuing full scope Medi-Cal coverage to pregnant women with incomes from 109 percent up to and including 138 percent of the Federal Poverty Level (FPL) so community health centers may continue to reach and serve this population and help curb infant mortality rates among poor and minority populations. This aligns with the new federal initiative focused on Black maternal and infant mortality disparities.

Section 4 – Initiatives Being Discontinued or Transitioned Under CalAIM

Medi-Cal Managed Care

- **Population Health Management**
  - DHCS has indicated plans will be required to implement a needs assessment based on NCQA standards. In this approach, each health plan may design its own algorithm to determine population health stratification based on such an assessment. This could prove to be challenging for regions with multiple plans. As a stakeholder representing at-risk entities, I would like to be included in the development of any algorithms not only for development of a standard but to be sure delegated entities align.
  - **I request DHCS allow stakeholder input on selection of the population health tool and requisite data capture, and I recommend DHCS set a standard for all plans to use in stratification of patients based on use of the selected tool.**
- **Payments and Incentives**
  - I commend DHCS for recognizing the importance of structuring payments and aligning incentives to achieve the goals of CalAIM, that support whole person care approaches, address social determinants of health and equity, to improve outcomes and drive delivery system transformation. The waiver proposes that managed care plans will be incentivized to support outreach and provide the infrastructure necessary for ECM and ILOS. However, such incentives do not always make it down to the provider level, where engagement of hard -to-reach populations occurs. Additionally, today providers receive the same reimbursement for all Health Homes Program enrollees (per managed care payer) regardless of enrollees' needs and the amount of time and effort expended outreaching to and working with enrollees on their care plans.
  - **I recommend DHCS specifically include a commitment that CalAIM incentives will make it down to the provider level, and providers be afforded the opportunity to receive managed care plan shared savings. I recommend DHCS build-in risk stratification, even within the most complex populations.**

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- **Accountability and Oversight**
    - DHCS has taken steps to increase managed care oversight and accountability, but it is unclear how DHCS will expand this with so many CalAIM initiatives being implemented. Does DHCS have the bandwidth or necessary funding to deploy staff and resources in this regard? Further, accountability and oversight run downstream to delegated providers and groups, who will also need support. Guidelines, forms, and policy must be standardized and implemented at every level. Has this been fully accounted for or captured in DHCS' budget and expenditures?
    - **I recommend DHCS include detailed information about how accountability and oversight factor into the budget as part of the CalAIM 1115 & 1915(b) Waivers.**

Whole Person Care (WPC) and Health Homes Program (HHP)

- I support DHCS in transitioning key services from the WPC and HHP into the managed care delivery system through Enhanced Care Management and In Lieu of Services benefits**. However, I have concerns there is not sufficient time to move these services**.
- DHCS is not expected to begin negotiations with managed care plans until the summer of 2021. Normal negotiations can take more than 1-2 years with payers. This work, including establishing new contracts with downstream providers, some of which will be completely new relationships, will need to be done in less than six months to meet the current timeline.
- Also, one could draw the conclusion, based on the state's recent request (mid-April 2021) to plans and providers for ILOS data, that the state may not have all the pricing information necessary to support the full range of services that will be required when ILOS moves to managed care. To ensure sustainable program costs and a smooth transition of these services,
    - **I suggest DHCS consider delaying the implementation of ECM/ILOS to allow sufficient time for the state, payers, and providers to adequately prepare to deliver these new benefits under Medi-Cal.**
- While I appreciate the state has doubled the budget as WPC and HHP transition into managed care as ECM/ILOS under CalAIM, I am concerned this will not be enough to meet the need of an expanded population under Medi-Cal. It is a heavy lift. ECM and ILOS are ambitious reforms that will take time and support to implement, at the same time as we will be trying to recover from the COVID-19 public health emergency.
    - **I recommend the state allow for a phased-in approach for targeted populations and allow managed care plans to select only 1-2 ILOS services to initially implement, rather than try to implement a broad array of ILOS services.**

Coordinated Care Initiative (CCI)

- I appreciate DHCS' intent to better align care coordination of dual-eligibles by contracting only with Dual Special Needs Plans (D-SNPs) where Medicare and Medi-Cal are administered by the same company. **However, I am concerned in the transition of components of CCI into a statewide aligned enrollment structure, that narrows networks in the special needs plans (D-SNP) to reduce potential risk exposure, one result would be limited access and provider participation.**
- This could result in disrupted care for this vulnerable population. This concern is only heightened if plans are not selected to continue serving the Medi-Cal Managed Care System as part of the open procurement process. In the Waiver, DHCS indicates an intention to selectively

contract with Dual Special Needs Plans (D-SNPs), but there is no indication as to the criteria they will use for this selection process.

- Limiting health plan choice from the beneficiary perspective will be problematic, and networks could be affected impacting access and adequacy.
    - **I request a transparent process in development of the criteria that will be used to select D-SNPs and to request that DHCS commit to seeking open input from local stakeholders to help inform this process.**

Oral Health Services

- I applaud DHCS for establishing a new, statewide dental benefit for children and certain adults and expanding pay-for-performance initiatives under the state plan. This builds upon what was learned through key initiatives that worked well in the Dental Transformation Initiative (DTI) program. The DTI initiative improved statewide access to dental preventive services for children and high-risk adults.
    - **I recommend DHCS structure the program in a meaningful way so FQHCs may continue to participate by receiving the incentive outside of their PPS rate, as was the case in the DTI program.**

Finally, as providers continue to support the administration in the COVID-19 vaccination effort, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operations.

Again, I appreciate this opportunity to submit comments on the waiver proposal. I look forward to working with you to implement these major changes. If you have any questions, please contact me directly.

Sincerely,

[redacted]

President and Chief Executive Officer

CC: California Primary Care Association (CPCA)

Health Center Partners of Southern California, a family of companies, includes a 17-membership organization of federally qualified health centers, Indian Health Services Organizations, both urban and sovereign, and Planned Parenthood of the Pacific Southwest, collectively serving 917,000 patients each year, for 3.9 million patient visits each year, at 160 practice sites across San Diego, Riverside and Imperial counties, and is the seventh largest provider group in the region. Read our latest Impact Report.

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Vista Community Clinic

May 05, 2021

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 Demonstration Application and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Omni Family Health writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of the CalAIM Demonstration Application and 1915(b) Waiver Proposals (collectively, "Cal-AIM"). To the extent CalAIM incorporates Medi-Cal Rx into its framework, Omni Family Health urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

Omni Family Health is an FQHC that cares for Medi-Cal and uninsured patients in Kern, Kings, Fresno and Tulare counties. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through 7 in-house pharmacies and 80 contracted pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Omni Family Health to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, Omni Family Health annually saves an estimated savings of $4 million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Omni Family Health to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care system, Omni Family Health

patients have better access to more services, just as Congress intended in enacting the 340B program.1

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."2 As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx. Omni Family Health incorporates by reference the CHCAPA public comment letter into this letter. Omni Family Health fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, Omni Family Health urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Omni Family Health and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. Omni Family Health looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Joseph Hayes, DO, MMM
Chief Medical Officer
Omni Family Health

Enel.

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1 The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

2 Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attomey-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

May 6, 2021

Submitted via: CalAIMWaiver@dhcs.ca.gov

Director Will Lightbourne
Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413
Attn: Angeli Lee and Amanda Font

Re: CalAIM Section 1115 & 1915(b) Waiver

Dear Director Lightbourne;

ViiV Healthcare Company (ViiV), wishes to offer the following comments to the California Department of Health Care Services (DHCS) regarding the proposed California Advancing & Innovating Medi-Cal (CalAIM) 1115 Demonstration & 1915(b) Waiver.[1]

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

As an exclusive manufacturer of HIV medicines, ViiV is proud of the scientific advances in the treatment of this disease. These advances have transformed HIV from a terminal illness to a manageable chronic condition. Effective HIV treatment can help people with HIV to live longer, healthier lives, and has been shown to reduce HIV-related morbidity and mortality at all stages of HIV infection.[2,3] Furthermore, effective HIV treatment can also prevent the transmission of the disease.[4]

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[1] CA.gov, State of California Department of Health Care Services "Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration" DRAFT FOR PUBLIC COMMENT April 2021, https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Waiver-Renewal-Application.pdf (Accessed April 26, 2021)
[2] Severe P, Juste MA, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med*. Jul 15 2010;363(3):257-265. Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=20647201.
[3] Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. Apr 30 2009;360(18):1815-1826. Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19339714.
[4] Rodger et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. The Lancet. Published Online May 2, 2019 https://dx.doi.org/10.1016/S0140-6736(19)30418-0.

CalAIM 1115 Demonstration & 1915(b) Waiver

ViiV recognizes the work California has done in creating this proposal for a new delivery system framework, program reform across Medi-Cal, and particularly, the extensive stakeholder input and feedback process the state undertook in creating CalAIM.[5] We appreciate the state's goal to move the whole state towards a whole-person care approach under CalAIM with a focus on improving health and primary goals of addressing social determinants of health (SDOH), reducing health disparities and inequities, improving health quality outcomes, and driving innovation through value-based initiatives, modernization of systems, and payment reform.[6]

Medicaid has played a critical role in HIV care since the epidemic began, and it is the largest source of coverage for people with HIV.[7] In fact, more than 42 percent of PLWH who are engaged in medical care have incomes at or below the federal poverty level.[8] Medicaid is an essential source of access to medical care and ART drug coverage for people with HIV. This medical care and drug treatment not only preserves the health and wellness of people with HIV and improves health outcomes, but it also prevents new HIV transmissions. Despite groundbreaking treatments that have slowed the progression and burden of the disease, treatment of the disease is low – only half of people with HIV are retained in medical care, according to the Centers for Disease Control and Prevention (CDC).[9] Therefore, it is imperative that traditional Medicaid and Medicaid managed care plans (MCPs) work to expand access to HIV prevention, to preserve continuous access to comprehensive high-quality health care and antiretroviral therapy (ART) for people with HIV in order to improve health outcomes and reduce new transmissions.

In 2019, the U.S. Department of Health and Human Services (DHHS) released the "Ending the HIV Epidemic: A Plan for America (EHE)." [10] This plan proposes to use scientific advances in antiretroviral therapy to treat people with HIV and expand proven models of effective HIV care and prevention. The plan also focuses its efforts to stop the HIV epidemic across government agencies. California plays a central role in EHE efforts, having 8 counties identified by the plan for high rates of new HIV infections (Alameda, Los Angeles, Orange, Riverside, Sacramento, San Bernardino, San Diego, San Francisco).[11]

In order to promote the goals of the EHE plan, it is imperative that all state Medicaid programs align with local and national efforts to end the HIV epidemic, and promote policies that contribute to HIV public health goals, such as preserving continuous access to comprehensive health care, including ART. This includes promoting EHE goals within Medi-Cal MCPs, since they will be a key feature of

[5] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[6] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[7] Kaiser Family Foundation. Medicaid and HIV, http://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.
[8] Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. https://www.cdc.gov/hiv/ library/reports/hiv-surveillance.html. Published June 2019. Accessed February 2021. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf
[9] Understanding the HIV Care Continuum, CDC, https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf Accessed June 19, 2019.
[10] HIV.gov "Ending the HIV Epidemic" https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview (Accessed: April 20, 2021)
[11] Ending the HIV Epidemic Counties and Territories, https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf Accessed March 12, 2020.

the new CalAIM system.[12] In this spirit, ViiV offers the following suggestions and recommendations for your CalAIM waiver:

1. Innovation and Value in HIV care

We appreciate the state's goal to move the whole state towards a whole-person care approach under CalAIM with a focus on driving innovation through value-based initiatives, modernization of systems, and payment reform.[13]

One of the values offered in HIV care is that effective treatment of HIV not only improves the health outcomes of people with HIV, but also can prevent transmission of HIV to others.

When a person with HIV receives and maintains effective HIV treatment and receives quality medical care, they can reach viral suppression. Viral suppression means that the virus has been reduced to an undetectable level in the body with standard tests.[14] Viral suppression results in reduced mortality and morbidity and leads to fewer costly medical interventions.[15]

Viral suppression also helps to prevent new transmissions of the virus. When successful treatment with an antiretroviral regimen results in virologic suppression, secondary HIV transmission to others is effectively eliminated. The National Institute of Allergy and Infectious Diseases (NIAID) supported research that demonstrated when people with HIV achieve and maintain viral suppression, there is no risk scientifically of transmitting HIV to their HIV-negative sexual partner.[16] Multiple subsequent studies also showed that people with HIV on ART who had undetectable HIV levels in their blood, had essentially no risk of passing the virus on to their HIV-negative partners sexually.[17, 18, 19] As a result, the CDC estimates viral suppression effectiveness in preventing HIV transmission at 100 percent.[20]

Reduced transmissions not only improve public health, but also save money. Preventing new transmissions offers a substantial fiscal benefit to the state. In studies sponsored by the NIH, investigators have shown that when treating the HIV-positive partner with antiretroviral therapy,[21] there were no linked infections observed when the infected partner's HIV viral load was below the limit of detection. It is estimated people with HIV who are not retained in medical care may transmit

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[12] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[13] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[14] National Institutes of Health (NIH) "Ten things to Know about HIV Suppression" https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression.
[15] "Retention in Care and Adherence to ART are Critical Elements of HIV Care Interventions," Stricker, et al, AIDS and Behavior, October 2014, Volume 18, Supplement 5, pp 465–47,: https://link.springer.com/article/10.1007/s10461-013-0598-6
[16] NIAID, https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable. Accessed August 1, 2018.
[17] Bavinton, et al. The Opposites Attract Study of viral load, HIV treatment and HIV transmission in serodiscordant homosexual male couples: design and methods. BMC Public Health. 2014; 14: 917. doi: 10.1186/1471-2458-14-917.
[18] Cohen, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. September 1, 2016. N Engl J Med 2016; 375:830-839. DOI: 10.1056/NEJMoa1600693.
[19] "HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention" National Institute of Allergy and Infectious Diseases https://www.niaid.nih.gov/diseases-conditions/treatment-prevention.
[20] Centers for Disease Control and Prevention (CDC) "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV" https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html Accessed September 20, 2019.
[21] Rodger et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. The Lancet. Published Online May 2, 2019 http://dx.doi.org/10.1016/S0140-6736(19)30418-0.

the virus to an average of 5.3 additional people per 100-person years.[22] A recent study of commercially insured PLWH compared to individuals without HIV found that mean all-cause costs were almost seven times higher in those with HIV, culminating in an average discounted incremental cost of $850,557 in cumulative costs from ages 25-69.[23] Successful treatment with an antiretroviral regimen results in virologic suppression and virtually eliminates secondary HIV transmission to others. As a result, it is possible to extrapolate that successful HIV treatment and medical care of each infected patient may save the system up to $4.5 million by preventing further transmission to others. These savings can only occur if people with HIV have access to medical care, receive treatment, and remain adherent to their prescribed therapy.

ViiV encourages Medi-Cal to work with its MCPs, health care providers, and service organizations to promote awareness of this separate but dual benefit of HIV "treatment as prevention" (TasP).[24] The fact that achieving and maintaining viral suppression for people with HIV can also prevent new infections is an important point of understanding for those in public health and health care.

2. Social Determinants of Health (SDOH)

ViiV appreciates the state's goal to move the entire state towards a whole-person care approach under CalAIM with a focus on improving health with one of the primary goals of addressing social determinants of health (SDOH).[25] People with HIV often face a variety of medical challenges that impede access to, engagement in, and adherence to HIV care and treatment. In 2020, the DHHS released The HIV National Strategic Plan (HIV Plan),[26] which includes a focus on the role of SDOH in ending the HIV epidemic. The HIV Plan notes that SDOH can represent a significant barrier to health care access, and states that: "Inequities in the social determinants of health are significant contributors to health disparities and highlight the need to focus not only on HIV prevention and care efforts, but also on how programs, practices, and policies affect communities of color and other populations that experience HIV disparities."[27] ViiV offers the follow recommendations on SDOH:

a) Model SDOH on the Proven Interventions of the Ryan White Program

ViiV urges the state, in developing policies around SDOH, to review and model elements of the Ryan White HIV/AIDS Program (RWHAP), that have proven to be effective in supporting optimal patient care and driving treatment success in HIV.

The RWHAP over the last 30 years has developed a model of successfully addressing the complex needs of HIV/AIDS patients and producing unparalleled success in health and medical care among this population. The RWHAP provides services that demonstrated success in supporting the health and well-being of patients. These services offer best practice examples for how interventions focused on the social determinants of health can contribute to medical

[22] Skarbinski, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med*. 2015;175(4):588-596.
[23] Cohen JP, et al. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. PharmacoEconomics - Open (2020) 4:687–696. https://doi.org/10.1007/s41669-020-00209-8
[24] HIV.gov, For HIV, Treatment is Prevention, https://www.hiv.gov/blog/hiv-treatment-prevention
[25] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[26] National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025 https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf
[27] Id.

success. The RWHAP provides medical support services such as medical case management, medical transportation, and medical nutrition services, as well as oral health and dental care. The program also offers individual support services including food services, meal delivery, housing, transportation, legal services, linguistic services, case management, childcare, psychosocial and mental health services, rehabilitation and respite care, and substance abuse services. As a result of the program's services, in 2018, 87.1 percent of Ryan White HIV/AIDS Program clients were reported to be virally suppressed. This far exceeds the national viral suppression average of 62.7 percent.[28] We urge California to continue to work with Ryan White program officials to learn from the data the program has collected on effective interventions, and to seek best practices in addressing SDOH for Medicaid populations.

b) Stigma as a Social Determinant of Health

ViiV applauds the state for requiring the MCPs to engage in SDOH strategies. Furthermore, we urge the state to collaborate with people with HIV and HIV stakeholders to develop approaches that address and combat HIV stigma and LGBTQ stigma as a key social determinant of health.

Stigma is a significant concern in addressing the HIV epidemic.[29, 30, 31] HIV stigma - the negative attitudes or beliefs around HIV disease - can lead to discrimination and prejudice from others, and even by healthcare providers.[32] HIV stigma is often rooted in lack of information and awareness combined with outdated beliefs and scientific misconceptions about how HIV is transmitted and what it means to live with HIV today. According to the CDC, HIV stigma and discrimination can keep people from getting tested for HIV, learning their HIV status, accessing treatment, or staying in care. HIV stigma can also affect those at risk of HIV by discouraging them from seeking HIV prevention tools and testing.[33]

HIV continues to have a disproportionate impact on certain populations, particularly racial and ethnic minorities and gay and bisexual men. Populations disproportionately affected by HIV are also often affected by stigma due to, among other things, their gender, sexual orientation, gender identity, race/ethnicity, drug use, or sex work. [34] Therefore, the CDC recommends that, "The perspectives and needs of LGBT individuals should be routinely considered in public health efforts to improve the overall health of every person and eliminate health disparities."[35]

ViiV Healthcare supports appropriate education and awareness on HIV which seeks to reduce stigma and discrimination against people with HIV and populations at high risk for HIV. We would like to suggest that the state issue a Medi-Cal Information Bulletin to all providers in the state with resources and information about stigma, HIV, and the populations disproportionately

[28] HIV.gov Blog, "HRSA Announces Highest HIV Viral Suppression Rate in New Ryan White HIV/AIDS Program Client-Level Data Report," Cheever, December 11, 2019 https://www.hiv.gov/blog/hrsa-announces-highest-hiv-viral-suppression-rate-new-ryan-white-hivaids-program-client-level-0
[29] Mahajan, Anish P et al. "Stigma in the HIV/AIDS epidemic: a review of the literature and recommendations for the way forward." *AIDS (London, England)* vol. 22 Suppl 2,Suppl 2 (2008): S67-79. doi:10.1097/01.aids.0000327438.13291.62
[30] Centers for Disease Control and Prevention, "Dealing with Stigma and Discrimination" https://www.cdc.gov/hiv/basics/livingwithhiv/stigma-discrimination.html Accessed August 10, 2020
[31] HIV.gov "Standing Up to Stigma" https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma Accessed August 10, 2020
[32] "What is HIV stigma?" CDC.gov https://www.cdc.gov/hiv/basics/hiv-stigma/index.html
[33] "What is HIV stigma?" CDC.gov https://www.cdc.gov/hiv/basics/hiv-stigma/index.html
[34] HIV.gov "Standing Up to Stigma" https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma Accessed August 10, 2020
[35] CDC.gov "Lesbian, Gay, Bisexual, and Transgender Health" https://www.cdc.gov/lgbthealth/index.htm

affected by HIV including LGBTQ populations, and also require the MCPs to provide information to their networks.

c) Housing

The Housing Opportunities for Persons with AIDS (HOPWA) program can also offer an example of how addressing the SDOH can have a significant impact on health care improvement in a population with a complex condition. The HOPWA program was created in 1992 to address the housing needs of people with HIV.

The HIV Plan notes that housing instability or homelessness represents a significant barrier to health care access, and that people with HIV experiencing unstable housing or homelessness have lower rates of viral suppression, and therefore require services to support engagement in care and viral suppression.[36]

Homelessness and housing instability remain obstacles to effective HIV treatment. Access to stable housing can be a key intervention in stabilizing medical care for many vulnerable populations. A systematic literature review found that 94 percent of studies associated worse HIV medical care outcomes among those who were homeless, unstable, inadequately housed compared to "housed" people with HIV, and 93 percent found worse rates of adherence to antiretroviral treatment among those who were homeless or unstably housed.[37] Of the 13 studies that examined emergency room (ER) and inpatient visits among people with HIV, all found higher rates of ER visit or inpatient stays among those who were homeless or unstably housed.[38]

Additionally, among homeless people with AIDS who received supportive housing, there was an 80 percent reduction in mortality.[39] This is not surprising given that people with HIV and stable housing are much more likely to access health services, attend primary care visits, receive ongoing care and receive care that meets clinical practical standards.

According to the National AIDS Housing Coalition, "It is clear that housing improves health outcomes of those living with HIV disease and reduces the number of new HIV infections. The end of HIV/AIDS critically depends on an end to poverty, stigma, housing instability, and homelessness."[40]

We encourage the state to further consider the impact of homelessness on HIV care and treatment, and continue to work together with HOPWA program officials in California to seek coordination and share best practices.

[36] National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025 https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf
[37] The National Center for Innovations in HIV Care, "Housing as a Determinant of HIV Health Outcomes: Results from a Systematic Review of Research 1996-2014 & Implications for Policy and Program," https://targethiv.org/sites/default/files/supporting-files/Housing%20and%20HIV%20Health%20Outcomes%20Final.pdf
[38] Id.
[39] The National AIDS Housing Coalition http://nationalaidshousing.org/housing-and-health/
[40] The National AIDS Housing Coalition http://nationalaidshousing.org/

3. Reducing Health Disparities and Inequities

As mentioned, ViiV appreciates the state's goal to move the state towards a whole-person care approach under CalAIM, and this includes a focus on reducing health disparities and inequities.[41] We urge the state to collaborate with people with HIV and HIV stakeholders to develop strategies that identify, address and combat disparities and inequities of care for people with HIV in the state, as well as for populations that are at high risk for HIV.

HIV continues to have a disproportionate impact on certain populations, particularly racial and ethnic minorities and gay and bisexual men. [42] In California, as of 2018, 88.2 percent of people with HIV were male, and 88 percent of new HIV diagnosis were male as well.[43] Furthermore, as of 2018, 38.1 percent of people with HIV were Hispanic/Latinx, however 48.1 percent of new HIV diagnosis were Hispanic/Latinx.[44] This indicates a need for renewed focus on HIV prevention in that community.

We are pleased to note that the statewide End the Epidemics Coalition has re-centered its priorities on racial disparities. We encourage Medi-CAL to work with the California End the Epidemics Coalition to seek alignment between efforts, and to inform the work of CalAIM Initiative.[45]

As a further suggestion, we recommend that CalAIM seek alignment with the Covered California Multicultural Health certification program, which seeks to address disparities in access and outcomes experienced by certain racial and ethnic groups and those facing language and cultural barriers among the private plans in the state.[46]

4. Improving Health Quality

We acknowledge that the state of California initiated administrative reporting of viral load suppression (VLS) to CMS for measurement year 2019.[47] However, of great concern, based on the most recent Medi-Cal Managed Care Accountability Set (MCAS) for the Medi-Cal Managed Care Health Plans (MCPs) Measurement Year 2021 / Reporting Year 2022, the state has removed the VLS measure.[48] This is not in line with the CalAIM goals of reducing health disparities and addressing the SDOH in key populations.

The "HIV Viral Load Suppression (VLS)"[49] measure is the gold standard in HIV quality, as it signifies that a patient has reached the goal of HIV treatment, which is viral suppression. When a patient becomes virally suppressed, it means that the virus has been reduced to an undetectable level in the

[41] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[42] HIV.gov "Standing Up to Stigma" https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma
[43] AIDS Vu, Local Data: California, https://aidsvu.org/local-data/united-states/west/california/ (Accessed April 29, 2021)
[44] Id
[45] "End the Epidemics: Californians Mobilizing to End HIV, HCV, and STDs," PowerPoint Presentation (ciesandiego.org) Ramers, et al. 2019 (accessed May 4 2021)
[46] Covered California, Plan Management & Delivery Systems Reform, "California's Health Benefit Exchange – Plan Management (coveredca.com)" https://hbex.coveredca.com/stakeholders/plan-management/ (Accessed May 4, 2021)
[47] Quality of Care for Adults in Medicaid: Findings from the 2019 Adult Core Set Chart Pack page 94, (Accessed May 4, 2021)
[48] Medi-Cal Managed Care Accountability Set (MCAS) for the Medi-Cal Managed Care Health Plans (MCPs) Measurement Year 2021 / Reporting Year 2022, "RY2022 MCAS Final3 (12-31-2020)," https://www.dhcs.ca.gov/dataandstats/reports/Documents/RY2022-MCAS-12-31-2020.pdf (Accessed May 4, 2021)
[49]HIV/AIDS Bureau Performance Measures, "HIV Viral Load Suppression," https://hab.hrsa.gov/sites/default/files/hab/About/clinical-quality-management/coremeasures.pdf Accessed May 15, 2020

body with standard tests.[50] The National Institute of Allergy and Infectious Diseases (NIAID) recently supported research that demonstrated that achieving and maintaining a "durably undetectable" viral load not only preserves the health of people with HIV, but also prevents sexual transmission of the virus to an HIV-negative partner.[51] This builds a strong case for implementing a process and outcome HIV-focused, quality measures to encourage testing, linkage to care, and ongoing treatment so people with HIV can achieve viral suppression and ultimately improve their health outcomes.

Since Medicaid is the largest source of health care coverage for people with HIV, it is imperative for Medicaid programs to prioritize HIV care and viral load suppression by measuring and reporting VLS in order to align with the EHE strategies of rapid treatment and HIV transmission prevention.[52] Several state Medicaid programs have linked HIV quality measures to managed care performance, thus incentivizing achievement of viral suppression for their people with HIV. For example, the New York State's Ending the Epidemic Plan recommends that HIV providers, facilities, and managed care plans report and monitor viral suppression rates and provide financial incentives for performance.[53] Consequently, New York State's Department of Health requires Medicaid managed care organizations to report HIV-specific measures, including the VLS outcome measure, and awards financial incentives based on performance on these HIV measures.[54] New York's managed care efforts have significantly improved viral suppression rates among Medicaid beneficiaries; by linking many people with HIV to care, managed care organizations report that more than 40 percent of their Medicaid beneficiaries who were identified as unsuppressed, have now achieved viral suppression.[55]

Louisiana's Medicaid managed care program, Bayou Health, has included the VLS outcome measure in its contracts with managed care plans. To further drive improvement, managed care organizations have incorporated resources from the Louisiana Office of Public Health's (OPH) STD/HIV Program into disease management programs after the state added measures to their contracts. The Medicaid managed care plans will continue to support the ambitious HIV care and treatment programs that have achieved 57 percent viral suppression among people with HIV in Louisiana.[56]

Optimal outcomes for people with HIV can only occur if systems are measured and are able to benchmark their performance against the current standard of care in the HIV care continuum. The use of HIV-related quality measures will promote standards of health care coverage that support adherence to current HIV clinical and federal guidelines.[57] We strongly urge DHCS to reinstate the VLS measure for its core reporting.

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[50] National Institutes of Health (NIH) "Ten things to Know about HIV Suppression" https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression.
[51] NIAID, https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable.
[52] Kaiser Family Foundation. (October 1, 2019). Medicaid and HIV. Retrieved from https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/.
[53] New York State Department of Health. 2015 Blueprint. Retrieved from https://www.health.ny.gov/diseases/aids/ending_the_epidemic/docs/blueprint.pdf.
[54] NASHP. December 2017. Prioritizing Care: Partnering with Providers and Managed Care Organizations to Improve Health Outcomes of People Living with HIV. Retrieved from https://nashp.org/wp-content/uploads/2017/09/HIV-Affinity-Provider-MCO-Engagement-Brief.pdf.
[55] New York State Department of Health. Ending the Epidemic Progress Report: March 2018. Retrieved from https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/Executive_Summary_2018_.pdf.
[56] Louisiana HIV/AIDS Strategy 2017-2021, published by the Louisiana HIV Planning Group; August, 2016. Accessed at https://www.louisianahealthhub.org/wp-content/uploads/2018/10/LouisianaHIVAIDSStrategy.pdf.
[57] HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures (Updated) February 2015. Available at: http://paetc.org/wp-content/uploads/2015/04/Tools_for_Monitoring_Issue_Brief_update-April-2015.pdf. Accessed April, 14, 2020.

Additionally, we encourage the state to include HIV screening measures as part of the state's efforts to address opioid misuse. The HIV Screening measures would support preventive care and treatment while reducing transmissions of HIV. According to the CDC, substance use disorders are closely associated with HIV and other sexually transmitted diseases.[58] In people with HIV, substance use can also lower adherence to treatment and worsen health outcomes.[59] Health officials in several states have reported increased HIV transmissions due to injection drug use currently driving the opioid epidemic.[60,61] To address this, the USPSTF and the American Society of Addiction Medicine (ASAM) have both recommended frequent HIV screening for people who inject drugs, as well as screening for HIV while assessing and diagnosing opioid use disorders.[62,63] The CDC recommends HIV screening as routine care for all adults and adolescents, but advocates for more frequent screening for people who inject drugs.[64]

5. HIV-Specialized Providers

A key feature of CalAIM that builds off the success of Medi-Cal 2020 Whole Person Care (WPC) pilots and the State's Health Homes Program (HHP) is the introduction of Enhanced Care Management (ECM) which the Medi-Cal Managed Care Plan (MCP) and a member, can substitute for covered Medi-Cal services.[65]

Access to qualified medical care providers is important for people with HIV in order to monitor disease progression and ensure viral suppression is maintained.[66,67] Access to infectious disease specialists and HIV-specialized providers[68] is vital for people with HIV, as HIV patients see better outcomes when treated by an experienced HIV provider.[69]

Since the beginning of the HIV epidemic, providers from a variety of specialties (such as Infectious Disease Specialists and family medicine) and licensures (physician's assistants, nurses, nurse practitioners) have focused in HIV care and treatment and served this vulnerable population. There

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[58] Centers for Disease Control and Prevention (2019). HIV and Substance Use in the United States. Retrieved from https://www.cdc.gov/hiv/risk/substanceuse.html.
[59] Centers for Disease Control and Prevention (2019). HIV and Substance Use in the United States. Retrieved from https://www.cdc.gov/hiv/risk/substanceuse.html.
[60] Northern Kentucky Health Department. Press Release: *"Health Officials See Increase in HIV Infection Among Individuals Who Inject Drugs."* January 9, 2018. https://nkyhealth.org/2018/01/09/health-officials-see-increase-in-hiv-infection-among-individuals-who-inject-drugs/.
[61] Massachusetts, Department of Public Health, MDPH Clinical Advisory, HIV Transmission through Injection Drug Use, November 27, 2017. https://hmccreg3.org/wp-content/uploads/sites/90/2017/12/112707ClinicalAdvisory_HIV.pdf.
[62] American Society of Addiction Medicine (2015). The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Accessed at https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24.
[63] USPSTF (2019). Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. *JAMA 321*(23):2326-2336. https://jamanetwork.com/journals/jama/fullarticle/2735345.
[64] Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, Lyss SB, Clark JE (2006). Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR. 55*(RR14);1-17. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.
[65] CA.gov, State of California Department of Health Care Services "DEPARTMENT OF HEALTH CARE SERVICES NOTICE OF GENERAL PUBLIC INTEREST RELEASE DATE: APRIL 6, 2021," https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-1915%28b%29-Joint-Public-Notice.pdf (Accessed April 26, 2021)
[66] Kitahata MM, Koepsell TD, Deyo RA, Maxwell CL, Dodge WT, Wagner EH. Physicians' experience with the acquired immunodeficiency syndrome as a factor in patients' survival. New Engl J Med. 1996;334:701–7. [PubMed]
[67] Gallant, Joel E. et al. "Essential Components of Effective HIV Care: A Policy Paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition." Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America53.11 (2011): 1043–1050. PMC. Web. 20 Dec. 2017.
[68] Identifying Providers Qualified to Manage the Longitudinal Treatment of Patients with HIV Infection and Resources to Support Quality HIV Care Revised: March 2013, HIV Medicine Association https://www.hivma.org/globalassets/hivma/logos/revised-qualified-hiv-provider-policy-statement-approved-3-16-13-1.pdf.
[69] Gallant, et al. Essential Components of Effective HIV Care. *Clinical Infectious Diseases*. 2011 Dec; 53(11):1043-50

is no board certification for HIV medicine, but several professional organizations have identified criteria for designation of HIV specialists, [70] and some states have also codified HIV specialty.[71]

The importance of continuity of care for medically underserved patients, particularly people living with HIV, is significant. Patients retained in active medical care often have long-standing, trusting relationships with their medical provider, which is a key piece of the successful management of HIV. Exclusion of these providers from coverage networks can lead to care interruptions and may cause beneficiaries to forgo care entirely, rather than visit an unfamiliar provider without experience caring for disadvantaged or complex care populations. Achieving control of the virus requires regular access to a medical provider. Gaps in HIV treatment of days to weeks can reverse viral suppression, increase risk of transmission to others, and lead to serious complications, including development of a virus that is drug resistant, and more difficult to treat.[72]

For these reasons, we encourage DHCS to require that the MCPs contract with all available HIV providers in the state and to allow people with HIV to maintain access to their current HIV care management providers. We also offer the following suggestions around provider requirements for the MCPs:

a) Include Essential Community Providers in Network

We encourage DHCS to require MCPs to contract with all essential care providers in the state, including federally qualified health centers, rural health centers, community health centers, Ryan White clinics, and local health departments.

Health care providers that serve a large proportion of low-income or medically underserved individuals are given a designation of “essential community providers” (ECP) under federal law. CMS identifies Federally Qualified Health Centers (FQHCs) and FQHC "Look-Alike" clinics, Ryan White HIV/AIDS Program Providers, Indian Health Providers, and STD clinics as ECPs among others. Commercial plans in the state exchanges are required to have a sufficient number and geographic distribution of ECPs to ensure access to a broad range of such providers for low-income, medically underserved individuals.[73]

We encourage DHCS to also require the MCPs in the state to cover access to these same providers, as many of these entities serve people with HIV and at-risk populations. Including them in provider networks would further serve to ensure people with HIV can stay retained in care with their established provider.

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[70] HIV Medicine Association (HIVMA), American Academy of HIV Medicine (AAHIVM), and Associations of Nurses in AIDS Care (ANAC). The AAHIVM has a credentialing process for HIV physicians, nurse practitioners, physician’s assistants and pharmacists. ANAC created the HIV/AIDS Nursing Certification Board for certification of registered nurses and nurse practitioners in HIV nursing.
[71] Florida Agency for Healthcare Administration, Medicaid Managed Care Contract, The HIV/AIDS Specialty Plan, Attachment II, Exhibit II-C, HIV/AIDS Specialty Plan, November 1, 2015, https://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2015-11-01/Exhibit_II-C-HIV-AIDS_2015-11-01.pdf Accessed July 6, 2020
[72] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf [Discontinuation or Interruption of Antiretroviral Therapy].
[73] Kaiser Family Foundation, “Contract Offering and Signing Standards for Essential Community Providers (ECPs) in Marketplaces,” 2015, https://www.kff.org/other/state-indicator/contract-offering-and-signing-standards-for-essential-community-providers-ecps-in-marketplaces/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D Accessed July 30, 2020

b) HIV Medical Training Opportunities

We suggest that DHCS requires the MCPs to provide information about HIV education opportunities, including information on HIV prevention, to all physicians operating under the state Medicaid program as well as resources for consultation for inexperienced providers treating people with HIV.

As mentioned above, eight California counties are identified by the federal EHE initiative for its high rates of new HIV infections.[74] This indicates a need for increased attention and education on HIV prevention and treatment among providers in the state. Providers in the state should be made aware of the HIV education and consultation options offered by the federal government.

The federal Health Resource Services Administration (HRSA), which administers the Ryan White program, offers direct provider-to-provider consultation services through the National HIV/AIDS Clinician Consultation Center, including several hotlines: the "HIV Management Service Warmline," the Post-Exposure Prophylaxis Hotline (PEPline), Perinatal HIV Consultation and Referral Services (Perinatal HIV Hotline), the Pre-Exposure Prophylaxis Service (PrEPline), and the Clinical Substance Use Consultation (Substance Use Warmline).[75]

Additionally, the Ryan White AIDS Education Training Centers (AETCs) are regional bodies which offer resources and program for provider education on HIV.[76] MCPs should advise network providers on the offerings of the AETCs.

DHCS would benefit from requiring that all providers in the state fulfill a minimum amount of continuing medical education (CME) training on HIV. Due to the high burden of HIV incidence, the District of Columbia requires licensed health professionals to complete at least ten percent of their continuing education in the public health priorities of the District, including HIV[77] and LGBTQ cultural competency to help health care professionals to better understand the health challenges faced by these communities.[78] This is especially important for those providers who treat only a few people with HIV, as studies show that HIV patients see better outcomes when treated by an experienced HIV provider.[79]

6. Open Access to HIV ART

We applaud the state of California for its statutory coverage of access to ART for people with HIV in Medicaid. We would be remiss if we didn't mention the importance of continuing policies that ensure open access to life-saving treatment for people with HIV, including newer single tablet regimens and other innovative treatments, as well as the need for access to HIV prevention medications without utilization management for vulnerable populations in both Medi-Cal and in the MCPs.

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[74] HIV.gov "Ending the HIV Epidemic" https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview Accessed July, 15, 2019.
[75] National Clinician Consultation Center: https://aidsetc.org/aetc-program/national-clinician-consulation-center
[76] HRSA's AIDS Education and Training Center (AETC) Program: https://aidsetc.org/
[77] DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH, PUBLIC NOTICE: IDENTIFYING PUBLIC HEALTH ISSUES FOR CONTINUING EDUCATION, REGISTER VOL. 66 - NO. 45 NOVEMBER 1, 2019 https://dchealth.dc.gov/sites/default/files/dc/sites/doh/service_content/attachments/10%25%20CE%20-%20Public%20Notice%20-%2066%20DCR%2014518-14519.pdf
[78] DC.gov Board of Medicine, Continuing Education Requirements, https://dchealth.dc.gov/bomed
[79] Gallant, et al. Essential Components of Effective HIV Care. *Clinical Infectious Diseases*. 2011 Dec; 53(11):1043-50

Treatment of HIV is a dynamic area of scientific discovery, and treatment protocols are changed and updated to reflect advances in medical science. In clinical settings, health care providers work closely with patients to select HIV treatment options with great specificity for each patient. Effective treatment of HIV is highly individualized and accounts for a patient's size, gender, treatment history, viral resistance, coexisting illnesses, drug interactions, immune status, and side effects. In fact, the DHHS Guidelines[80] state that, "Regimens should be tailored for the individual patient to enhance adherence and support long-term treatment success."

With the success of ARV's in the treatment of HIV, many PLWH must now also contend with other diseases related to normal aging, including non-HIV related comorbidities[81] that require polypharmacy which creates a higher risk of drug-drug interactions between antiretroviral drugs and concomitant medications. Clinically significant drug interactions have been reported in 27 to 40 percent of HIV patients taking antiretroviral therapy requiring regimen changes or dose modifications.[82]

Studies comparing the use of a STR versus a multi-tablet regimen (MTR) in people with HIV across government sponsored plans, such as Medicaid, compared to commercially insured enrollees showed that more people in Medicaid are using a MTR.[83,84] Analyses have shown that those on a STR had fewer hospitalizations and lower overall health care costs. A recent analysis published by Express Scripts reported people living with HIV enrolled in a government sponsored health plan were more likely to use a MTR than those enrolled in commercial insurance.[85] However, adherence was higher in the STR users as compared to the MTR users.[86] For all health plan types evaluated, those on a MTR had higher health care costs regardless of their adherence status but the difference was greater for those adherent to a STR which was $5,427 less than a patient adherent to a MTR.[87]

Therefore, broad access to the full array of available treatment options is vital in HIV treatment. People with HIV must have access to a robust formulary that provides physicians with the ability to prescribe the right treatments at the right time for their patients.

ViiV also encourages the state to also consider requirements for the MCPs and CalAIM to cover newly FDA-approved therapies for people with HIV. These treatments represent new options that could greatly benefit some patients, such as a treatment option for those who have multi-drug resistance to currently available ARVs, and the first ever long-acting HIV treatment. [88] It is vital that the state ensure patients who could benefit from these options have access to them.

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[80] DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines
[81] Schouten J, et al. Clin Infect Dis. 2014 Dec 15;59(12):1787-97.
[82] Evans-Jones JG et al. Clin Infect Dis 2010;50:1419–1421; Marzolini C et al. Antivir Ther 2010;15:413–423.
[83] Express Scripts. Viral Signs: U.S. trends in HIV medication use, care and cost. November 2018. http://lab.express-scripts.com/lab/publications/viral-signs-understanding-hiv-medication-use.
[84] Kangethe A, et al. Real-world health plan data analysis: Key trends in medication adherence and overall costs in patients with HIV. *JMCP*. Vol 25(1), January 2019. Pp 88-93.
[85] Express Scripts. Viral Signs: U.S. trends in HIV medication use, care and cost. November 2018. http://lab.express-scripts.com/lab/publications/viral-signs-understanding-hiv-medication-use.
[86] Id
[87] Id
[88] HIV.gov "Long-Acting HIV Prevention Tools" https://www.hiv.gov/hiv-basics/hiv-prevention/potential-future-options/long-acting-prep

Finally, ViiV supports coverage of pre-exposure prophylaxis (PrEP) to all at-risk populations. Additionally, the US Preventive Services Taskforce (USPSTF) recently issued a "Grade A" rating of HIV PrEP treatment.[89] The new USPSTF recommendation means that Medicaid programs that cover PrEP without cost-sharing along with other preventive services can receive an FMAP increase under the ACA, similar to coverage of HIV testing.

Conclusion

Thank you for your consideration of our comments. We hope that California will continue to work towards the goal of ending the HIV epidemic, and as such, use this CalAIM initiative to advance these objectives. Please feel free to contact me at kristen.x.tjaden@viivhealthcare.com with any questions.

Sincerely,

[redacted]

Kristen Tjaden
Government Relations Director
ViiV Healthcare

[89] US Preventive Services Task Force Final Recommendation Statement, "Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis," June 11, 2019 https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#:~:text=The%20USPSTF%20recommends%20that%20clinicians,selection%20of%20effective%20antiretroviral%20therapy

We do commend the efforts made to improve access to care for vulnerable Californians with mental health needs. However,

the CalAIM 1915(b) waiver proposal does not go far enough to directly address the impact of racism on the social and emotional health of children. The proposal must be revised to:

Resist pathologizing adversity—as evidenced by proposed tools to "screen in for a high risk score" for ongoing services. We must honor the wisdom and intelligence of low income communities to determine their own definition of medical necessity. Any positive screen, and more importantly, any request for support from a beneficiary should qualify a child for services and support.

Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan--or if such a tool is to be used it must only be used during the course of treatment and treatment can not be stopped or interrupted until or if there is a transition in care.

Clarify unanswered questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

With appreciation,

Dr. Simona Cataldo, CEO
Victor Community Support Services
Victor Treatment Centers

CalAIM Waiver Public Comment

Feedback from L.A. Care Health Plan
May 6, 2021

In response to the Department of Health Care Services' draft CalAIM Section 1115 demonstration application and Section 1915(b) waiver overview, L.A. Care has drafted the following feedback for the Department's consideration.

Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration

Services for Justice-Involved Populations 30-Days Pre-Release

- **Logistics on release dates:**
  - In County jail, release dates are not straightforward to determine. There are numerous people being held as pre-trial (or unsentenced) so they do not have release dates and in some cases, people are released directly from the court without prior notification to programs (including Whole Person Care-LA) that may have been tracking eligibility for services/linkage to care.
  - The effort to instead 'pause' benefits while incarcerated instead of terminating them (as is currently the practice for anyone incarcerated longer than 1 year) is currently under discussion with L.A. County DPSS and DHCS. L.A. Care contends 'pausing' benefits would be more simple and effective at maintaining continuity and access to Medi-Cal for these beneficiaries.
  - Also, there are challenges associated with jail staff determining who would qualify for this early eligibility for Medi-Cal and connecting them to both Medi-Cal and Managed Care coverage. In L.A. County jail, it takes not just staff to collect and process applications, but also custody/sheriff staff to escort incarcerated people to complete the applications, as well as to check on actual release dates and to trigger Medi-Cal activation upon release.
- **Eligibility criteria for pre-release Medi-Cal coverage:**
  - As written, the vast majority of incarcerated persons will qualify for both Medi-Cal coverage and reentry enhanced care management (ECM).
    - For Medi-Cal coverage, broad coverage would be helpful but it could be hard for jail/prison staff to figure out who would NOT qualify.
    - For reentry ECM, the population could be very broad and exceed the low enrollment thresholds the state has messaged for rates.
  - Just the substance use disorders (SUD) criterion alone will make more than half the incarcerated population eligible for ECM.
    - "The majority of people in county jails (53%), state prisons (56%), or federal prisons (50%) met DSM-IV criteria for a SUD at the most recent national surveys [3,4,5]."[1]

[1] Chamberlain, A., Nyamu, S., Aminawung, J. et al. Illicit substance use after release from prison among formerly incarcerated primary care patients: a cross-sectional study. Addict Sci Clin Pract 14, 7 (2019). https://doi.org/10.1186/s13722-019-0136-6

- **Challenges with providing reentry ECM pre-release:**
    - For people incarcerated in state prisons, it will be challenging to require them to be assigned to a Medi-Cal Managed Care Plan (MCP) to provide ECM before release because people are often sent to a different county than expected at the last minute; this would potentially delay care and coverage if they have to have their Medi-Cal county and MCP switched (not a fast process). The California Department of Corrections and Rehabilitation (CDCR) would also need significant staffing support to share healthcare information with MCPs and their contractors before release, and would need to allow access to incarcerated persons for ECM staff (e.g. virtual visits to opt in to the ECM program and start care planning, even if an in-person visit may not be possible due to geographic distance from the state prison).
    - For people incarcerated in county jails, starting ECM 30 days pre-release will be challenging because release dates are so variable and many people will likely not be enrolled in Medi-Cal Managed Care before they leave incarceration; it will not be feasible to do retroactive authorization, approval, claims/encounter data, and billing for reentry ECM before enrollment in the MCP. This would be better done by county partners, who could then share information and coordinate with MCPs.
    - The L.A. County WPC-LA reentry teams and, in particular, the Community Health Workers (CHWs) with lived experience (i.e. having a record) have struggled to get the appropriate security clearances from the L.A. County Sheriff Department to enter the jails and meet in person with clients (pre-COVID-19). In many cases, they have to rely on phone calls or word-of-mouth to connect with potential clients.
    - Internet connections/virtual visits have not been feasible for many reasons. In some cases, not having a semi-private office space to meet, spotty internet connection, lacking the staff to provide access to clients, etc. have all been barriers to CHWs and WPC-LA staff being able to meet pre-release. The pre-release work is better done by County partners who can then coordinate with MCPs.

California Advancing and Innovating Medi-Cal (CalAIM) 1915(b) Waiver Overview April 2021

Specialty Mental Health Services

L.A. Care actively supports the following provisions included in this section:

- Transition SMHS funding from CPE methodology to a rate-based methodology
- Diagnosis not necessary for reimbursement
- SMHS enhancements for foster youth and families

Drug Medi-Cal Organized Delivery System (DMC-ODS)

L.A. Care actively supports the following provisions included in this section:

- Transfer DMC-ODS authority from 1115 waiver to 1915b waiver
- Transition DMC-ODS funding from CPE methodology to a rate-based methodology
- Facilitate DMC-ODS services for members who are leaving incarceration
- Diagnosis not necessary for reimbursement
- Require MAT services or access for levels of care between ASAM 1.0-4.0

- Add Contingency Management as a DMC-ODS benefit to treat stimulant/methamphetamine use disorders
- Remove annual limits on Residential Treatment (RTC) episodes
- Reimburse for Culturally Specific SUD healing practices

Mission Neighborhood Health Center

240 Shotwell Street San Francisco, CA 94110 - Phone: (415) 552-1013 - Fax: (415) 431-3178
info a mnhc.org - www.mnhc.org

May 5, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Mission Neighborhood Health Center writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, Mission Neighborhood Health Center urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

Mission Neighborhood Health Center is an FQHC that cares for Medi-Cal and uninsured patients in San Francisco. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through our in-house pharmacy and 26 contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Mission Neighborhood Health Center to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, Mission Neighborhood Health Center annually saves an estimated $1.4 million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Mission Neighborhood Health Center to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care

system, Mission Neighborhood Health Center patients have better access to more services, just as Congress intended in enacting the 340B program.1

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."2 As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which Mission Neighborhood Health Center incorporates by reference into this letter. Mission Neighborhood Health Center fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, Mission Neighborhood Health Center urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Mission Neighborhood Health Center and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. Mission Neighborhood Health Center looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

Brenda Storey,

[redacted]

1 The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

2 Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

May 03, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding Removal of Pharmacy Services from Medi-Cal Managed Care in Conjunction with CalAIM Section 1915(b) Waiver Proposal

Dear Director Lightbourne:

The Community Health Center Alliance for Patient Access ("CHCAPA"), a non-profit organization composed of 31 federally-qualified health centers ("FQHCs") and support organizations, writes to object to the California Department of Health Care Service ("DHCS") proposal to carve pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of Medi-Cal managed care in connection with implementation of DHCS' California Advancing and Innovating Medi-Cal ("CalAIM"). The proposed removal of pharmacy benefits and services from Medi-Cal managed care is also known as "Medi-Cal Rx."[1]

Medi-Cal Rx is antithetical to the stated goals of CalAIM. Indeed, in the Background and Overview section of the Executive Summary, DHCS touts the benefits of Medi-Cal managed care as follows:

> Medi-Cal has significantly expanded and changed over the last ten years, most predominantly because of changes brought by the Affordable Care Act and various federal regulations as well as state-level statutory and policy changes. During this time, the DHCS has also undertaken many initiatives and embarked on innovative demonstration projects to improve the beneficiary experience. In particular, DHCS has increased the number of beneficiaries receiving the majority of their physical health care through Medi-Cal managed care plans. These plans are able to offer more complete care coordination and care management than is possible through a fee-for-service system. They can also provide a broader array of services aimed at stabilizing and supporting the lives of Medi-Cal beneficiaries. [Emphasis added.]

CHCAPA agrees that Medi-Cal managed care plans are able to offer more complete care coordination and care management than is possible through a fee-for-service ("FFS") system. Carving pharmacy benefits or services by a pharmacy billed on a pharmacy claim out of managed care, and instead reimbursing these benefits or services on a FFS basis, increases,

[1] Specifically, page 18 of the CalAIM Executive Summary and Summary of Changes, Proposal 3.1, identifies as an element of "Managed Care Benefit Standardization" that benefits to be carved out include: "4/1/21: Pharmacy benefits or services by a pharmacy billed on a pharmacy claim." https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-Executive-Summary-02172021.pdf Medi-Cal Rx was not implemented on 4/1/21, and has not been implemented to date, with no implementation date yet announced to the public.

rather than decreases, system fragmentation and renders care coordination and care management more, rather than less, difficult.

Integrating pharmacy and medical services in managed care allows FQHCs to better serve patients. The FQHCs can serve as a one-stop-shop for all of their patients' medical needs, and integration facilitates the FQHCs' ability to assist patients in following their treatment plan, including pharmacy. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for historically underserved patients.

Additionally, providing pharmacy benefits and services in the context of Medi-Cal managed care enables FQHCs to effectively leverage discount drug pricing available through the 340B Drug Pricing Program. The savings available through participation in the 340B program allow FQHCs to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed on a FFS basis. As a result of the current managed care system, FQHC patients have better access to more services, as Congress intended in enacting the 340B program.[2]

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[3] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede FQHCs' ability to provide critical services to patients. The proposed FFS reimbursement, compounded with the loss of 340B savings and COVID-19 financial losses, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of the Medi-Cal program and CalAIM, which is to improve access to healthcare and reduce health inequities.

Finally, federal Medicaid law prohibits states from waiving the FQHC reimbursement requirements described in 42 U.S.C. § 1396a(bb) under a 1915b waiver.[4] California's Medi-Cal program does not currently have a compliant manner of reimbursing FQHCs for Medi-Cal's share of the cost of providing pharmacy services outside of the managed care system.

On the dispensary side, DHCS has not implemented the requirements of Welfare & Inst. Code § 14132.01 relating to reimbursement of Medi-Cal drugs provided through a clinic dispensary and has made no attempt to ensure that the dispensing fee for FQHC pharmacies or

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[2] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

[3] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

[4] 42 U.S.C. § 1396n(b).

dispensaries reimbursed under the fee-for-service alternative payment methodology are not less than the specific FQHC site would receive under the PPS floor. Moreover, the Mercer study that supported the pharmacy fee-for-service dispensing fees completely failed to address the requirements of 42 U.S.C. § 1396a(bb)(6)(B).

In addition, Medi-Cal has failed to adopt a standard for avoiding duplicate discounts on drugs dispensed through contract pharmacies, as required under HRSA's 2010 Contract Pharmacy Guidance, thus the transition would eliminate use of contract pharmacies for fee-for-service claims.

As a result, if Medi-Cal Rx is approved as part of the 1915b waiver, FQHCs will no longer be able to dispense Medi-Cal covered drugs through clinics' dispensaries or contract pharmacies, and will not be reimbursed at their actual cost of providing the mandatory FQHC services benefit, in violation of 42 U.S.C. § 1396n(b),resulting in a backdoor waiver of the FQHC reimbursement and service requirements in violation of federal law

Please see the attached letter from CHCAPA to the Centers for Medicare and Medicaid Services ("CMS"), dated April 16 2021, for a full description of our substantive and procedural concerns regarding Medi-Cal Rx.

In conclusion, CHCAPA agrees with Secretary Becerra that FQHCs and DHCS should "work in partnership to provide individuals access to affordable healthcare, including prescription drugs." Therefore, CHCAPA urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration.

Thank you for your time and consideration. CHCAPA looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Encl.

17479823.2

HEALTH ACCESS CALIFORNIA

May 6, 2021

William Lighbourne, Director
Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

Re: Comments on CalAIM Section 1115 & 1915(b) Waiver

Dear Mr. Lightbourne:

Health Access California, the statewide health care consumer advocacy coalition committed to quality, affordable health care for all Californians, would like to offer the following comments on several key proposals included in the California Advancing and Innovating Medi-Cal (CalAIM) initiative and associated waiver extensions.

Health Access had been active in the planning stages of the CalAIM initiative—participating in workgroups, engaging with other advocate stakeholders, and support many of the initiative's broad goals in a variety of contexts, throughout the initial planning, the pandemic-related waiver extension process, and now during the restarting of the planning process.

In general, we are supportive of the overall concepts, from greater streamlining and standardization of the Medi-Cal program, to the general effort to provide more "whole-person care," especially for those vulnerable Californians with complex needs, such as the unhoused, those with multiple chronic conditions, justice system-involved populations, those with behavioral health needs, and the growing aging cohort of our state. We support the budget investment and general direction of the CalAIM proposal to provide enhanced care management and a number of in lieu of services (ILOS) that have the promise of providing better outcomes and potential savings. We also support the requirement of Medicaid managed care plans to have population health management programs.

Within this conceptual support, we align and have signed onto comment letters with other consumer advocates on the important details of these proposals. Some of our concerns go to the implementation, including whether the health plans are the best equipped to take on these massive responsibilities, and if they are being asked to do more, that DHCS is pro-active in holding the plans accountable. To

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date, the plans' track record on their core responsibilities to Medi-Cal recipients is mixed at best, and we so we will need extra vigilance for these additional expectations.

In addition to comments we may submit or support with others, we would like to focus our comments on the following areas with which we have been the most engaged.

National Committee for Quality Assurance (NCQA) Accreditation

NCQA is a private organization that develops quality and performance measures for managed care plans, and also offers plan accreditation. Cal-AIM would require all Medi-Cal managed care plans to become NCQA accredited by 2026.

Health Access supports the strategic use of NCQA measures and plan accreditation to increase oversight, standardization, and quality. Many other states require their Medicaid managed care plans to have NCQA accreditation, and the vast majority of California plans already do. Making this requirement universal to all Medi-Cal managed care plans makes sense. We would also strongly support a requirement that all Medi-Cal managed care plans are Knox-Keene licensed.

That said, California has led the way in establishing additional and/or higher benchmarks for quality, equity, and plan performance. Because our state standards often exceed those used nationally, we must be cautious that any new standards do not provide opportunity for weakening or undermining our existing protections. Health Access participated in a CalAIM workgroup on NCQA accreditation, where we found many differences between NCQA's requirements and California standards, which were more aligned with our health system goals and the diversity of our state.

We strongly urge that NCQA standards shall not be used for "deeming," which is the practice of allowing accreditation to act as an automatic fulfillment of state or federal standards. Because NCQA standards often fall short of the standards California has set, NCQA certification does not suffice as a means of "fast tracking" plans towards meeting benchmarks. Most states that require NCQA accreditation do not practice "deeming," and our review of the benchmarks suggest it is not appropriate for California.

Global Payment Program

Health Access is in strong support of the continuation of the Global Payment Program (GPP), which is critical to include in Cal-AIM to ensure our public hospital system can continue to provide comprehensive care for the uninsured. Established under the "Medi-Cal 2020" Medicaid 1115 waiver and currently set to expire at the end of 2021, the GPP has provided flexibility and incentives for public health care systems to provide preventive and primary care for the indigent and uninsured. The flexibilities allowed within the GPP's value-based framework have encouraged services within primary and preventive care settings, and rewards public health care systems for the value, rather than the volume, of care provided.

Health Access has worked with consumer and community groups in various counties who have been engaged in the development of their indigent care programs. We have been excited with what counties have been able to do to provide upstream care—not just at the emergency room of the public hospital, but also providing "medical home" services that include primary and preventive care, and a feeling of connection to the health system. While we have urged some counties to do more,

and will continue to do so, we recognize how important the GPP funding and flexibility is to provide these key services to the remaining uninsured.

Health Access supports continuation of the resources from both the funding streams from the Safety Net Care Pool, and for Disproportionate Share Hospitals (DSH), as well as the flexibility provided under GPP. Those Safety Net Care Pool dollars are especially helpful given the disruptions in our health system caused by the public health emergency in this pandemic.

California still has around three million uninsured despite the coverage options provided under Medi-Cal and Covered California, our health care marketplace. Extending the GPP, including the Safety Net Care Pool funding, will allow California counties to continue providing care to the most vulnerable. Furthermore, the GPP framework emphasizes an upstream approach that encourages public health care systems to not only provide one-off services, but to establish ongoing relationships with the uninsured which in turn facilitate preventive, comprehensive care.

In conclusion, Health Access appreciates the overall direction of CalAIM, and looks forward to continued engagement in the planning and implementation of the CalAIM initiative. If you have questions about any of our thoughts on CalAIM, please contact Diana Douglas at ddouglas@health-access.org.

Thank you for your consideration.

Sincerely,

Anthony Wright
Executive Director

CWDA
Advancing Human Services
for the Welfare of All Californians

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Sacramento, CA 95814
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cwda.org

May 5, 2021

Will Lightbourne
Director, Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

Re: CalAIM Section 1115 & 1915(b) Waiver Comments

Dear Director Lightbourne:

On behalf of the County Welfare Directors Association (CWDA), thank you for your leadership during this unprecedented pandemic and the special attention being paid to the vulnerable populations served by county human services agencies.

We are writing to convey our comments of the Department of Health Care Services' (DHCS) California Advancing & Innovating Medi-Cal (CalAIM) initiative. Specifically, we offer our thoughts and concerns regarding: 1) Medi-Cal coverage 30-day pre-release for justice-involved populations, 2) jail pre-release mandate, 3) county monitoring and performance measures, 4) transitioning Whole Person Care to Enhanced Care Management/In Lieu of Services (ECM/ILOS) delivered by managed care plans, and 5) carve-in of Kaiser mental health patients to Solano and Sacramento counties.

Medi-Cal Coverage 30-Days Pre-Release for Justice-Involved Populations and Jail Pre-Release Mandate

We strongly support policies that provide health care services for justice-involved populations pre-release and policies linking justice-involved populations to health, behavioral health, and health plans post-release through the pre-release application process. Due to the interconnectedness of both proposals, we note there are issues that need to be addressed for the proposals to be successfully implemented. In addition to the below comments, we note that changes also may be needed to the proposal in order to accommodate the juvenile justice system, which is run by County Probation agencies, not the Sheriffs.

First, as highlighted in our budget memo on April 21, 2021, a present challenge for counties to conduct a jail pre-release process is the lack of required and timely data sharing between jails and sheriffs and human services agencies. A requirement for jails and sheriffs to share data and notify counties when individuals will be incarcerated longer than a period of at least 60 days, in addition to being notified of those who are being released with enough lead time for the county to either lift the suspension or process new eligibility for the jail to take advantage of the 30-day inreach window, will both be critical for county human services agencies to successfully implement these proposals. Our agencies must have sufficient lead time to either unsuspend or determine eligibility in time to support the 30-days pre-release coverage proposal. A data-sharing requirement would also facilitate a more effective and consistent suspension process and reduce the need for applications when individuals would otherwise only require a suspension of existing eligibility to be lifted.

Secondly, we have questions on how the Medi-Cal coverage 30-days pre-release proposal would be operationalized. DHCS estimates that approximately 250,000 individuals annually will receive Medi-Cal services under the proposal, and we would like to further discuss how this interacts with the suspending and unsuspending of benefits; it may be the case that the most effective way to implement the proposal would be to forgo the suspending and unsuspending of benefits. The interaction between the two proposals is complex and needs further discussion prior to implementation.

Thirdly, as both proposals are state mandates and could potentially impact hundreds of thousands of individuals annually, we note that automation changes in SAWS, CalHEERS, and MEDS to support a simplified and streamlined process will be critical. Currently, the suspension and unsuspension process are manual and labor intensive. For example, we note that the CalHEERS system is programmed in such a way that coverage may be discontinued for someone who is reported as incarcerated, which is counter to the Medi-Cal rules (though consistent with the rules for APTC coverage, which differ) and also is inconsistent with the suspension process. Therefore, changes to system functionality in all three systems will need to be addressed so counties can effectively support inmates. This could result in a need to delay implementation past the date set forth in the proposed statute.

Lastly, we note that counties must be given adequate lead time to develop their local processes to comply with the proposals. For instance, counties who do not have a pre-release application process in place will need time to engage and coordinate with their Boards of Supervisors and potentially establish local MOUs with sheriffs, given that different methods may be used from one county to the next. While the proposals are proposed to be effective January 1, 2023, it is currently unknown when DHCS would gain approval from CMS. Consequently, we ask that counties be given at least one year to determine their local processes.

County Monitoring and Performance Measures

As noted in our budget memo on April 21, 2021, we have no concerns with restarting the county monitoring and performance review process consistent with current statute, but have submitted proposed amendments to the Administration's TBL that include convening a stakeholder workgroup to: 1) review the current corrective action processes and explore the creation of a continuous quality improvement process rather than the current penalty based structure, 2) the Department of Health Care Services to provide technical assistance to counties related to performance measures, 3) determine a method for sharing county performance data through a dashboard to the extent a method does not already exist, 4) review and update guidance on processes related to current law in this area, and 5) recommend other actions that could improve performance, including reviewing guidance and regulations related to Medi-Cal eligibility, and updating guidance and regulations on changes to program rules and requirements. This language is reflected in AB 875 (Wood) under consideration by the Legislature. We look forward to continuing our engagement with you on this language.

Whole Person Care Transition

As noted in prior comments on the CalAIM proposal, we continue to support a requirement that managed care plans that intend to implement Enhanced Case Management/In Lieu of Services first seek to contract with counties to leverage existing services, especially services and infrastructure created by counties that have been participating in the Whole Person Care pilots. These pilots have successfully demonstrated the ability to provide comprehensive services to particularly vulnerable populations that will benefit from the ECM/ILOS approach. Additionally, ensuring the ECM services take into account, coordinate with, and where possible utilize, existing case management services provided by counties to these populations is critical to the success of this aspect of the proposal.

Carve-In of Kaiser Mental Health Patients to Solano and Sacramento Counties

We believe the proposed transfer of responsibility for specialty mental health services from Kaiser to county behavioral health plans in Sacramento and Solano counties should not occur in the absence of associated funding and transition planning. This change would add a substantial number of beneficiaries with serious mental illness to the responsibility of each county behavioral health plan in a very short period. We would support this proposal if there were adequate funding and DHCS works with the counties to identify a feasible transition date to allow for the coordination and planning of ensuring a safe and appropriate transition for these beneficiaries.

Conclusion

We appreciate the inclusion of CWDA in the ongoing conversations on CalAIM, including aspects that are not yet reflected in the state's proposal, including the discussion of improving health care delivery and outcomes for children and families involved in foster care and the child welfare system. As you know, those discussions are ongoing and due to wrap up over the summer. We will comment separately on this issue at the appropriate time.

Thank you for consideration of our comments. Please contact me at csend@cwda.org or 916-443-1749 if you have questions regarding these comments or wish to discuss any aspects further.

Sincerely,

[redacted]

Cathy Senderling-McDonald
Executive Director

cc: Jacey Cooper, Chief Deputy Director & State Medicaid Director, DHCS

County of San Diego

NICK MACCHIONE, FACHE
AGENCY DIRECTOR

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ANDREW PEASE
CHIEF OPERATIONS OFFICER

May 6, 2021

Will Lightbourne, Director
Department of Health Care Services
State of California
P. O. Box 997413, MS 0000
Sacramento, CA 95899-74173

CalAIM Section 1115 & 1915(b) Waiver Comments

Dear Mr. Lightbourne: Will

The County of San Diego's Health and Human Services Agency (County) is pleased to submit comments on both the Section 1115 Demonstration and 1915(b) Waivers. These comments reflect input from across the County of San Diego Health and Human Services Agency (HHSA), including Aging and Independence Services, Behavioral Health Services, Medical Care Services, Public Health Services, Housing and Community Development Services, Self-Sufficiency Services and Integrative Services, the group that manages the Whole Person Care Pilot (known in San Diego as Whole Person Wellness, WPW Pilot), and San Diego Advancing Innovations in Medicaid (SDAIM), the office that participates in CalAIM discussions and interfaces with all involved County departments. These comments also incorporate input from the Public Safety Group, which consists of the County agencies that serve the justice-involved population.

The County has participated successfully in multiple Medi-Cal Waiver programs: the Low-Income Health Program (LIHP) and the Coordinated Care Initiative (CCI)-Cal Medi-Connect in the Bridge to Reform Waiver (2010 -2015) and the Whole Person Wellness (WPW) Pilot, the Health Homes Program (HHP), and Drug Medi-Cal – Organized Delivery System (DMC-ODS) in the current Medi-Cal 2020 Waiver. Given this experience, we offer the following broad perspectives for consideration:

1. **ECM/ILOS:** Under Geographic Managed Care (GMC) in San Diego County, seven Managed Care Plans (MCPs) currently serve the Medi-Cal population. As presented in the ILOS proposal, each MCP has the flexibility to propose the subset of ILOS to include in its contract with DHCS. The County strongly recommends that DHCS encourage all 7 MCPs to offer all 14 of the pre-approved ILOS and to collaborate with each other and the County in using new incentive funds to create needed service infrastructure. The ability to successfully transition current enrollees in the WPW Pilot and the HHP into CalAIM and to expand these services to all Medi-Cal MCP members meeting eligibility criteria depends upon the availability of these community-based services to complement the new Enhanced

Care Management (ECM) benefit. Regarding the ECM benefit, it will be important to establish thresholds for eligibility that are rooted in a combination of health data and *functional assessment* and that reflect risk predictive analytics, rather than high service utilization. Also, ensure that rate structure and regulatory guidelines support ongoing service provision, rather than anticipate that service volume for a patient will necessarily diminish over time in a linear fashion. In the provision of ECM services, County Behavioral Health departments should be given preference as providers and as essential participants in ECM partnerships.

2. **Providing Access and Transitioning Health (PATH):** The PATH initiative included in the proposed Section 1115 Demonstration Waiver (Section 3.8, pp. 40 -1, Slide 25 of the DHCS Public Hearing April & May 2021 Presentation) indicates that funding is being sought for IT systems for community-based ECM/ILOS and capacity building for community-based organizations. While details have not yet been provided, coordinating PATH funds and MCP ILOS contracts/incentives at the County level would greatly facilitate creation of the desired community service infrastructure that leverages our local interoperability efforts between hospitals, clinics, community health and social service nonprofits and our county's Public Safety Group and Health & Human Services Agency.

3. **Services for the Justice-Involved Population:** As noted in our March 2021 comments on the proposed DHCS-MCP ECM-ILOS Contract Template, the justice-involved population presents unique challenges in coordination across Public Safety, Housing, Behavioral Health and Public Health Services. Requiring each of the seven MCPs to individually navigate the complexities of the justice system, from the Sheriff, to Probation, to the District Attorney, will not achieve the objectives of this initiative. Instead, the County suggests that DHCS contract directly with our Health and Human Services Agency to ensure adequate and seamless connection of the MCPs with the various components of the Public Safety system, Behavioral Health, Public Health, Medical Care Services/Emergency Medical Services, health care providers and the range of housing and social service supports needed for this complex population to succeed.
    - Re-entry work is already an intense focus in the County, and ECM through MCPs could be a great boost to individuals experiencing these transitions. However, case management during re-entry must be integrated among the various services that support re-entry rather than a siloed benefit. It is also important to note that many justice-involved high-needs community members do not spend 30 days in jail. Re-entry services for this group may be different, but they will be equally important for these individuals and for the community.
    - The County strongly supports the Peer Support Specialist Initiative included in the Section 1115 Waiver, but requests that qualifying criteria for Peer Support Specialists do not prohibit participation by people with prior justice system involvement. Peers with this lived experience make important contributions to the successful outcomes achieved in current programs.

4. **Population Health Management:** While not specifically addressed in the proposed Waiver documents, Section 2.1 "Population Health Management Program" (pp. 24 – 43 in the full CalAIM proposal) states: "Medi-Cal managed care plans shall consult with their local public health department and county behavioral health department during the development of the population health management program" (p. 25). It further specifies that the population health management program shall:

- Include the goal to improve the health outcomes of communities and groups;
- Utilize data to analyze community and population level health and health-related social needs and set measurable goals for improvement;
- Utilize initial and ongoing assessments of data to analyze individual member's needs and identify groups and individuals within groups for targeted interventions. (p. 25)

Implementation Date is January 1, 2023, and many details are still to be developed.
The County requests stronger requirements than the current language of "consulting with" Public Health and Behavioral Health Services. Instead require the MCPs in San Diego to work collaboratively with the County, each other, and key community stakeholders in developing a joint Population Health Management Plan for the County. Several planning processes already exist as part of *Live Well San Diego*, Mental Health Services Act planning, and Community Health Needs Assessments/Community Health Improvement Plans conducted by local health systems. Linking the Population Health Management efforts required of MCPs by DHCS with these established processes would be of great benefit in achieving more cost efficient and quality care services to the San Diego Medi-Cal population and the population more broadly.

5. **Data Sharing/Information Technology (IT) Infrastructure**: Key factors in the success of CalAIM will be the ability to characterize the population, collaborate in health management, and measure outcomes. Data sharing and IT infrastructure are essential elements recognized throughout the CalAIM proposal and both proposed Waivers. Through our experience in the WPW Pilot and in many broader community efforts, the County has the following recommendations at the County, DHCS, and CalAIM levels:
   - County: Effective bidirectional information exchange is essential to "care management." In recent years, San Diego as a community has made significant strides in information linking community-based organizations with heath care agencies. Data Use Agreements, Memoranda of Understanding, Care Plans, and a variety of other tools to support the exchange of "personally identifiable information" have been developed, and the MCPs have been active participants in these efforts. To assure continued progress, CalAIM must build upon and enhance these existing structures, bringing additional resources such as those proposed to be provided by PATH and incentives to the MCPs.
   - DHCS: The first CalAIM goal is to "identify and manage member risk and need through whole person approaches and addressing Social Determinants of Health." Establishing standardized, transparent protocols for risk stratification, including Social Determinants of Health, as a factor, as the Commonwealth of Massachusetts is now doing, is a fundamental step toward achieving this goal. If each MCP uses its own methodology, Medi-Cal beneficiaries will not have consistent access to the new benefit and services CalAIM seeks to achieve. The County urges DHCS to undertake this effort and create an Advisory Group, both with necessary technical expertise and inclusive of MCPs, Counties, and other impacted stakeholders, to inform and guide.
   - CalAIM: "Information Infrastructure" transcends IT and encompasses the knowledge and experience of the array of entities that will be involved in implementing CalAIM. The County urges DHCS to create a "Learning Collaborative" similar to the WPC Pilot Collaborative that has provided an essential venue for information-sharing since the earliest days of the Pilot. This CalAIM Collaborative should include a cross-section of "lead entities" with front-line involvement at DHCS, MCPs, Counties, CBOs, health care providers, and others critical to successful implementation. DHCS currently has been meeting separately with MCPs and Whole Person Care Pilot LEs in preparation for transitioning Pilot enrollees into CalAIM. In our experience, it is much more

effective to have all entities at the same table to gain the benefit of all perspectives. We urge DHCS to bring this Collaborative together now and to continue meetings throughout CalAIM implementation.

6. **"Lessons Learned" from addressing the COVID-19 Pandemic:** The County's intense engagement with all sectors of the community through the still ongoing pandemic has provided several valuable insights that should be leveraged in CalAIM:
    - Public Health infrastructure is fundamental to community health and impacts every sector with critical importance in helping health equity communities as identified by the State's use of the Healthy Places Index.
    - Social Determinants of Health predict not just longevity associated with chronic disease but also mortality due to infectious disease.
    - Shared health information and timely bi-directional exchange are essential to identify health and social service needs, risk-stratify individuals, support care management, and avoid duplications in care.
    - Telehealth is a vital modality across the health, housing and social service delivery system.
    - Government agencies, healthcare systems, community-based organizations, and health plans must work in collaboration by sharing expertise, information, and funding to achieve health for the individual, community, and county.

In conclusion, our over-arching recommendation is that CalAIM enable San Diego County to build upon our "learnings" and achievements from participating in the current Medi-Cal Waivers and addressing the challenges of COVID-19. We want to strengthen public-private partnerships between the County and MCPs and co-invest with the State in the infrastructure needed to serve all Medi-Cal Managed Care beneficiaries in our County and the community more broadly. Implementing CalAIM should facilitate the "health system transformation" in San Diego County already underway.

Please contact Rick Wanne at (619) 338-2869, richard.wanne@sdcounty.ca.gov with any questions or for further details.

Thank you for the opportunity to offer this feedback.

[redacted]

NICK MACCHIONE, FACHE, Agency Director
Health and Human Services Agency

CC: Nathan Fletcher, Chair, County of San Diego Board of Supervisors
Helen Robbins-Meyer, Chief Administrative Officer, County of San Diego
San Diego Advancing Innovations in Medicaid (SDAIM) Leadership Team

SHASTA CASCADE HEALTH CENTERS
McCLOUD HEALTHCARE CLINIC | McCLOUD DENTAL CENTER
DUNSMUIR COMMUNITY HEALTH CENTER | SHASTA VALLEY COMMUNITY HEALTH CENTER

May 5, 2021

Via Electronic Submission (CalAIMWaiver@dhcs.ca.gov)

Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Shasta Cascade Health Centers writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, Shasta Cascade Health Centers urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

Shasta Cascade Health Centers is an FQHC that cares for Medi-Cal and uninsured patients at three clinics in Siskiyou County. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through Rite Aid and CVS pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Shasta Cascade Health Centers to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, Shasta Cascade Health Centers annually saves an estimated $345,000 through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Shasta Cascade Health Centers to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care system, Shasta Cascade Health Centers patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

As Health & Human Services Secretary Xavier Becerra has stated, "the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States' uninsured and underinsured residents."[2] As California's Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that "help create a continuum of care for patients," which ultimately leads to improved public health outcomes.

Yet, Medi-Cal Rx will impede our and other FQHCs' ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access ("CHCAPA") raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which Shasta Cascade Health Centers incorporates by reference into this letter. Shasta Cascade Health Centers fully shares CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, Shasta Cascade Health Centers urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Shasta Cascade Health Centers and DHCS to "work in partnership to provide individuals access to affordable healthcare, including prescription drugs" as now-Secretary Becerra described.

Thank you for your time and consideration. Shasta Cascade Health Centers looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

James S. Proffitt, CHFP
Chief Executive Officer

[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.