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LA MAESTRA
COMMUNITY HEALTH CENTERS
City Heights · El Cajon · National City · Lemon Grove

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:

La Maestra Family Clinic Inc., dba. La Maestra Community 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, La Maestra 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.

La Maestra is an FQHC that cares for Medi-Cal and uninsured patients in San Diego California. 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 three in house pharmacies seventy-three contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows La Maestra 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, La Maestra annually saves an estimated $2,500,000 through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow La Maestra 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, La Maestra 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 La Maestra incorporates by reference into this letter. La Maestra 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, La Maestra 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 La Maestra 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. La Maestra looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Zara Marselian, Ph.D FACHE
President and CEO
La Maestra Family Clinic Inc.

[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

[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,

Anthony White
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,

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,

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

KATHRYN E. DOI
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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,

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[1]	X[1]	X[1]	X[1]	X[1]	X[1]
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.						

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
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

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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

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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.
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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:

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

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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

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, Inc. (Magellan), 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. In addition, Medi-Cal Rx will 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. 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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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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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.

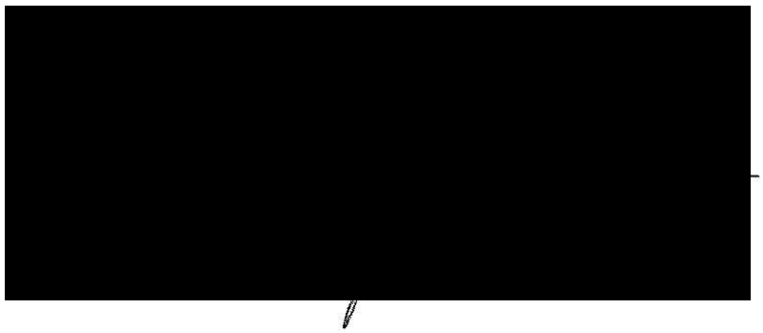

Exhibit D
to letter dated 4/16/2021

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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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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 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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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.

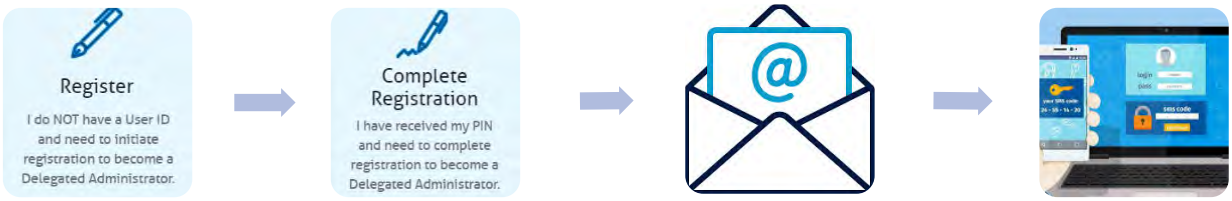
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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

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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

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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

Encl.

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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/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

[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,

Anthony White
President

Encl.

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PARTNER
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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,

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,

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,

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]

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
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.						

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
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

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
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
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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.						

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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
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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

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[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

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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>

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>
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

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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

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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

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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.

/ / /

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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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

DocuSign Envelope ID: 4E9DD7B1-26B2-4D36-AB63-C29CFE059C6D

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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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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 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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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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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

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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.

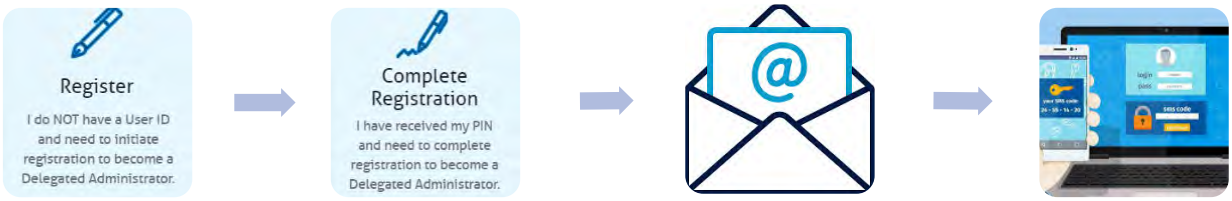
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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

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For Questions, Visit Our Help and Support Center

May 6, 2021

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

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:

Eisner 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, Eisner 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.

Eisner Health is an FQHC that cares for Medi-Cal and uninsured patients in throughout Los Angeles 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 our downtown

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Eisner Health and our 13 sites 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, Eisner Health annually saves an estimated $1.2 million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Eisner 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, Eisner 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. Eisner Health incorporates by reference the CHCAPA public comment letter into this letter. Eisner 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, Eisner 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 Eisner 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. Eisner Health] looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

Warren J. Brodine
President + CEO

Encl.

[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

[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,

Anthony White
President

Encl.

KATHRYN E. DOI
PARTNER
DIRECT DIAL (916) 491-3024
DIRECT FAX (916) 491-3079
E-MAIL kdoi@hansonbridgett.com

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,

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,

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,

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

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
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.						

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
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]

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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

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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.						

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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.						

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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

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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).

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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

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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

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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

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, Inc. (Magellan), the project's contracted vendor.

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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. In addition, Medi-Cal Rx will 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. 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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Email: rboyle@cliniclaw.com

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.

/ / /

/ / /

/ / /

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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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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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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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

DocuSign Envelope ID: 33111318-BDA2-4858-8D63-480B2225697B

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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 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

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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.

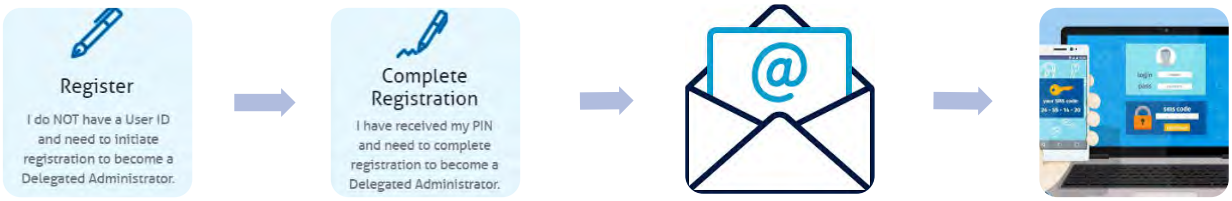
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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

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For Questions, Visit Our Help and Support Center

Dear DHCS Colleagues:

Thank you for the opportunity to provide comments on the proposed California Advancing & Innovating Medi-Cal (CalAIM) initiative, including the proposal to submit to the Centers for Medicare & Medicaid Services (CMS) an amendment and five-year renewal of California's Section 1115 demonstration and a corresponding amendment and renewal expanding the existing Section 1915(b) waiver.

I wanted to particularly commend the following aspects of your proposals, which have the potential to benefit people living with and at risk for HIV, sexually transmitted diseases (STDs), viral hepatitis, and other communicable diseases.

1. Changes to Drug Medi-Cal Organized Delivery System
    a. Addition of contingency management for stimulant use disorders as an optional benefit in opt-in counties
    b. Requirement that DMC-ODS providers either provide or offer referrals to medication assisted treatment (MAT)
    c. Addition of peer support services as a component of DMC-ODS services in opt-in counties
2. Prerelease Services for Justice-Involved Individuals; and
3. Overall efforts to simplify and streamline Medi-Cal benefits and offer enhanced case management (ECM) and in lieu of services (ILOS) to vulnerable populations that benefited from the Whole Person Care and Health Home Program pilots.

Substance use plays a critical role in increasing risk for hepatitis C infection through sharing of injection drug use equipment, and methamphetamine use (along with unstable housing, incarceration, and survival sex) is concerningly common among people who give birth to babies with congenital syphilis in California, highlighting the urgent need for contingency management. Medication assisted treatment (MAT) has been shown to reduce the risk of hepatitis C among young people who inject drugs by 50 percent. Given the stigma associated with behavioral health disorders, peers will play an important role in meeting the needs of DMC-ODS beneficiaries.

To maximize the benefit of these evidence-based interventions, I would like to offer the following recommendations for your consideration:

1. Changes to Drug Medi-Cal Organized Delivery System
    a. Addition of contingency management for stimulant use disorders as an optional benefit in opt-in counties
        i. Given the rise in methamphetamine-related deaths and congenital syphilis cases in California, DHCS should consider making contingency management a required, rather than an optional, activity for DMC-ODS opt-in counties
    b. Requirement that DMC-ODS providers either provide or offer referrals to medication assisted treatment (MAT)
        i. Yes; If there is a local syringe services program DMC-ODS providers should be aware of and refer to SSPs as well
    c. Addition of peer support services as a component of DMC-ODS services in opt-in counties
        i. Addiction is often framed as a chronic, relapsing condition. Yet many people who relapse may not be ready or willing to return directly to drug treatment or

have the immediate goal of abstinence. For people who relapse, the risk of fatal overdose, and of HIV/HCV infection and other drug related harms, is greater than ever. For these reasons, in addition to *preventing* relapse, the goal of peer support specialists should be to support people who are unable or unwilling to stop using in the first place and/or who have relapsed and who are not yet ready to re-engage in treatment. This would mean their role and training could explicitly include a harm reduction conceptual framework, naloxone distribution, and peer education on preventing fatal drug overdose and infectious diseases related to drug use.

2. Prerelease Services for Justice-Involved Individuals
    i. Building on the success of models established in Los Angeles, participating counties should be required to distribute (or at least make available) naloxone upon release from jail, such as in a no-cost vending machine in the discharge room.
    ii. Given that people are at 12x the risk of a fatal overdose in the two weeks following release from prison or jail, DHCS should also include assessing changes in deaths related to fatal opioid overdose post-release as an evaluation measure.
    iii. If DHCS estimates that two-thirds of people incarcerated in prisons and jails and youth facilities would be eligible for prerelease services, then it may be easier for administrators to offer prerelease services to everyone who falls within the Medi-Cal eligible population, rather than administer the kinds of risk assessment that would be needed to otherwise determine eligibility under the current prioritization scheme. Our experience with risk-based vs. infectious disease screening guidelines is that uptake of risk-based screening is low because it requires individual assessment, whereas recommending universal screening (such as for HIV) results in higher uptake among health care providers.

Kudos on all your thoughtful and hard work on these proposals, especially during COVID!

Thanks again for your consideration.

Rachel

Rachel McLean, MPH *(she/her)*
Chief, Office of Viral Hepatitis Prevention
STD Control Branch
California Department of Public Health
Phone: 510-620-3403 | Mobile: 510-809-5120 *(working remotely)*
Email: Rachel.McLean@cdph.ca.gov
www.cdph.ca.gov/ovhp

alzheimer's association®

May 5, 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 – Population Health Management/Dementia Quality Measures

Dear Director Lightbourne:

Thank you for the department's outstanding work to engage stakeholders throughout the CalAIM waiver process. Specifically, Jacey Cooper and Anastasia Dodson have been exceptional thought partners and have been extraordinarily generous with their time in taking meetings on a variety of topics related to seniors, people with disabilities, and our constituents – the 690,000 Californians living with Alzheimer's disease and related dementias. We have confidence in the final waiver proposal, and great hope for the new Medicare Office of Innovation and Integration should it be funded by the Legislature.

To model a statewide standard of dementia care to the nation, as recommended in Governor Newsom's final Alzheimer's Task Force report, we urge DHCS to consider adoption of, *at a minimum*, one dementia quality improvement measure in its waiver application. To drive system change, ideally, there would be three measures, one in each of three interdependent domains: 1) identification, 2) diagnosis and 3) care planning.

Identification Measures:

a. Proportion of Medicare beneficiaries who receive the Annual Wellness Benefit
   Source: Medicare Current Beneficiary Survey (MCBS), CMS

b. % of older adults [or patients] aged 65 and older who had cognition assessed
   Source: American Academy of Neurology

c. Proportion of older adults who talk to their healthcare provider about changes in their memory
   Source: Healthy People 2030 DIA-3

Diagnosis Measures:

a. Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period
   Source: Merit-based Incentive Payment System (MIPS)

b. Proportion of adults aged 65 years and older with diagnosed Alzheimer's disease and other dementias, or their caregiver, who are aware of the diagnosis
Source: Healthy People 2030 DIA-1

c. Percentage of patients with mild cognitive impairment (MCI) or memory loss who received a cognitive and functional assessment
Source: American Academy of Neurology

d. Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12-month period
Source: Physician Quality Reporting System (PQRS)

e. Percentage of patients with MCI who had their diagnosis disclosed, were educated on cognitive prognosis, and counseled on treatment plan options at least once in the measurement period
Source: American Academy of Neurology

Care Planning Measures:

a. Proportion of Medicare beneficiaries with diagnoses of cognitive impairment who receive a care planning service at least once per year in time interval (CPT 99498)
Source: Medicare Current Beneficiary Survey (MCBS), CMS

b. Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan
Source: Merit-based Incentive Payment System (MIPS)

c. Proportion of preventable hospitalizations in adults aged 65 years and older with diagnosed Alzheimer's disease and other dementias
Source: HP2030 DIA-2

d. % of patients with dementia whose caregiver(s) were provided education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months
Source: Merit-based Incentive Payment System (MIPS)

Thank you for your consideration of the Alzheimer's Association's request to include a dementia quality improvement measure(s) in California's CalAIM waiver application.

Sincerely,

Susan DeMarois
California Policy Director
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