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May 5, 2021

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

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

Re: Public Comment Regarding the Medi-Cal Rx Initiative as Incorporated in the CalAIM Section 1115 and 1915(b) Waiver Proposals

Dear Director Lightbourne:

Community Health Centers of the Central Coast, Inc (CHCCC) writes to object to the incorporation of the so-called "Medi-Cal Rx" initiative as part of CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, CHCCC urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

CHCCC is an FQHC that cares for Medi-Cal and uninsured patients in San Luis Obispo and Santa Barbara Counties. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through 1 in-house and 75 contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows CHCCC to better serve patients. We can serve as a one-stop-shop for all of our patients' medical needs, which enables us to help patients readily follow their treatment plan. Doctors can directly coordinate all of the patient's care, monitor their medication compliance, and provide additional services as necessary. This model of care leads to better health outcomes and removes barriers for traditionally underserved patients.

Additionally, CHCCC annually saves an estimated net savings of \$8,382,552 in 2020 through participation in Medi-Cal managed care (the 340B Drug Discount Program). The savings allow CHCCC to provide vital services to more patients, such as transportation assistance, subsidized prescriptions, substance abuse treatment programs, and expanded clinician availability. These benefits are not available to FQHCs when reimbursed for pharmacy

on a FFS basis. As a result of the current managed care system, CHCCC patients have better access to more services, just as Congress intended in enacting the 340B program.¹

As Health & Human Services Secretary Xavier Becerra has stated, “the more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States’ uninsured and underinsured residents.”² As California’s Attorney General, Secretary Becerra recognized that 340B savings are vital to expanding access to medication and other services that “help create a continuum of care for patients,” which ultimately leads to improved public health outcomes.

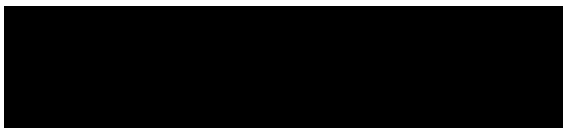
Yet, Medi-Cal Rx will impede our and other FQHCs’ ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which is to improve access to healthcare and reduce health inequities.

Please see the attached public comment from the Community Health Center Alliance for Patient Access (“CHCAPA”) raising concerns about the impact of Medi-Cal Rx on the 11 million Medi-Cal patients who would be directly impacted by Medi-Cal Rx, which CHCCC incorporates by reference into this letter. CHCCC fully shares CHCAPA’s concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

In conclusion, CHCCC urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS’ consideration. Doing so will enable CHCCC and DHCS to “work in partnership to provide individuals access to affordable healthcare, including prescription drugs” as now-Secretary Becerra described.

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

Sincerely,



Ronald E. Castle, CEO
Community Health Centers of the Central Coast, Inc

¹ The purpose of the 340B program is to enable FQHCs to “stretch scarce federal resources” to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)

² Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: <https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program>.



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May 6, 2021

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

Submitted via email to: CalAIMWaiver@dhcs.ca.gov

RE: CSAC Comments on CalAIM Section 1115 & 1915(b) Waivers and Related Efforts

Dear Director Lightbourne,

On behalf of the California State Association of Counties (CSAC), representing all 58 of California’s elected county Boards of Supervisors, I wish to thank you and your team for the opportunity to provide the county perspective on the ambitious and necessary California Advancing and Innovating Medi-Cal Initiative, or CalAIM.

Counties strongly support the Department of Health Care Services’ (DHCS) effort to streamline and improve the Medi-Cal program while preserving the opportunity to access critical federal funding for safety net health care services. Counties also applaud the Department’s proposed restructuring of both the Section 1115 and 1915(b) Medicaid waivers and the overarching goal of enhancing and improving the health and behavioral health of low-income beneficiaries in the state.

CalAIM is a complex undertaking that touches multiple aspects of federal and state statute and regulation, state policy, and local practice – to name a few. CalAIM would also consolidate and streamline many portions of the Medi-Cal program, which impacts multiple populations served by counties. Because of the comprehensive and interconnected nature of the CalAIM Initiative, we have endeavored to provide the county perspective on all county-related aspects of the proposal, regardless of in which waiver vehicle or state-only policy process a specific provision resides.

ROLE OF COUNTIES

While Medi-Cal is a state-administered program, counties provide the non-federal share of Medicaid matching funds for mental health and substance use disorder services, public hospital and clinical services, eligibility administration, and public health services.

Additionally, counties retain multiple integral health-related roles at the local level, including identifying beneficiaries; determining eligibility; caring for patients at

county-run clinics and public hospitals/health systems; providing specialty behavioral health services through county Specialty Mental Health Plans and substance use disorder treatment programs; and monitoring and preventing infectious diseases and protecting community health via county public health departments.

Moreover, counties manage many crucial health-adjacent activities at the local level, including leading multidisciplinary efforts to address the crisis of housing and homelessness; administering eligibility for cash assistance, nutrition, and employment services; operating county jails and probation programs; leading culturally competent outreach to underserved and special communities; operating parks and community recreation programs; ensuring accessible public transportation; and overseeing the emergency medical services transport system.

FOUNDATIONAL REQUESTS

Counties are crucial to the health of all Californians and CalAIM must acknowledge this by requiring Managed Care Organizations (MCOs) to provide counties the right of first refusal to contract and collaborate on essential components, including Enhanced Case Management (ECM) across all existing programs, In Lieu of Services (ILOS), behavioral health services, population health management, outreach services, homelessness and housing services, and Whole Person Care personnel and data.

Furthermore, counties, county departments, and county public hospitals that contribute to improvements in the health of Medi-Cal beneficiaries must be eligible for all CalAIM incentive payments, whether directly or as a pass-through from the MCOs.

Lastly, as key Medi-Cal stakeholders, counties must be included as primary partners in all CalAIM discussions, major decisions, fiscal implications, timeline development, and other important details of the waivers. Thus far, DHCS has been collaborative and inclusive of counties in the development of CalAIM, and we request that this constructive working relationship continue through negotiations with the federal government on the final terms and conditions, the state legislature and policy process, and all aspects of CalAIM implementation and oversight.

SPECIFIC COMMENTS

Since counties touch so many aspects of the CalAIM proposal, we are providing the following comments based on each proposal area or specific issue.

1. **ECM and ILOS Implementation and Transition of WPC:** While CSAC and our affiliate partners continue to desire a continuation of the successful WPC pilots, we understand the state's decision to attempt to transition some of these successful county-led interventions to the MCO's in order to ensure continued federal financial participation in these important services for our most vulnerable populations.

As stated above, it is of utmost importance that MCOs be required to offer counties the right of first refusal to contract for important WPC services and data sharing. For non-WPC counties, the contracting requirement is just as important, as county services for

vulnerable populations and those who are unhoused even in non-WPC counties provide a foundation for success in implementing ECM or ILOS.

Counties appreciate the recent loosening of some of the ambitious timelines for transitioning populations into ECM and ILOS to 2023 and ask that DHCS continue to assess the need for additional timeline and transition adjustments to ensure a successful procedural and fiscal implementation of ECM/ILOS.

Counties remain concerned about the CalAIM structural gap between identifying a beneficiary or special population in need of ECM and ILOS services and actually connecting individuals with those services. Outreach to special populations and timely data are critical to ensuring access to Medi-Cal services and care. Counties, not health plans, retain the core competencies and local partnerships required to reach underserved populations in a culturally competent manner. Because of this fact, MCOs should be required to contract with counties and their local partners to do this important work. The county role in data collection and sharing must also not be ignored.

For ECM specifically, counties appreciate the state's goal to eliminate redundant and complicated case management activities and the acknowledgement that some county-led case management activities must continue under CalAIM. Counties specifically request that current county-led case management efforts within existing programs, such as providing targeted case management within specialty behavioral health services and the California Children's Services program, be grandfathered into CalAIM to allow counties to continue to provide these critical services to beneficiaries. This will also assist with reducing redundancies in case management activities and allow the MCOs to focus on the new-to-the-plan populations under CalAIM.

Finally, on this topic, counties must have access to CalAIM's promise of adequate federal funding for administering these critical services and performance incentives on par with the MCOs.

2. **Public Hospital and Health System Improvement and Funding:** It is not an exaggeration to acknowledge that California's previous Section 1115 Medicaid waivers prevented the fiscal collapse of the county public hospital and health care safety net. CalAIM provides a somewhat different structure and waiver vehicles to achieve the shared goal of preserving the county public hospital safety net, and counties applaud the inclusion of a Global Payments Program successor with an added equity pool in the Section 1115 waiver request and the proposed continuation of quality improvement incentives similar to Program of Public Hospital Redesign and Incentives in Medi-Cal (PRIME).

These mechanisms represent critically needed federal funding for county public hospitals and health systems, especially in the wake of the COVID-19 pandemic in which public hospitals experienced steep increases in uncompensated care for uninsured patients. Flexibility within these programs is also of critical importance to assist public hospitals and health systems with meeting the goals of CalAIM.

- Behavioral Health Administrative Improvements:** The largest and most innovative changes proposed under CalAIM are aimed squarely at reducing the state and federal red tape and bureaucratic delays imposed on the county-run Specialty Mental Health and Drug Medi-Cal programs that result in delays or hurdles to care. Counties strongly support the CalAIM proposal to move from a cost-based, untimely, and burdensome reimbursement system to at least a more nimble and flexible intergovernmental transfer structure with the goal of eventually implementing a capitation-based system to allow county mental health plans to better serve more beneficiaries and make investments in the local system. Transition funding to do this work and shift between payment structures is still required, as are reasonable rates to provide these critical behavioral health services.

The proposed payment reforms are the foundation for other CalAIM proposals supported by counties, including MHP access to quality improvement program funds, the relaxation of clinical auditing standards, efforts to streamline paperwork and documentation requirements, and the opportunity to develop non-geographic rates for similar counties.

Counties also strongly support the effort to redefine medical necessity to ensure improved access to all behavioral health services, the continuation and expansion of the Drug Medi-Cal Organized Delivery System under the Section 1115 Waiver request, and the request for an Institutes of Mental Disease (IMD) waiver from the federal government. If approved, these proposals promise to improve access to mental and substance use disorder services in the least-restrictive setting and regardless of age throughout the state.

- County Public Health:** CalAIM promises to tackle equity and population health issues, but MCOs are not experienced nor equipped to undertake these core public health roles. County public health departments have led population health management, prevention, and equity efforts for our communities regardless of health care coverage for decades. The expertise of our local health jurisdictions is crucial for any population health efforts. This is why counties strongly support a requirement for MCOs to contract with local health jurisdictions to support continuing and innovative population health management, equity, and data sharing efforts.

Counties also look forward to close collaboration on the CalAIM non-waiver proposal to enhance the oversight and monitoring of the California Children's Services (CCS) and Child Health and Disability Prevention (CHDP) programs. Counties support a robust technical assistance structure and continuous improvement process in lieu of any penalties on these small but important programs.

On the Dental Transformation Initiative (DTI), counties welcome the continuation of the project, but also request the continuation of Domain Four, which allows for local DTI pilot projects. Domain four was hampered by a late start under the current extended waiver, and counties wish to continue to partner with local dental providers, First 5 Commissions,

schools, and other community stakeholders to improve dental care for our most vulnerable populations.

5. **County Eligibility Improvements:** Counties support CalAIM’s proposed stakeholder process to improve and update guidance and regulations pertaining to county Medicaid eligibility functions – with counties serving as a key partner – as well as several proposals within the state’s Section 1115 Medicaid waiver request. These include peer support specialist services – especially as California works to implement SB 803 (Chapter 150, Statutes of 2020), extending Medi-Cal to former foster youth who live out of state, and support for some form of community-based adult services. As mentioned above in the public health section, counties support a robust technical assistance framework and a continuous improvement process in lieu of any penalties. And, of course county human services representatives must serve as key partners in all of these efforts to improve eligibility functions.
6. **Limited Services and Case Management for Justice-Involved Individuals:** CSAC has long been a strong supporter of services to connect county jail and other correctional facility inmates with health and behavioral health services upon release. CalAIM includes two related proposals to allow limited Medicaid services inside jails up to 30 days before an inmate is released, and to provide ECM-like case management services and a warm hand-off from jail medical providers to MCOs and county MHPs upon release.

While counties support the above proposals, it is important to note that the County Sheriff and Chief Probation Officer must retain the authority to approve any entities that might enter a jail facility to ensure the continued safety of the entity’s workforce, jail staff, inmates, and juvenile offenders. Additionally, each county Board of Supervisors must have the flexibility to decide how to structure jail services 30 days before release and how to implement jail in-reach/warm handoff efforts. Because county jail and juvenile hall health, pre-release eligibility efforts, and care coordination is handled a number of different ways throughout the state, the Board and Sheriff or Chief Probation Officer must determine the safest, most effective route for implementing these two laudable proposals. As stated above on the social services portions of CalAIM, counties, Sheriffs, and Chief Probation Officers must be key partners in the development and implementation of these proposals, along with county social services and relevant community stakeholders.

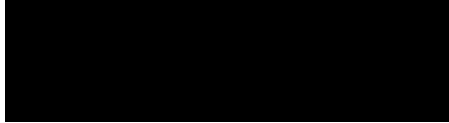
Lastly, funding must be available – whether state or federal – to implement and provide these services, as they represent new duties for counties and county jails and juvenile detention centers.

CONCLUSION

In closing, we wish to thank DHCS for the opportunity to provide these comments on behalf of all 58 elected county Boards of Supervisors. Furthermore, we commend the Department’s innovative and expansive thinking regarding the improvement of the state’s Medi-Cal program and safety net services within the next 1115, 1915(b), and IMD waivers as well as the policy process. While California’s counties do not negotiate waivers with the federal government, CSAC

and county affiliates must nevertheless serve as the state's primary stakeholder and partner on the CalAIM issues outlined above. Counties are committed to working arm-in-arm with DHCS to ensure the success of CalAIM by improving the overall health of Californians.

Thank you,



Farrah McDaid Ting
Senior Legislative Representative
California State Association of Counties

cc Dr. Mark Ghaly, Secretary, California Health and Human Services Agency
Jacey Cooper, State Medicaid Director & Chief Deputy Director, DHCS

CalPACE Comments on Proposed 1915(b) Waiver Renewal and Amendment Application

The overview documents for the 1915(b) waiver renewal and amendment application state that DHCS intends to shift authority to the new consolidated 1915(b) waiver to continue to allow Medi-Cal beneficiaries to enroll in PACE independent of the COHS managed care plan in “select Medi-Cal COHS counties (currently Humboldt and Orange)”.

As part of its managed care procurement, the department is also allowing counties to submit letters of intent to change their type of managed care, including to convert to single plan counties or to join with an existing COHS plan. Several counties that currently have PACE have indicated their intent to do that, including Alameda and Contra Costa as single plan counties, and Placer, Sutter and Yuba counties, which are seeking to join Partnership health plan. PACE applications could also be forthcoming in other counties that either are, or convert to COHS or single plan status, during the time period the 1915(b) waiver is in place.

The department’s current policy, as reflected in the attached letter from 2012, is to allow beneficiaries in counties that convert to COHS status to continue to enroll in PACE independent of the COHS plan. However, under the department’s current policy, if these conversions occur or a PACE application comes forward in COHS or single plan county that currently does not have PACE, additional waivers will be required to ensure that beneficiaries are able to enroll in PACE independent of a COHS or single county plan. This will be time consuming and disruptive to care arrangements already in place and create barriers to timely access to PACE for beneficiaries who need PACE.

To avoid disruption to care arrangements and to ensure timely access to PACE we strongly urge the department to update its policy and to incorporate in the 1915(b) waiver general authority to allow Medi-Cal beneficiaries to enroll in PACE independent of a COHS plan, either in current or newly designated COHS or single plan counties, for the time period covered by the 1915(b) waiver.

In counties that have PACE that become COHS or single plan counties during the time period covered by the waiver, we believe the waiver should allow beneficiaries to enroll in PACE independent of a COHS plan without a need for any additional approvals or waivers.

In counties that are not served by PACE that either are or become COHS or single plan counties, and PACE applications come forward, we believe the 1915 (b) waiver should allow beneficiaries to enroll in PACE independent of a COHS plan without a need for any additional waivers, although the department may wish to extend its policy of requiring a PACE applicant to have approval from the COHS or single plan as part of its application to commence operations.

We believe these changes are consistent with the department’s current policy on independent operation of PACE in COHS and single plan counties but also provide a more streamlined approach to ensuring that beneficiaries have uninterrupted and timely access to PACE in these counties. For these reasons, we urge DHCS to include these provisions in the 1915(b) waiver application and look forward to an opportunity to discuss them with the department.

Thank you for your consideration of our comments.

Peter--

Peter Hansel

Chief Executive Officer

CalPACE

1315 I St. Suite 100 | Sacramento, CA 95814 | 916-469-3368 | 916-428-4250 (fax)

phansel@calpace.org www.calpace.org





TOBY DOUGLAS
DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



EDMUND G. BROWN JR.
GOVERNOR

April 26, 2012

ON LOK
APR 27 2012

Robert Edmondson
Chair, CalPACE Board
CEO, On Lok Senior Health Services
1333 Bush Street
San Francisco, CA 94109

Dear Mr. Edmondson:

Thank you for your April 4th letter addressing the concern of CalPACE about the growth of County Organized Health Systems (COHS) and the impact COHS growth has on the ability of PACE organizations to operate and expand. The Department of Health Care Services (DHCS) recognizes your concern and appreciates your willingness to partner with the COHS to make the PACE model of care available to eligible beneficiaries in COHS counties.

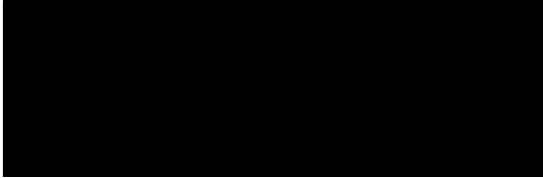
First, I want to take this opportunity to assure you that existing PACE organizations face no threat from the possibility of COHS expansion into counties in which PACE currently operates. DHCS has made a commitment that, in the event discussions begin in the future to convert one of these counties to a COHS, DHCS would take the steps required by the Centers for Medicare and Medicaid Services (CMS) to allow PACE to continue in those counties.

Secondly, in consideration to the request that PACE programs be allowed to operate in all COHS counties, DHCS encourages CalPACE and the individual PACE organizations to work with the COHS and California Association of Health Insuring Organizations (CAHIO) to explore possibilities for the provision of the PACE model of care in COHS counties. DHCS will continue to focus on developing a coherent integrated delivery system for all Medi-Cal beneficiaries – including duals – in COHS and all other dual demonstration counties.

In closing, CAHIO has also indicated its desire to meet with CalPACE and further discuss contracting arrangements that will meet your shared goal of providing PACE services to eligible beneficiaries in COHS counties. DHCS encourages these discussions and looks forward to reviewing proposals for these partnerships.

Robert Edmondson
Page 2
April 26, 2012

Once again, thank you for your expressing your concerns regarding the co-existence of PACE and COHS. If you have any questions please contact Mr. Joseph Billingsley, Chief, PACE/SCAN Unit, at (916) 440-7538.



John Shen, Chief
Long Term Care Division

cc: Toby Douglas
Director
Department of Health Care Services
Director's Office, MS 0000
P.O. Box 997413
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Jane Ogle
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Health Care Delivery Systems
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May 6, 2021

Sustaining Supporters

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

Alliance of Catholic Healthcare
Sutter Health
Sharp HealthCare
Cedars-Sinai Medical Center
Blue Shield of California
Snowline Hospice

Via: CalAIMWaiver@dhcs.ca.gov

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Lee and Ms. Font:

The Coalition for Compassionate Care of California (CCCC) thanks you for the opportunity to provide comment on the CalAIM 1915(b) Waiver. CCCC is a statewide collaborative of healthcare providers, consumers, and policy leaders working to create a future where Californians of all ages can live their best lives possible in the face of serious illness.

In order to achieve that goal, Californians need access to palliative care – which provides relief from the pain, symptoms and stress of a serious illness – starting at the point of diagnosis, and throughout the course, of a serious illness. Typically, palliative care is provided alongside curative or rehabilitative care. In addition, Californians should be provided with the support they need to think about and document their treatment preferences, along with assurances that the healthcare system will honor those preferences.

We believe palliative care and advance care planning are strongly aligned with – and can help achieve the goals of – CalAIM, including but not limited to whole person care, improved quality outcomes and value-based initiatives. We support CalAIM proposals that will make it easier to provide palliative care to Medi-Cal beneficiaries, including the ability to address social determinants of health, increased system flexibility, and payment reform.

We stand ready to assist DHCS with thinking through how to best fully integrate palliative care and advance care planning into CalAIM, so that Medi-Cal beneficiaries of all ages can receive high-quality person-centered care and decision making support during serious illness.

With respect to the specific CalAIM initiatives, we have the following comments:

Population Health Management

A part of population health should be keeping members healthy during serious illness through palliative and advance care planning.

Enhanced Care Management (ECM)

Some of the target population for ECM would benefit from palliative care and likely overlaps with the population eligible for SB 1004 Medi-Cal palliative care. Yet it is unclear how ECM interfaces with palliative care. Can palliative care be provided alongside ECM? If so, how do the two programs interrelate? Or is palliative care a part of ECM? If neither one, where does palliative stop and ECM start?

In Lieu of Services

We believe that In Lieu of Services could be very beneficial in meeting the whole-person and social determinant needs of seriously ill members. With respect to seriously ill children, we strongly recommend that CalAIM authorize the provision of and payment for expressive therapies, which was found to be a particularly beneficial component the Pediatric Palliative Care Waiver.

Standardized Managed Care Plan Benefit

In developing standardized managed care benefits, we strongly recommend the inclusion of palliative care as well as advance care planning as a part of and separate from palliative care. We also like to highlight the importance and value of POLST in standardizing care for seriously ill beneficiaries, as well as the need for a statewide electronic registry for POLST to provide seamless access to this important information.

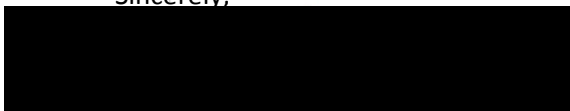
Serious Mental Illness

Advance care planning should be supported for individuals at risk for institutionalization with serious mental illness through specialized forms and support services, such as the [Making a Plan – Thinking Ahead](#) workbook, a toolkit and program developed by the Behavioral Health Division of the County of Sonoma, the Community Network for Appropriate Technologies and CCCC.

Conclusion

Thank you for this opportunity to comment on CalAIM. CCCC is available to answer any questions you may have or provide additional information that might be helpful. You can reach me at (916) 779-7500 or jthomas@coalitionccc.org. Please don't hesitate to contact us.

Sincerely,



Chief Executive Officer



May 5, 2021

Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7417

Delivered via email to: CalAIMWaiver@dhcs.ca.gov

Re: California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 & 1915(b) Waivers

The SCAN Foundation (Foundation) commends the Department of Health Care Services' (DHCS) bold leadership in developing the CalAIM initiative, which has the potential to streamline services and enhance the care experience for California's 1.5 million dual eligible (Medicare/Medi-Cal) individuals. A recent [evaluation](#) of the Cal MediConnect program, funded by the Foundation, offers many important considerations for the future of integrated service delivery for dual eligible individuals in California, particularly in regard to [care coordination](#), data sharing, and other issues. We provide the following recommendations to the CalAIM demonstration waiver that build from lessons learned in the Cal MediConnect evaluation, and reflect principles that underlie a person-centered, integrated service delivery system.

Crosscutting Issues

Alignment with the Master Plan for Aging as a Driving Vision

The [Master Plan for Aging's](#) (Master Plan) five bold goals chart a path forward for comprehensive system reform over the next ten years, including streamlined access to services and supports. While the goals of CalAIM – to improve the quality of life and health outcomes of Medi-Cal members – align conceptually with those outlined in the Master Plan, there is no reference to the Master Plan in the 1115 and 1915b waiver proposals and it is easy to lose sight of how the two initiatives relate.

- We recommend that the 1115 and 1915b Waiver proposals acknowledge the broader vision outlined in California's Master Plan, particularly as they align with Master Plan goals to better integrate/coordinate care across health care, long-term services and supports, and social determinants of health.

Equity as the Basis for CalAIM

California's low income adults served by the Medi-Cal program represent racial, ethnic, linguistic, and cultural diversity while having extensive health needs and daily living support needs. To address disparities in health care, high mortality rates and access to services in underserved communities, any model of integrated care must prioritize equity in service delivery to ensure access across race, ethnicity, sexual orientation, and gender identity.

- We recommend establishment of a consumer advisory committee comprising the diversity of voices impacted by CalAIM, in order to ascertain the extent to which program initiatives are addressing equity concerns and meeting the needs of the target population.
- We recommend that the DHCS utilize the Master Plan for Aging Equity Workgroup's [equity tool](#) in planning and implementing the CalAIM initiative.

Part I: Integrated Care

Outline a Vision and Plan to Increase Access to Fully-Integrated Care on a Statewide Basis

Accessing health care and long-term services and supports (LTSS) is a cumbersome process for many older adults and families. All too often, individuals cannot access the range of services they need to remain at home, leaving them at-risk of institutionalization. Dual eligible individuals often face the greatest challenges, with significant health and functional needs that often fall through a care gap. California should work toward achieving the fullest amount of care delivery and associated financing integration possible; yet true integration is illusive with the majority of LTSS carved out of the Medi-Cal managed care delivery system. Additionally, the importance of behavioral health services, specialty mental health services, and substance use disorder services must be recognized, particularly for dual eligible individuals who are maneuvering two systems and multiple funding streams.

Utilizing the basic Duals-Special Need Plan (D-SNP) structure and managed LTSS (MLTSS) can be a good first step in expanding access to integrated care throughout the state. However, LTSS carve-outs and care coordination structures create barriers to offering fully-integrated care options. The state and Medi-Cal Managed Care Plans (MCPs) should examine all potential pathways to offer fully-integrated care options for dual eligible Californians.

- We recommend DHCS develop and communicate a comprehensive vision, strategy, and work plan, in concert with the [D-SNP transition proposal timeline](#), to move toward fully-integrated and streamlined services for dual eligible Californians living in any county. This plan should clarify the provision of Enhanced Care Managed (ECM) and In Lieu of Services (ILOS) for dual eligible individuals, coordinated with carved-out services and supports (e.g., behavioral health/specialty mental health services, substance use disorder services, In-Home Supportive Services), as well as quality, accountability, and oversight.

Part II: Managed Long-Term Services and Supports

Evaluating Lessons Learned and Outlining Quality Standards for MLTSS

With the state preparing for the rollout of MLTSS on a statewide basis, it is critical to understand how well MLTSS under the Coordinated Care Initiative (CCI) is serving individuals and where there may be opportunities for improvement. Yet, the state lacks MLTSS data on beneficiary access to services, including care coordination and LTSS.

In order for the state to identify whether MLTSS beneficiaries' needs are being met, we recommend DHCS take the following actions:

- Establish access standards for the Community-Based Adult Services (CBAS) and nursing facility (NF) carved-in services, as well as future MLTSS home-and community-based benefits to ensure individuals can access needed services that align with their goals and preferences

- Report on beneficiary access to services in MLTSS, including referrals to CBAS, NF, transitions, care coordination, and use of other carved-out services (including behavioral health). If these data are not available, the state should identify a data point that can be collected to better understand MLTSS delivery and beneficiary experience.
- Contract with a University of California entity to conduct an evaluation of existing MLTSS system including timely access to services, care coordination and beneficiary satisfaction to be completed prior to MLTSS expansion.
- Require MCPs to submit a MLTSS transition plan to ensure system readiness for MLTSS implementation. The transition plan shall be reviewed for network adequacy, care coordination standards, and access to services and supports.
- Require MCPs to report the new [LTSS HEDIS measures](#), and require NCQA accreditation that includes the [LTSS Distinction Survey](#).

Implement Policies That Afford the Strongest Consumer Choice and Protection

Regardless of enrollment choice, all dual eligible individuals and Medi-Cal only Seniors and People with Disabilities should be ensured access to MLTSS and care coordination for identified needs. As an example, [Minnesota](#) has developed strong requirements for their MLTSS plans.

- We recommend DHCS develop strong consumer protections and quality standards for MLTSS that includes LTSS assessment, person-centered care planning, and strong care coordination standards to ensure dual eligible individuals can access the services they need no matter their enrollment choice.

Standardization of Benefits and Equity Considerations

We applaud DHCS' recognition of the importance of non-medical services, including home- and community-based services (HCBS), in meeting a person's broader health care needs. As part of CalAIM's MLTSS program, standardization of identified benefits is critical for equity considerations, in order to ensure access to services for all eligible individuals. We offer the following considerations with regard to program authority and statewide access to MLTSS benefits:

- Authority for Enhanced Care Management and In Lieu of Services: We recognize that the 1915b waiver application provides the authority for Medi-Cal Managed Care Plans, and authority for both Enhanced Care Management (ECM) and In Lieu of Services (ILOS) will likely be provided through the plan contracts and policy directives.
 - Given that the success of the MLTSS program relies on the success of both ECM and ILOS as a statewide benefit, we recommend that the 1915b waiver application outline core principals and program components, including data collection and progress measurement, for both ECM and ILOS.
- Standardization of ILOS as a Statewide Benefit: The proposed framework for ILOS is bold and, if successful, will make significant progress towards achieving an integrated service delivery system. However, we also recognize that the proposal presents challenges in regard to achieving equity and statewide access to services. Given that ILOS are voluntary for MCPs, some beneficiaries will have their needs better met than others, depending on the MCP and county of residence. We believe this is inconsistent with DHCS' efforts to move towards statewide standardized Medi-Cal benefits.

- We recommend that DHCS provide a blueprint for infrastructure development and plan readiness, including technical assistance to develop the systems and community capacity necessary for statewide ILOS adoption. Additionally, DHCS should identify the statewide access needs for CBAS through the [HCBS Gap Analysis/Roadmap](#).
- **Community-Based Adult Services (CBAS)**: In 2012, the Adult Day Health Care program was discontinued as a Medi-Cal State Plan benefit, then renamed CBAS and transitioned to the 1115 waiver as a managed care benefit. CBAS is a critical component of the HCBS system, providing a range of services in an outpatient setting to at-risk older adults and people with disabilities, including individual assessment; professional nursing services; physical, occupational, and speech therapies; mental health services; personal care; nutritional counseling; and transportation, among others. While CBAS is identified as a benefit of the MLTSS program, it is available in only 30 of the state’s 58 counties. This reality runs counter to DHCS’ efforts to standardize benefits statewide. Further, DHCS has included CBAS in the 1115 waiver proposal, but has transitioned all other MLTSS and related components to the 1915b waiver authority. It is unclear why CBAS remains as a demonstration program rather than including it as a permanent program as a managed care benefit.
 - We recommend that DHCS provide a blueprint for CBAS to be adopted as a permanent program through the 1915b waiver authority. Additionally, DHCS should identify the statewide access needs for CBAS through the [HCBS Gap Analysis/Roadmap](#).

Additional Strategies for Increasing Access to HCBS

With appropriate incentives, MCPs can contribute to rebalancing LTSS, bolstering HCBS, and reducing avoidable nursing facility use. As part of Cal MediConnect, the Health Plan of San Mateo and Inland Empire Health Plan increased access to LTSS to help individuals transition out of nursing facilities. These MCPs dedicated funding from their reserves to provide access to services such as assisted living and independent housing. The use of these strategies was included in a CHCS report, [Facilitating Community Transitions for Dually Eligible Beneficiaries](#). The waiver proposal allows for in lieu of services to begin to address HCBS needs, but these services are not standardized across plans and are only available to targeted populations thereby potentially limiting access.

- We recommend that DHCS work with counties, MCPs, and other stakeholders, such as consumer advocates and labor representatives, to devise a fiscal arrangement that encourages appropriate incentives and allow for HCBS as alternatives to institutionalization where feasible and in accordance with an individual’s needs, desires, and preferences.

Part III: Consumer Assistance

Ensure Access to Ombudsman Services Specializing in Integrated Care for Dual Eligible Individuals (building off the Cal MediConnect Ombudsman Program)

California’s Cal MediConnect Ombudsmen program is essential to helping dual eligible individuals residing in CCI counties understand their choices, navigate appeals, advocate when mistakes were made, and help resolve system issues across Medicare and Medi-Cal programs. Under the CalAIM proposal, it is unclear how the state Ombudsman program will address the needs of this population once the Cal MediConnect ombudsman program ends. When other states, such as Virginia and Massachusetts, have engaged in similar transitions, they continued to engage an [integrated care ombudsman program](#) and expanded it to serve other allied Medicaid populations.

- We recommend the Cal MediConnect ombudsman program expand statewide and continue to serve dual eligible individuals as part of the CalAIM demonstration, with consideration given to how ombudsman services will be provided for MLTSS enrollees who are not eligible for or enrolled in an integrated care program.

Thank you for the opportunity to review and comment on the proposed CalAIM demonstration. California is at a critical transition point. The important provisions outlined in CalAIM and the [Master Plan for Aging](#), along with creation of the Office of Medicare Innovation and Integration, provide opportunities to think strategically through an equity lens about the future of aging in our state. Please feel free to contact us for any additional information.

Sincerely,



Sarita A. Mohanty, MD, MBA, MPH
President and CEO

May 6, 2021

Submitted via Email: 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, California 95899-7413

Re: State of California Department of Health Care Services (DHCS) Medi-Cal (CalAIM) 1915(b) Waiver Public Comment Opportunity

GlaxoSmithKline (GSK), in conjunction with ViiV Healthcare, appreciates this opportunity to submit comments on the State of California Department of Health Care Services' (DHCS) Medi-Cal (CalAIM) 1915(b) Waiver Application. GSK is a science-led global healthcare company. We have three world-leading businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines, and consumer healthcare products. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, improves patient outcomes and achieves higher-value care.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment. We respectfully offer the following comments related to the 1915(b) waiver application:

GSK urges DHCS to add the Viral Load Suppression (VLS) measure back into the MCAS

In 2019, GSK supported DHCS' proposal to require Medical Managed Care Plans (MCPs) to report measures, including the HIV Viral Load Suppression (VLS) measure, in the Managed Care Accountability Set (MCAS). However, despite the proposal outlined in the Comprehensive Quality Strategy (CQS) to include the VLS measure,¹ it appears it has been removed from the MCAS measure list for reporting years 2021² and 2022.³

¹ <https://www.dhcs.ca.gov/Documents/Managed-Care-Accountability-Set-Reporting-Year-2020.pdf>

² <https://www.dhcs.ca.gov/dataandstats/reports/Documents/Ry2021-MCAS-2020-12-01.pdf>

³ <https://www.dhcs.ca.gov/dataandstats/reports/Documents/Ry2022-MCAS-12-31-2020.pdf>

Although finalization of the CQS has been delayed due to COVID,⁴ it is more important than ever to make sure MCPs are doing everything they can to make sure their patients are adhering to their VLS medication because retention in care and adherence to VLS medication has been severely affected by COVID-19. For instance, there has been a **31% drop in VLS rates in San Francisco's Ward 86 HIV clinic, compared to pre-COVID level.**⁵ This needs to be a priority to get our most vulnerable patients back to being virally undetectable.

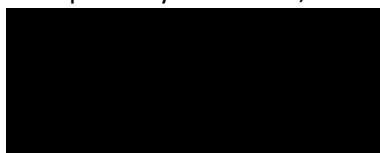
GSK supports the requirement that all MCPs be accredited by NCQA and encourages DHCS to include the Adult Immunization Status (AIS) and Prenatal Immunization Status (PRS) measures into the MCAS

To align with the National Committee for Quality Assurance (NCQA) accreditation, GSK encourages DHCS to include NCQA's Adult Immunization Status (AIS) and Prenatal Immunization Status (PRS) measures into the MCAS. Importantly, the PRS measure was added to the Child Medicaid Core Set⁶ and beginning in fiscal year 2024, states will be required to report quality measures in the Child Core Set.⁷ Therefore, DHCS should start to prepare for that requirement.

NCQA's AIS measure is a powerful tool to help prevent illness, increase uptake of immunizations, and promote health among adults. Increasing age-appropriate vaccine uptake among adults has been identified as a national priority in order to prevent infection, reduce the spread of disease, and contribute to safer environments for adult populations.⁸ Given the dramatic decreases in routine adult immunizations due to COVID-19, promoting vaccine uptake is crucial to preventing other outbreaks of other diseases, reducing hospitalizations due to vaccine-preventable diseases, and promoting wellness and prevention.

Thank you for this opportunity to comment on the 1915(b) waiver proposals. If you have any questions or GSK can provide additional insight, please do not hesitate to reach out to me at 201.715.1048 or margaret.n.mann@gsk.com.

Respectfully submitted,



Margaret Mann
VP, US Public Policy
GlaxoSmithKline

⁴ <https://www.dhcs.ca.gov/services/Pages/DHCS-Comprehensive-Quality-Strategy.aspx>

⁵ <https://www.medscape.com/viewarticle/940879>

⁶ https://www.mathematica.org/-/media/internet/features/2020/coreset/2021_csr_final_report.pdf?la=en

⁷ <https://www.healthaffairs.org/doi/10.1377/hblog20200817.901186/full/>

⁸ <https://health.gov/healthypeople/objectives-and-data/browse-objectives/vaccination/increase-proportion-adults-age-19-years-or-older-who-get-recommended-vaccines-iid-d03>



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May 6, 2021

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

Delivered by email to: CalAIMWaiver@dhcs.ca.gov

Re: Opposition to CalAIM proposal to expand mandatory managed care

Dear Department of Health Care Services:

We write to reiterate the concerns previously expressed by MCH Access and other consumer and provider organizations opposing the CalAIM proposal to expand mandatory managed care to the Accelerated Enrollment, Child Health and Disability Prevention (CHDP), and Pregnancy-Related Medi-Cal programs. We appreciate the opportunity to summarize those concerns and present several additional points as part of this latest state comment period.

As far as we are aware, the Department anticipates neither program cost savings nor improved health outcomes from these mandatory managed care proposals. A 2015 Urban Institute county-by-county study of the non-elderly found that there is no evidence **managed care** cut Medicaid costs-- but it **did increase the likelihood of ER visits, difficulty seeing specialists, and unmet need for prescriptions**.¹ Apparently, the Department's reason for including the mandatory managed care proposals in the CalAIM waiver is to simplify administration, but **administrative convenience should not outweigh serious health consequences for pregnant women and their families**.

Other alternatives to mandatory managed care that could benefit Medi-Cal consumers exist and should be considered, such as voluntary managed care and "managed fee-for-service" during pregnancy.

Children

Accelerated Enrollment: The proposal to make Accelerated Enrollment mandatory to managed care would reduce the amount of time families have in fee-for-service to find and visit pediatric providers and then decide on a plan for their children. The shortened time raises a number of concerns, as explained by a provider at a pediatric specialty center:

The process is so confusing for families. If they have been [supported] in this process, they may be

¹ Urban Institute (2015): *The Expanding Role of Managed Care in the Medicaid Program: Implications for Health Care Access, Use, and Expenditures for Nonelderly Adults*, https://journals.sagepub.com/doi/full/10.1177/0046958015575524?rfr_dat=cr_pub%3Dpubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org

trying to stay with their same provider. If they are new to the system [or] need a new provider, the challenge is finding someone taking patients, let alone someone that you connect with, has the expertise they are looking for, etc. Families will look at the list and start calling and learn that providers are not open to new patients. It is an arduous process for some.

Another provider concurs:

Honestly, they need more time, folks still struggle with this—by shortening the time, they are asking that clients know the clinic’s provider codes, etc. And at times the codes provided in the booklets are not accurate. Our own patients get defaulted. . .

For families facing particularly challenging situations, either because of the child’s health condition or other circumstances—e.g., an essential worker with two jobs caring for her children with limited child care; homeless families; residents of neighborhoods ravaged by drug addiction and violence—the more time the better, to facilitate locating providers and picking an appropriate plan or to connect with a Navigator for help getting through the selection process with the best provider and plan fit possible.

During the COVID pandemic, it has been taking MCHA much longer to help clients find the right providers and plans, since families have both been disproportionately affected by COVID-19 and have also been moving a lot, disrupting routines and neighborhood knowledge base. In addition, some individuals need to be seen in person, but arranging such visits now requires much more time, due to staffing limitations for even answering the phone, and the reliance on telehealth for social distancing. As telehealth becomes integrated into Medi-Cal, families will continue to need the additional time in fee-for-service during AE to connect with providers and research plan networks.

CHDP Deemed Eligible Infants: Incidents like the one described in our correspondence of February 16, 2021-- of a newborn with infections and a collapsed lung who had a dangerous six-week delay in getting an appointment with the pediatrician she needed to see after discharge from a Neonatal Intensive Care Unit—are unfortunately not isolated. Instead, they flow from the Department’s policy to enroll newborns into the mother’s plan when the newborn is referred to the county, without even notifying the family that the plan enrollment will occur, what to do if enrollment in the mother’s plan is not what the family wants, and how to prevent delays in accessing specialty or other care until the infant’s plan can be switched. The existing policy and lack of protections are inconsistent with existing state law. Such significant, impactful changes to longstanding consumer protections should not be extended through the CalAIM waiver to CHDP infants.

Pregnancy and Postpartum

- **Reducing access to midwifery services:** The shortage of OBs and other pregnancy care providers in California could become worse if more pregnant women have to enroll in Medi-Cal managed care. This because plans are permitted to contract with as few as one certified nurse midwife and one licensed midwife, with some plans having failed to do even that much in the recent past. By eliminating fee-for-service access to midwifery services for all citizen and lawfully present immigrant women, **the CalAIM proposal would effectively reduce the number of pregnancy care providers in Medi-Cal overall.**

Losing fee-for-service access to midwives also negatively impacts consumers for the additional reason that **midwifery services improve birth outcomes among the Medicaid population**, as extensive research by the federal government and others shows.² Experts agree that **midwifery is key to reversing the U.S. maternal mortality crisis**, as explained in a 2021 study co-chaired by Kathleen Sebelius and Tommy Thompson, both former Governors and U.S. Secretaries of Health and Human

² See, e.g., *Midwifery and Birth Centers Under State Medicaid Programs: Current Limits to Beneficiary Access to a High-Value Model of Care* (2020): <https://www.milbank.org/quarterly/articles/midwifery-and-birth-centers-under-state-medicare-programs-current-limits-to-beneficiary-access-to-a-high-value-model-of-care/>.

Services:

Midwifery-led care and freestanding birth centers are two models with significant evidence . . . demonstrating that they can reduce maternal mortality and morbidity, providing high-quality, patient-centered, accessible care for the vast majority of pregnancies, which are low risk. Yet significant barriers within the Medicaid program and related state laws and regulations limit the adoption of these models. In order for Medicaid to reach its potential in addressing the maternal mortality crisis, it must emerge from historical policies, many of which have racist origins, and be reimagined around women’s health needs.³

- **Reducing access to perinatal specialty centers:** These providers treat the most highly at-risk individuals. Some perinatal specialty centers decline to participate in Medi-Cal managed care contracts but do accept fee-for-service beneficiaries. As it unlikely that all centers will be required to contract with Medi-Cal plans as a condition of participating in Medi-Cal at all, **the practical effect of the CalAIM proposal is to further reduce access to specialty care for many very high risk women.**
- **Case examples of negative impacts for consumers deprived of fee-for-service access to medical care during pregnancy:** It is extremely difficult under the Department’s rules for a pregnant woman to be granted a “medical exemption request” (MER) from mandatory managed care when a provider declines to participate in a “continuity of care” arrangement with the plan. The following are but a few examples of cases for which we have provided assistance or reviewed fair hearing decisions involving pregnant women denied MER approval because they did not meet the Department’s criteria. **The CalAIM proposal would place even more women in a similarly untenable position.**
 - **MERs are automatically denied when the woman has been in a plan for more than 90 days even before becoming pregnant:** Many women enroll in Medi-Cal before becoming pregnant or even without intending to become pregnant. Under the Department’s rules, being in a plan over 90 days results in automatic MER denial, as occurred in each of the following cases:
 - One woman developed complications during her two prior pregnancies and had to have emergency C-sections both times. For her second pregnancy, she had found a doctor she could trust and wanted to be in his care for her third pregnancy as well.
 - Another woman, who had had a difficult pregnancy and suffered a miscarriage, feared that having to see a doctor who lacked the experience of having treated her before could increase the risk of losing her current pregnancy.
 - A woman with multiple autoimmune problems and diabetes had had two premature deliveries. According to the non-networked perinatologist who the woman wanted to see again, she would require bed rest for her current pregnancy, weekly progesterone injections, and perinatal specialty services unavailable in her plan’s network.
 - Another woman had severe abdominal pain with unknown causes and a family history of Down Syndrome.
 - Another wanted to deliver her baby at the hospital located only 15 minutes from her home instead of at the plan hospital an hour away because, for her previous child, she had almost given birth in the car on her way to the hospital closest to her home.

Had these women, and many others like them, been in Medi-Cal fee-for-service instead of having to

³*Reversing the U.S. Maternal Mortality Crisis* (2021) (page 12):
https://www.medicaidinnovation.org/images/content/AHSG-Reversing_the_US_Maternal_Mortality_Crisis-Report_2021.pdf

enroll and remain in a managed care plan, they would have been able to preserve continuity of care with providers they knew and trusted.

- **MERs to preserve continuity of care are also denied for women whose medical conditions are not deemed “complex”:** In each of the following cases, the woman wanted to remain with her current fee-for-service provider but her MER was denied because, according to the state, her medical condition wasn’t complex or serious enough.
 - One woman had a prior C-section and wanted to have her current doctor perform the C-Section for her latest pregnancy.
 - Another woman’s fee-for-service provider had diagnosed her with low pregnancy-associated plasma protein A.
 - Problems with vulvar varicose veins during a previous pregnancy, low blood pressure, and hyperthyroidism were the reasons one woman wanted to stay in the care of her fee-for-service provider.
 - For another woman, being in the third trimester with a history of miscarriages and shortened cervix that created a risk of premature birth or C-section was not considered sufficiently complex.
 - Nor was uncontrolled and untreated anxiety disorder that had led to a recent panic attack and ER visit for another woman. The MER was denied even though the woman trusted her current provider to assist with her mental health condition.
- **SDOH services under CPSP are missing from Medi-Cal plans:** Adequate food and nutrition, help with housing, getting transportation to medical appointments, and protection from domestic violence are among the many “social determinants of health”(SDOH) interventions that are covered by the Comprehensive Perinatal Services Program (CPSP). Yet **the Department has never even included this part of the CPSP benefit package in any of its reviews or audits of the Medi-Cal plans.** Our experience with clients indicates that plans have taken this as a cue to provide little if any SDOH services for pregnant or postpartum members.

While the Department intends to include CPSP’s SDOH services in plan audits in the future, until the Department can show that Medi-Cal plans are delivering SDOH interventions under CPSP at adequate levels, more pregnant women should not be required to enroll in managed care.

To be sure, there are many challenges with CPSP in fee-for-service as well, but the solution is not to make more women enroll in plans. Other alternatives should be considered, such as “managed fee-for-service”.⁴ In the meantime, Perinatal Health Coordinators in each of the 58 counties and three city public health systems, who are responsible for reviewing the charts of fee-for-service providers, can better work with such providers to connect their patients to SDOH interventions.

- **Confusion and fear for the undocumented:** Under Obamacare, the Department certified that fee-for-service “pregnancy-related” Medi-Cal provides essentially the same scope of services as full scope Medi-Cal does through managed care plans. But confusion about the intended scope of pregnancy-

⁴ State of Conn (2/22/2016); Wall Street Journal (3/18/16): *Conn Moves Away from Private Insurers*: <https://www.wsj.com/articles/connecticut-moves-away-from-private-insurers-to-administer-medicaid-program-1458325696>; Harvard Report (March 2016): *Innovations and Insights in Medicaid Managed Care*: <https://www.chlpi.org/?s=Innovations+and+Insights+in+Medicaid+Managed+Care>; Connecticut Health Policy Project (Jan 2017): *Busting Medicaid Spending Myths*: <https://cthealthpolicy.org/index.php/2017/01/09/busting-medicaid-spending-myths/>.

related services persists since Department policies consistently describe pregnancy-related coverage as “limited” or “restricted”, i.e., as less than “full”. Providers who fear that the state will reject a claim as insufficiently pregnancy-related may decline to accept the patient’s Medi-Cal. **The CalAIM proposal would make access problems flowing from ambiguity about the scope of pregnancy-related Medi-Cal even worse for the one group of women who would remain in limited scope fee-for-service Medi-Cal— undocumented women— while all others are in full scope during pregnancy.**

In addition, undocumented immigrants, already reluctant in many instances to participate in public benefits programs, would have yet another reason to fear being singled out by enrolling in Medi-Cal.

Sincerely,



Lynn Kersey, MA, MPH, CLE
Executive Director, MCHA

cc: Will Lightbourne, Director
Jacey Cooper, Medi-Cal Director
Senate Health and Senate Budget Committees
Assembly Health and Assembly Budget Committees

*ALCOHOL AND DRUG SERVICE PROVIDERS ASSOCIATION
OF SAN DIEGO COUNTY*

Alcohol and Drug Services Provider Association of San Diego (ADSPA)

CalAIM Stakeholder Feedback

May 4, 2021

About ADSPA

The Alcohol and Drug Services Provider Association (ADSPA) is a diverse coalition that represents 36 legal entities, 75 SUD-related programs, and over 160 contracts with San Diego County Behavioral Health Services (BHS). We pride ourselves on broad representation, with ADSPA's member organizations providing nearly 100% of San Diego's DMC-ODS services that reach more than 18,500 San Diegans annually.

Documents Reviewed

- [California Advancing & Innovating Medi-Cal \(CalAIM\) Proposal](#) (January 2021)
- [Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstrate; Draft for Public Comment](#) (April 2021)
- [CalAIM 1915\(b\) Waiver Overview](#) (April 2021)

Stakeholder Feedback

- In support of CalAIM's goals:
 - > ADSPA's highest recommendation is that DHCS identify additional administrative relief for DMC-ODS providers and reconsider the purpose of disallowances, limiting their use to material discrepancies (i.e. *not* administrative errors) and/or evidence of fraud, waste, and abuse.
 - > To support an integrated approach for individuals who have co-occurring conditions, clarify that therapy delivered by an LPHA is an allowable, billable component of DMC-ODS services. Given the high rates of trauma amongst individuals with a SUD, for example, EMDR is highly effective and should be an available intervention for individuals served in the DMC-ODS.
 - > To support increased access to care for individuals with behavioral health conditions, identify a funding mechanism to support outreach as a distinct and billable service.
 - > Network adequacy remains more important than ever in the wake of COVID-19 and with the rising behavioral health needs of our community. While the DMC-ODS significantly increased the volume of individuals served, the residential capacity has remained relatively stagnant in our County and, in the case of residential withdrawal management, has significantly decreased. It is critically important that – at a minimum – we retain the existing capacity, especially for residential programs with conditional use permits. Current data collection practices have failed to capture the true need for residential services (i.e. requirements to report “no waitlist”), and additional investment is needed to ensure true network adequacy.
- *Residential stay limits:* We are supportive of removing the limit on the number of residential stays; however, the State's 30-day average should not be treated as a target and, instead, medical necessity should determine the length of stay (LOS).

- *Criteria for services:* Especially as it relates to pre-release beneficiaries, ensure that Medi-Cal beneficiaries have access to ECM and ILOS, regardless of whether they are assigned to a managed care plan.
- *MAT expansion:* Further clarify that OTPs may serve youth and ensure network adequacy for both youth MAT and tapers from benzodiazepines.
- *Recovery services:* In support of clarifying that beneficiaries are not prohibited from accessing recovery services while they are receiving long-term MAT, revise the same-day billing matrix to allow same-day billing for RS and OTP services.
- *Evidence-based practices:* Many underserved communities have been traditionally excluded from the research that validates EBPs, so limiting interventions to EBPs may inadvertently perpetuate such disparities. While the proposed language adds – but does not limit – EBPs to include contingency management, DHCS should encourage providers to identify and utilize community-informed practices.
- *Administrative integration and fiscal reform:*
 - > While we acknowledge and support the need to achieve administrative efficiencies and integration, it is important to recognize that there are clear and distinct differences between mental health and SUD services, which may serve the same populations but still require some level of specialty care. Similarly, while we support fuller integration with physical health, it is important to acknowledge the uniqueness and value of SUD care and ensure that specialty care remains largely accessible outside of “mainstream healthcare” settings.
 - > In an effort to promote equity, as well as linguistic and cultural diversity, of the behavioral health workforce – and to support recruitment and retention challenges – reduce documentation burdens in behavioral health settings.
 - > Based on lessons learned under the 1115 demonstration and the challenges in reconciling individual, time-based services with group visits that must be allocated across the number of participants, ensure that the proposed mixture of HCPCS Level II codes and CPT codes for DMC allow for flexible service delivery, “apples to apples” reporting, and a reduction in overall administrative requirements.
 - > Incorporate provider feedback into the new rate-setting methodology.

Dear Esteemed Colleagues:

I write to endorse the request for a demonstration (waiver) to transform important components of the California Medicaid (Medi-Cal) system on January 1, 2022 to:

1. Identify and manage member health risk and health needs via Social Determinants of Health and whole-person care approaches;
2. Facilitate Medi-Cal to be more consistent and seamless by increasing alignment across delivery systems, reducing complexity and increasing flexibility; and
3. Improve quality outcomes, reduce health inequities, and foster delivery system transformation and innovation via value-based initiatives, system modernization, and payment reform.

In particular some recent projects in Los Angeles and San Mateo have shown important gains in children's health – both oral health and general health – with dental and medical integration, so dental-medical integration should be included and approved in this demonstration (waiver) request. Moreover, transitioning the Dental Transformation Initiative will be important to sustain the gains achieved and diffuse innovative good practices for adaptation.

Thank you for your time and work on these important initiatives and in incorporating stakeholder feedback.

Sincerely,
Dr Stuart Gansky

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May 5th, 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

Further Changes Needed to CalAIM Section 1115 & 1915(b) Waivers

Dear DHCS Directors:

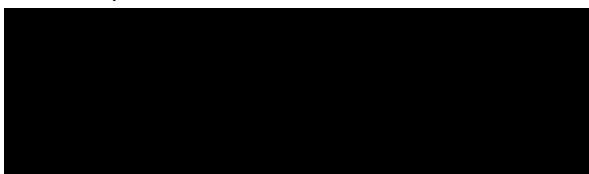
On behalf of Lincoln Families, which provides preventative support services that disrupt cycles of poverty and trauma in Alameda and Contra Costa counties, I urge DHCS leadership to reconsider the changes to the CalAIM proposal regarding waivers. CalAIM is a once in a generation opportunity for reform to our behavioral health systems of care, and a necessary response to the COVID-19 pandemic and growing youth mental health crisis. We commend DHCS for working with advocates and stakeholders on this initiative and hope to see a return to some of the initial elements of the proposal.

Specifically, the CalAIM 1915(b) waiver proposal does not go far enough to directly address the impact of racism and poverty on the social and emotional health of children. The proposal must be revised to:

- Resist pathologizing adversity—as evidenced by proposed tools to “screen in for a high risk score” for ongoing services. We must honor the wisdom and intelligence of low income communities to determine their own definition of medical necessity. Lincoln serves low and extremely low income families and youth in the Bay Area, knowing first hand that our current systems of care fail to recognize the impact of poverty, racism, and oppression. To improve inclusivity and access, any positive screen, and more importantly, any request for support from a beneficiary should qualify a child for services and support.
- Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan—or if such a tool is to be used it must only be used during the course of treatment and treatment cannot be stopped or interrupted until or if there is a transition in care. These changes to the original proposal create further barriers to care for youth already experiencing complex trauma.
- Clarify unanswered questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT). We are excited to see a move to IGT but are equally concerned about the lack of transparency on these key specifics.

The time has come for California to place a higher priority on children's behavioral health and ensure children and families receive the services and supports they need to grow and thrive. Please contact me at 510.867.0944 or allisonbecwar@lincolnfamilies.org if you have questions. Thank you so much for committing to this transformative work.

Sincerely,



Allison Staulcup Becwar
President & CEO
Lincoln



BARBARA FERRER, Ph.D., M.P.H., M.Ed.
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May 3, 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

SUBJECT: CALAIM SECTION 1115 AND 1915(b) WAIVERS PUBLIC COMMENT

Dear Director Lightbourne,

The Los Angeles County Department of Public Health (DPH) appreciates the opportunity to comment on the Department of Health Care Services (DHCS) California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 and 1915(b) waiver applications.

As the local entity responsible for the provision of specialty substance use disorder (SUD) treatment services under the Drug Medi-Cal Organized Delivery System (DMC-ODS), DPH supports DHCS’ efforts to create a patient-focused SUD service delivery system and move the field towards parity with physical and mental health systems. The renewals and policy changes included within the 1115 and 1915(b) waiver applications are a significant step forward in improving care and outcomes for individuals with emerging and chronic SUD needs. However, operationalizing these policies in a timely manner will likely require significant State-level system updates, alignments, and clarification to ensure the intent of these progressive actions are quickly and meaningfully implemented upon approval.

We look forward to collaborating further to ensure a successful implementation for the providers we work with and the communities and patients we serve.

[CalAIM 1915\(b\) Waiver Overview April 2021](#)

1915(b) SMHS: Documentation Requirements

Under the Specialty Mental Health Services (SMHS) Program, it states that “DHCS proposes to remove the following requirements: point-in-time treatment plan, and requiring that each chart note tie to the treatment plan” and additionally “proposes to remove the requirement for clients to sign the treatment plan, as evidence does not show that shared decision-making is achieved through signature requirements” (page 27). For parity with SUD systems and to encourage process alignments that will support the transition to a single behavioral health contract, DHCS should offer these same allowances to DMC-ODS participants.

1915(b) DMC-ODS: EPSDT Eligibility and Payment

DHCS emphasizes counties' responsibility in providing Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) services to youth and young adults. We ask for further clarification regarding how these services are funded and operationalized within DMC-ODS.

DHCS' proposal indicates "beneficiaries under age 21 are currently, and will remain, eligible to receive DMC-ODS services without a diagnosis" (page 11), and goes on to say "Counties are responsible for the provision of medically necessary DMC-ODS services pursuant to the EPSDT mandate" (page 34) and reiterated under services to say "DHCS is reiterating the counties' obligation under the EPSDT mandate" (page 43) when describing SBIRT services. We agree that youth and young adults should receive EPSDT services and that nothing in DMC-ODS overrides EPSDT requirements, however the disconnect lies in whether counties can actually submit these claims for payment via the Short-Doyle system and receive federal financial participation (FFP) funds from DHCS, or if "responsibility" means that counties must identify non-DMC (i.e., local) funds to pay for the full cost of this service. There remains a significant lack of clarity State-wide on how SUD services under EPSDT impacts DMC specifically and separately from what is allowable under the SMHS Program.

DPH was permitted to offer at-risk EPSDT services (i.e., services for those under age 21 without a diagnosis but who have demonstrated risk for SUDs) until July 2020, when DHCS removed it from the State/County Interagency Agreement, and DHCS has subsequently denied similar efforts by other counties to offer at-risk services. Furthermore, claims without a qualifying Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis are being denied by the State. For these reasons, counties are currently unable to be compliant with the EPSDT mandate to provide services to those under age 21 as medically necessary, even if services are prior to a diagnosis, under DMC-ODS unless these pre-diagnosis services are paid with 100% local funds. We are hoping that the State's inclusion of this language in the initial DMC-ODS Special Terms and Conditions and the current 1915(b) application signals a commitment to resolve this long-standing problem which adversely impacts the ability of young people to address their substance use issues before it progresses into a chronic condition. Updating DHCS' claims system to include qualifying diagnosis will significantly help counties in operationalizing this mandate.

1915(b) DMC-ODS: Non-Residential Only Pre-Diagnosis Reimbursement

DPH fully supports the ability to receive FFP for services delivered prior to completion of the American Society of Addiction Medicine (ASAM) assessment and establishment of medical necessity, especially given the challenges engaging this difficult to reach population and the possibility that patients cease participation prior to completion of this assessment process. State guidance is still needed on how this will be operationalized, particularly how allowable diagnosis will be expanded to account for this and ensure the ability to be reimbursed for claims. Unfortunately, DHCS indicates these pre-diagnosis services are only proposed in non-residential settings (page 11), presumably because of residential preauthorization requirements. However, additional clarity is needed since "a full ASAM Criteria assessment shall not be required to begin receiving DMC-ODS services" (page 35) and the *Initial Assessment and Treatment Services* section indicates the ability to establish a DSM diagnosis within 30- to 60-days without reference to setting. If this excludes residential treatment (ASAM 3.1, 3.3, 3.5) and residential or inpatient withdrawal management (3.2-WM, 3.7-WM, 4-WM), these residential and inpatient providers will be at risk for disallowance if required documents are not completed before discharge (page 33). From a patient-facing perspective, DHCS should consider applying the same pre-diagnosis criteria in residential and inpatient levels of care (ASAM 3.1, 3.3, 3.5, 3.2-WM, 3.7-WM, 4-WM) as it does in outpatient levels of care.

1915(b) DMC-ODS: Initial Assessment and Treatment Services and Level of Care

Again, DPH fully supports the ability to receive federal FFP for services delivered prior to completion of the ASAM assessment and establishment of medical necessity and further appreciates the flexibility of up to 60 days of reimbursement based on the need for persons experiencing homelessness (PEH).

DHCS should also expand the 60-day timeframe to include individuals under the age of 21 as the subsequent *Level of Care* section indicates that “for beneficiaries under 21, the ASAM Criteria assessment shall be completed within 60 days of the client’s first visit” (page 34) which means that the County/provider would not be reimbursed between the 31st and 60th days if the individual did not complete the assessment process even though DHCS permits the extended time period. Similarly, the *Level of Care* section indicates that “for beneficiaries 21 and over, the ASAM Criteria assessment shall be completed within 30 days of the client’s first visit” (page 34), but it does not outline allowances for the PEH population. For auditing and payment purposes, we recommend that information from the *Initial Assessment and Treatment Services* and *Level of Care* sections align.

Furthermore, DHCS should clarify that counties/providers would be reimbursed under DMC and receive FFP if the patient leaves treatment before the ASAM assessment is completed, but medical necessity with a qualifying diagnosis is established, as outlined under the *Services After Assessment* section. It is also essential that allowable diagnoses in the Short-Doyle payment system be updated to accommodate these payment changes.

1915(b) DMC-ODS: SBIRT (ASAM 0.5) Services

Clarification is needed on whether the scope of SBIRT services for adults 21 years of age and older is limited to DMC-reimbursable pre-diagnosis services given the statement that “SBIRT also represents components of assessment and treatment services when done by DMC-ODS providers” (page 42). Otherwise, it is unclear what services DMC-ODS counties are specifically responsible for other than EPSDT for those under the age of 21.

1915(b) DMC-ODS: Residential (ASAM 3.1, 3.3, 3.5) and Inpatient (ASAM 3.7, 4.0) Services

Table 2 – Required and Optional Services for Participating DMC-ODS Counties (page 42) and the *Residential Treatment* description (page 45) lists levels 3.7 and 4.0 under residential treatment as opposed to inpatient treatment. The ASAM criteria specify different staffing in hospital-level (inpatient) and residential settings; therefore, DHCS should not classify 3.7 and 4.0 as residential levels of care and instead appropriately classify them as inpatient levels of care. Without this distinction, it is unclear how residential (ASAM 3.1, 3.3, and 3.5) and inpatient (ASAM 3.7, 4.0) are different. Counties would also need to make this distinction when setting rates for ASAM 3.7 and 4.0. For this reason, we recommend adding a different service level for inpatient.

Residential treatment service components include “Incidental Medical Services (IMS)” (page 46); however, the subsequent section *Medication Services* indicates this is not required. Therefore, we recommended that DHCS indicate that IMS is optional as indicated under DHCS Information Notice [18-031](#).

Regarding Medications for Addiction Treatment (MAT) (page 47), we recommend including guidance on requiring admission of patients prescribed MAT and verifying that providers need to properly store and safeguard controlled medications onsite to prevent individuals from being turned away. MAT should not be treated differently than other medications; therefore, IMS should

not be required for this purpose and if the patient is self-administering their medications. As Los Angeles County seeks to reduce access barriers due to prescribed MAT, we support the protections DHCS has emphasized for beneficiaries needing or utilizing MAT under the *Access to MAT* section.

1915(b) DMC-ODS: Group and Patient Education Services

Further clarification is needed on, “All services provided....can be provided in person, by synchronous telehealth, or by telephone (audio-only)” (pages 43, 44, 45, 50) for outpatient, residential, inpatient and recovery levels of care as by definition this would include group counseling and patient education sessions which typically benefit from at minimum visual interaction and discussion among participants, and this change to offer groups and patient education session by telephone would represent a departure from traditional practice. For this reason, we recommend that group/patient education generally be practiced using a video platform (telehealth) where patients have the option to not use the camera function rather than giving providers the option to deliver these services solely via telephone.

1915(b) DMC-ODS: Contingency Management

The inclusion of contingency management as an evidence-based practice is a welcomed opportunity. As it appears that this is limited to individuals with a stimulant use disorder in outpatient only settings, more information is needed on if the “DHCS-approved mobile or computer application” (page 44) will require providers to verify a qualifying diagnosis and appropriate outpatient level of care, and if DHCS rather than counties will be responsible for paying and submitting any associated claims under DMC. Additionally, explicit clarity from DHCS would be helpful around if Medi-Cal will be reimbursing the noncash rewards of contingency management up to the maximum cumulative allowable amount per beneficiary of \$599 per calendar year.

1915(b) DMC-ODS: Additional MAT

While DHCS indicates that “DMC-ODS counties may choose to reimburse providers for medications, including long-acting injectables, in DMC facilities under this optional provision” (page 49), it would be helpful to clarify further that this is available outside of the DMC reimbursable benefit but rather as a Medi-Cal pharmacy benefit to avoid confusion. Current language frames this as a DMC benefit that counties have the option to offer, which may result in confusion that counties are restricting access to MAT when this is already a covered Medi-Cal pharmacy benefit.

1915(b) DMC-ODS: Recovery Services

DPH strongly supports and appreciates DHCS’ clarification that individuals can access services “based on self-assessment or provider assessment of relapse risk” and that “the diagnosis of ‘remission’ is not required to access recovery services” (page 49). We look forward to changes in the Short-Doyle billing system for implementation and claims submission. It will also be critical to ensure that recovery services are a separate level of care, rather than what is presumed to be tied to the last level of care according to DHCS [MHSUDS 17-045](#), to prevent denied claims. This is also critical to enable access to recovery services “after incarceration with a prior diagnosis of SUD” (page 49).

1915(b) DMC-ODS: Professional Staff

To honor the contribution of registered and certified counselors, particularly given the dominance of these staffing levels in the delivery of SUD treatment, we recommend changing “staff” and identifying another term such as “clinician” (page 51). Otherwise, it may be interpreted that counselor positions are not considered “professional.”

1915(b) DMC-ODS: Medi-Cal Benefits

The transfer of Medi-Cal benefits between counties has been and continues to be a major barrier in access to care and financial liability for the receiving County.

When a client moves to a new County and initiates an inter-county transfer, it is not operationally possible for the new County to be “immediately responsible for DMC-ODS treatment services and claim reimbursement from DHCS through the Short Doyle Medi-Cal System, as of the date of the inter-county transfer initiation” (page 55). This is because, at minimum, Medi-Cal benefits remain with the prior County through the remainder of the month. Therefore, it has been the experience of Los Angeles County that a patient who requests a transfer of benefits on January 15, for example, and enrolls in treatment the same day, their benefits will not transfer until February 1 at the earliest, assuming everything is processed per regulatory timeframes, which is often not the case. Counties also experience delays in enrollment for individuals with new Medi-Cal applications within the County. State guidance and support are strongly needed to ensure patients can access new and transfer existing Medi-Cal benefits in a timely manner or immediately upon taking residence in another County. This would ensure that lack of coverage does not inadvertently prevent SUD treatment admissions and subsequent reimbursement/liability at the provider and County level. Assistance in this area would greatly improve access to care and reimbursement.

Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request

1115 DMC-ODS: Cost- to Rate-Based Reimbursement

DPH appreciates the transition from cost-based to fee-for-service (FFS) based reimbursement, given the anticipated opportunities to improve patient care and outcomes with more flexible reimbursement arrangements (page 24). However, given where the State is with the implementation process, this cannot begin with the 2022-2023 Fiscal Year. County behavioral health systems not only need to understand the new expectations fully, but they must also have sufficient time to establish the Intergovernmental Transfer (IGT) process, draft and execute new contracts as applicable, and shift electronic health record (EHR) claiming codes once the options are established. While we support an aggressive timeline, the timeline should fully account for the time to sufficiently consider and operationalize all the complexities and system changes needed for a successful launch. This is not a situation where DHCS can issue an information notice without understanding and addressing system-level barriers and changes first. Furthermore, the State should equally prioritize resolution of cost settlement which is several years behind since many counties will critically need the pending reimbursement to ensure the ability to make upfront IGT payments to the State.

1115 DMC-ODS: Peer Support Specialist Services

DPH supports expanding the behavioral health workforce by meaningfully including peers with sufficient training to engage and serve patients (page 31). However, a potential unintended consequence is that peers will have more training and experience than registered SUD counselors (i.e., peers will be certified with at least 80 hours of completed training before being

able to provide billable services, whereas the registered SUD counselor can begin billable services with only 9.5 hours of training). Rather than reducing expectations for peers, we strongly recommend that the State ends what were meant to be temporary accommodations to grow the certified counselor workforce and increase the number of training hours for registered counselors before being able to conduct DMC billable services. To achieve parity among the health systems and reach the objectives of CalAIM, behavioral health workforce skills must be addressed. State investment is needed to achieve this, especially since there is a concurrent shortage of SUD counselors in a field with numerous competitors for shared counselors and clinicians.

1115 PATH: Providing Access and Transforming Health Supports

The specialty SUD system only recently transitioned into the managed care environment with the launch of DMC-ODS and thus had a much shorter runway to achieve the expectations of managed care than did the mental and physical health systems. This transition has been difficult for both counties and community-based providers as systems and processes needed to be overhauled to better meet patient needs. Unfortunately, the specialty SUD system has limited access to flexible funding sources such as MHSA that can support the training and development needs of its provider network, including growing the capacity of registered and certified SUD counselors who need additional training opportunities to optimally perform expectations. Efforts like PATH (page 40) should be developed and include the specialty SUD service system; otherwise, it will remain behind physical and mental health systems while being held to similar regulatory standards.

We appreciate DHCS' leadership on these tremendous opportunities to improve our health and social service systems. We are also grateful for DHCS' continued support of the shared goal of ensuring access to quality SUD treatment services under DMC-ODS. We hope these comments will help further and strengthen this work and provide counties and providers with tools to successfully achieve the expectations under CalAIM and the 1115 and 1915(b) waivers.

Sincerely,



Barbara Ferrer, Ph. D., M.P.H., M.Ed.
Director
County of Los Angeles County, Department of Public Health

BF:gt

c: Kelly Pfeifer, MD
CBHDA

I am writing as a licensed mental health clinician who has worked for over 20 years in our public mental health systems with children, families, and young people. Currently, I also serve as Director of Trauma Transformed, a program of East bay agency for children in Oakland, CA.

I am writing to express serious concerns with the 1915(b) waiver, which as currently proposed by DHCS, erodes critical advancements in addressing the ways racism and inequity shape children and young people's behavioral health outcomes and exacerbate the very same systemic failures we had hoped to reform and re-imagine.

More specifically, requiring a threshold ACEs score to be eligible for services reinforces an approach to accessing care that prioritizes screening over treatment. Having administered many gatekeeping programs in county behavioral health systems over the years, this approach too often translates into over-investments in the gatekeepers and level-of-care decision-makers and under-investment in treatment providers. This proposed workflow and approach is often referred to as the "screen and refer to nowhere" by the assessment clinicians tasked with this gate-keeping function because while workflows can present as clear and sound on paper, they fail when implemented into a system that is abundant with screeners and gate-keepers (reified by higher reimbursement rates) and impoverished with treatment providers.

Threshold ACEs scores as eligibility criteria mimics the tactics used in for-profit medical gatekeeping and profit-motive systems that not only harm young people with complex vulnerabilities seeking care. It is not only coercive but problematizes families absent any contextualization and consideration of the social determinants of health and structural adversities that increase toxic stress and distress. I strongly recommend that those with power in this decision-making not make similar failures in courage and imagination and NOT require threshold ACEs scores, which is another manifestation of medical necessity, for accessing behavioral health services for children and adolescents. The risks of this approach are widely known, which makes the harms this approach could cause, completely preventative. While I am an advocate for ACEs science and prevention, using this tool in this way is neither recommended by leading scholars nor by the practitioners who work daily in public and nonprofit clinics that serve the behavioral health needs of children and adolescents.

As someone who has served in these gate-keeper and screening roles for public systems, I implore you to hold a more bold and audacious vision for our ability to care for children and young people experiencing distress and mental health challenges. They deserve more stories of healing and less stories of harm. They deserve our rigorous commitment to remove barriers and "wrong doors" and policies that fail to care for and affirm the strengths and the needs of young people while reinforcing narratives of failure for families. We can do so much better by our young people and lead the nation in creating systems that prioritizes and humanizes young people over the needs of our systems.

Jen Leland, LMFT
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Field Director, The School Crisis Recovery & Renewal (SCRR) Project

SAMHSA NCTSI Grantee

Re: Modernizing CBAS model under CalAIM Section 1115 & 1915(b) Waivers

I am writing in support of using the renewal of the 1115 Waiver through CalAIM to apply experience and knowledge accumulated during the Public Health Emergency to **modernize the Medi-Cal funded CBAS model** the following way:

1. **Temporary Alternative Services (TAS)** are an excellent fit for the person-centered approach embedded within CBAS. These services have proven effective and efficient and need to **be adopted as an ongoing feature.**
2. Incorporate **telemedicine** as a way of delivering traditional CBAS services.
3. Considering CBAS centers competencies and experience delivering services to participants doorstep, adopt **Home Health type of services** as a feature.
4. Demographics and the importance of expanding access to non-institutional community-based living for seniors dictate that **the CBAS program must regain the status of a State Benefit.**

My sincere thanks for your attention to my comments.

Best Regards,
Alexander Krul Sr.

We write in support of the California Department of Aging proposal to renew the 1115 Waiver through CalAIM to modernize the Medi-Cal funded CBAS model, incorporating lessons learned during the Public Health Emergency.

In short, our suggestions are as follows:

- 1. Modernize existing CBAS model by permanently Incorporating Temporary Alternative Services (TAS) flexibilities***
- 2. Modernize ways of delivery of traditional CBAS services by incorporating means of telemedicine. Considering our “Health Bus” and doorstep service experience (please see details below), we propose to modernize the CBAS model by adding Home Health services for those who would be discharged if not able to return to congregated setting.***
- 3. We believe it would be highly beneficial for participants and providers if CBAS were to regain a State Benefit Status.***

As we had to establish off-center services, we analyzed telemedicine options that could apply. Here are the creative things we implemented in addition to the regular services:

“Health Bus”. We transformed a few of our buses into mobile Physical Therapy/Nursing stations. Such a bus with a therapist or a nurse onboard visits several participants residences a day, brings each of them on board for services from their doorstep, shows them back to their homes when done. Please see the video below

<https://www.youtube.com/watch?v=NAprEHa5nuA>.

1. Health assessments over Zoom
2. Activity groups over Zoom
3. Social Groups over Zoom
4. Social Groups outdoor meetings for vaccinated participants

The services below turned to be a lifeline during the pandemic and would be essential for the disabled and elderly to continue on.

- Dietary prepared meals
- Produce and essential supply deliveries
- PPE, sanitizing, and hygiene item deliveries
- Regular phone/zoom assessments
- COVID-19 symptoms assessments

Adopting some telemedicine into the CBAS program can add flexibility for very disabled participants who cannot attend the center all scheduled days and prefer to combine congregated and remote services.

We surveyed and evaluated our participants for returning to congregated in-center services. We discovered that at least 12% would not be able to return due to frail health. As per our estimate, at least 58% of these people will not be able to continue living in the community as they depend on nursing/social work case management/visits and on receiving meals prepared according to their dietary orders. The rest, 42%, are at risk to gradually become a burden to their caregivers and may require placement. Remote services, deliveries, and visits we have been providing proved efficient and successful. Participants and caregivers can get a level of support; our

activities and social work departments engage them as scheduled and allow respite to caregivers. On the health side, our specialists regularly guide and educate participants and caregivers and see the participants at their doorstep

Very Respectfully,

Katy Krul



Administrator

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My name is Suzanne Pouransari, Co-owner at Grace ADHC, A CBAS Program. We appreciate the continued inclusion of Community Based Adult Services (CBAS) in the Section 1115 Demonstration Application and notes the expectation of increased enrollment into CBAS over the 5-year period as dual eligible beneficiaries are moved into MLTSS and aligned D-SNPs. We note that there is not enough capacity within the existing center-based structure of CBAS without expansion to underserved and unserved areas. This takes time and start-up funds. But using the lessons learned during the Public Health Emergency, we believe there are solutions to more quickly increase access to person-center care and these solutions, as outlined below, should be included in this next 5-year waiver period to demonstrate innovation and creative use of existing resources, consistent with the goals of the waiver.

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

1) Adopt TAS modalities as an Ongoing Feature: The Temporary Alternative Services (TAS) model has shown how to fully use the expertise and person-centered approach embedded within CBAS by empowering the CBAS MDT navigate outside of the four walls of the facility to “meet people where they are” in their home and community. This has deeply enriched the relationship between the center team and participants, and importantly, the unpaid caregiver and others providing support. CalAIM is an opportunity to demonstrate the durability of this PHE model that has enhanced the ability of the center teams to flexibly navigate within and outside of the center walls in a way that combines intensive care management with the unique benefit of center-based services delivered by an interdisciplinary team. This aligns perfectly with the Enhanced Care Management model envisioned in CalAIM as a separate billable service but could also be built into a “CBAS Plus” model with an enhanced rate.

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

3) Define presumptive eligibility for CBAS to expedite access to needed care: We have learned through TAS that many people who are discharged from a hospital or nursing facility and could benefit from CBAS right away or may need continued recovery and care management prior to being able to attend the center for required services during a 4-hour service day. Individuals who are within 60 days of a nursing home or hospital stay and who meet medical necessity criteria should be presumptively eligible for enrollment in CBAS without delay. The current process for enrolling a person into Medi-Cal managed care (if they are Medi-Cal beneficiaries or dual eligible) and being approved by that Medi-Cal managed care organization (MCO) can stretch into many months. The extended time spent in the enrollment process is not in the best interest of the person or the Medi-Cal system, as these periods of transitions back into the community are critical, as proper care can help prevent re-admission to institutionalized or acute care. The current process has also been a problem during wildfire emergencies when delays in getting approval for CBAS enrollment has delayed lifesaving care and, in some cases, led to preventable

homelessness, nursing home placement or hospitalization. Case studies of these negative impacts of approval delays can be provided as examples.

4) Encourage Enhanced Care Management as a feature of CBAS and CBAS Plus: We would like to see active encouragement of MCOs to contract with CBAS providers for Enhanced Care Management now in order to meet the demand for services when dual eligibles transition to Medi-Cal Managed Care as well as the growing population Medi-Cal only beneficiaries. See also recommendation #1 for building a CBAS Plus model for efficiency.

5) Create a CBAS STCs & SOP Work Group: The ability of DHCS, CDA and the CBAS leadership to work together during the PHE toward a common goal of supporting access to services while ensuring safety of participants and caregivers was exemplary. We would like to offer the expertise of the Vision Team that was first mobilized during the PHE to continue to work with DHCS and CDA to modernize the STCs and SOPs for CBAS. There are obsolete provisions and fresh refinements based on the ten years of experience in managed care should be incorporated to continue to evolve the CBAS program.

6) Transition to State Plan: Federal policy is leading in the direction of prioritizing and expanding access to non-institutional settings in the community. We would like to see CBAS transitioned back to a State Plan Benefit by the end of the next 1115 Waiver demonstration period.

Regards,

Grace ADHC (CBAS)
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suzanne@graceadultcare.com

NOTE: UCSF is a contracted with Alameda County as the skills development lead to support cross-sector learning and sector knowledge development in their Whole Person Care project. The following comments to the proposed CalAIM renewal and amendment application are given through this lens:

- We are disappointed that there is scant mention in the application about cross-training, technical assistance, workforce development, or quality improvement. It is difficult to imagine the integration of the current 1115 waiver initiative activities into 1915 without some acknowledgement and plan on this transition and the needed support to increase and sustain skills of those staff involved in this process.
- We are also concerned that with all of the additional population focus mentioned (e.g., recently released incarcerated) or focus on social determinants of health, there is no mention of the skills development needed for all related entities to successfully work across programs and to successfully engage with consumers. Again, we urge the state to include some focus in this application on strengthening the workforce.
- We recognize that the lack of details in these areas may be a strategy from the state to only talk about the high-level changes and that further details may be worked out in the implementation phase. However, we believe a plan that articulates the expected challenges and planned mitigation strategies would strengthen this application and the state's ability to reach the three CalAIM goals.

Thank you for your consideration of these comments.

Prescott Chow

—

Prescott Chow, MUP

Director

Pacific AIDS Education & Training Center | University of California, San Francisco



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phone: 415.476.6141

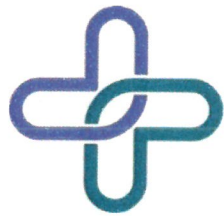
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Mountain Valleys HEALTH CENTERS

May 5, 2021

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:

Mountain Valleys Health Centers (MVHC) writes to object to the incorporation of the Medi-Cal Rx initiative as part of the CalAIM Demonstration. To the extent the CalAIM Demonstration incorporates Medi-Cal Rx into its framework, MVHC 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.

Mountain Valleys Health Centers consists of 7 FQHC's that care for Medi-Cal and uninsured patients in Shasta, Lassen & Siskiyou 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 the utilization of 16 contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows MVHC 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, MVHC annually saves an estimated \$1.5 Million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow MVHC 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, MVHC 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.)

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(530) 999-9030
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Burney Dental Center
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Fax (530) 335-5558

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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.

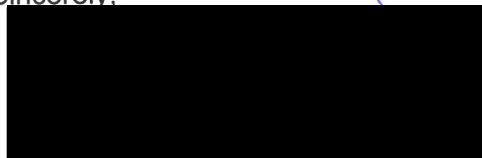
Yet, Medi-Cal Rx will impede our and other FQHCs’ ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which 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 MVHC incorporates by reference into this letter. MVHC 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, Mountain Valleys Health Centers urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS’ consideration. Doing so will enable Mountain Valleys Health Centers and DHCS to “work in partnership to provide individuals access to affordable healthcare, including prescription drugs” as now-Secretary Becerra described.

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

Sincerely,

A large black rectangular redaction box covers the signature area.

Shannon Gerig, CEO
Mountain Valleys Health Centers

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>.

May 6, 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
Submitted via: CalAIMWaiver@dhcs.ca.gov

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Lee and Ms. Font,

Children Now is writing in response to the call from Department of Health Care Services (DHCS) for public comment on the "CalAIM Section 1115 & 1915(b) Waivers" documents, with a particular emphasis on the impact of the CalAIM proposed policies for children and youth. Children Now is a non-partisan, whole-child research, policy development and advocacy organization dedicated to promoting children's health, education, and well-being in California. The organization also leads The Children's Movement of California, a network of more than 4,100 direct service, parent, youth, civil rights, faith-based and community groups dedicated to improving children's well-being.

Medi-Cal managed care authority. We appreciate that DHCS has made the long-term commitment to the Medi-Cal managed care delivery system; however, stronger efforts are needed for DHCS' core responsibility of accountability enforcement and quality oversight. Currently 92% of kids in Medi-Cal are enrolled in a contracted managed care plan for the majority of their health care. DHCS' first-ever *Preventive Services Report* showed an alarmingly low number of children and youth in Medi-Cal managed care are receiving preventive health care check-ups and screenings, and that Black, American Indian or Alaskan Native, Native Hawaiian or other Pacific Islander, and children living in households that speak a language other than English are even less likely to receive crucial preventive services to which they are entitled. Regardless of the legal area of authority from the federal government, accountability of Medi-Cal managed care plans by the state is critical. Numerous state audits have identified major areas with insufficient access to care for children due to DHCS' poor oversight of contracted health plans. The oversight, monitoring, and enforcement actions by DHCS make up the critical foundation from which CalAIM benefits and incentives are built on. Fundamentally, there is a financial disincentive in Medi-Cal managed care, where plans are currently paid with little regard to quality or performance. DHCS must rectify years of poor quality of and access to care for children by using the accountability levers – especially the financial ones – to hold plans accountable for delivering basic care and for meaningful quality improvement.

Capitation and other incentive payments to health plans must be clearly tied to performance and quality. For example, the state should establish capitation payment arrangements using withholds and incentives to encourage plans to improve care for children and youth, and the State should ensure that plans are spending a *minimum* amount on children’s preventive care guaranteed under EPSDT. Further, to facilitate plans in coordinating care, DHCS must do better at oversight and data sharing with other child-serving Medi-Cal programs and delivery systems, such as Medi-Cal Dental, California Children’s Services (CCS), and Child Health and Disability Prevention (CHDP). This is particularly true for the Enhanced Care Management (ECM) benefit, which would effectively coordinate all services, including oral and behavioral care, under EPSDT for child enrollees. The Special Terms and Conditions should require better financing for and monitoring of basic care coordination for children enrolled in managed care, especially the new populations required to mandatorily enroll in managed care under CalAIM (e.g., individuals participating in accelerated enrollment, Child Health and Disability Prevention infant deeming, etc.).

Dental managed care authority and dental fee-for-service. Similar to the accountability and oversight issues with Medi-Cal managed care described above, Medi-Cal Dental also suffers from insufficient oversight and enforcement. Specifically, oversight of the fee-for-service Medi-Cal Dental program needs to be integrated with the physical health side of Medi-Cal, particularly Medi-Cal managed care. Existing state statute (AB 2207 from 2016) requires health plans to make dental referrals for their members, conduct a dental assessment as part of a member’s initial health assessment, and put dental liaisons in place to facilitate access to care. Despite these longstanding requirements, the state has not provided compliance standards or outcome metrics by which to measure these requirements, allowing for far too few children to receive preventive dental care. In addition to ensuring compliance with previous legislation, the State should provide Medi-Cal managed care plans with dental fee-for-service data on a monthly basis to assist plans in facilitating the care coordination of dental services for their members. Currently, managed care plans do not have access to this data and so do not have any way of knowing or tracking the utilization of the dental benefit by their members. There is evidence to show that sharing of dental data with the medical community can yield positive results. In a study of the Los Angeles medical-dental coordination pilot, when dental utilization data was shared with primary care providers, an increase in the utilization of dental visits increase by over 50 percent among children ages 3 to 6. As evidence of the potential for improved systems integration, the CalAIM waiver proposal includes a pilot project at the Health Plan of San Mateo (HPSM) which would “carve in” the historically “carved out” dental benefit. The Special Terms and Conditions of the waiver should require robust outcome metrics and evaluation of the HPSM pilot’s successes and challenges.

Dental Transformation Initiative (DTI). At the end of 2020, DHCS submitted a request to the Centers for Medicare & Medicaid Services to extend the DTI by 12-months, allowing the State sufficient time to begin implementation of the dental proposal within the CalAIM initiative in January 2022. Per previous communications with DHCS, we understand that the department’s

preliminary analysis of funding indicates that DTI funding will run out in June 2021, which will have a detrimental impact on providers and beneficiaries. We look forward to reviewing the results of the final analysis and impact of the budget that DHCS said would be released with the Governor's May Revise, and the department's proposed options to implement CalAIM to avoid gaps in benefits and provider incentive payments.

Specialty Mental Health Services (SMHS) criteria for enrollees under 21. We are very pleased that DHCS has proposed adding the experience of trauma as an explicit pathway of eligibility for specialty mental health services (SMHS) and that children accessing SMHS based on criteria 1 will not need a mental health diagnosis in order to receive supports and services to address their trauma. Nevertheless, key aspects of criteria 1 need further clarification. Criteria 1 allows for eligibility if *"...the beneficiary is at high risk for a future mental health disorder due to experience of trauma, evidenced by: scoring in the high-risk range on a DHCS approved trauma screening tool, or involvement in the child welfare system, or experience of homelessness."* While Children Now strongly supports the proposal to provide automatic eligibility for SMHS for children involved in the child welfare system and/or youth experiencing homelessness, we recommend clarifying that the reference to "children involved in the child welfare system" includes children currently or formerly involved in the child welfare system. Additionally, for children who are not involved in child welfare or experiencing homelessness, we are very concerned that there is insufficient information on what "scoring in the high-risk range on a DHCS approved trauma screening tool" might look like, and this is a critical component of the decision-making process. We believe DHCS should have to share this tool and discuss and develop scoring guidelines with stakeholders before CalAIM is approved.

Criteria 2 as proposed is over complicated, lacks specificity for key definitions like "significant impairment," and is likely to lead to confusion. While not the Department's intent, the inclusion of on the phrase "impairment level" is likely to lead to some children being wrongfully denied SMHS as has occurred in the past. Instead, we recommend the following language be adopted:

Criteria 2A: The beneficiary must have at least one of the following:

- *A reasonable probability of significant deterioration in an important area of life functioning, or*
- *A reasonable probability a child will not progress developmentally as appropriate;*
- *Requires mental health services that are not included within the mental health; benefits that managed care plans are required to provide.*

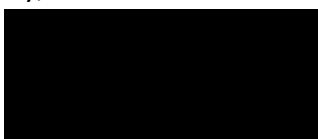
We believe the above options will allow for a broad-based understanding by providers on how to determine need. Additionally, under criteria 2 when services are provided based on a suspected mental disorder the DHCS proposal does not define if a diagnosis must be ultimately given and if so what timeframe it must be given within. We recommend that a mental health diagnosis not be required for these children to continue receiving services unless clearly indicated and clinically necessary.

Drug Medi-Cal Organized Delivery System for Enrollees Under 21. We appreciate the proposal’s inclusion of the American Society of Addiction Medicine’s 0.5 within the Drug Medi-Cal Waiver as we believe prevention is an important piece of the continuum of care. However, we would like to see more specificity on how youth can receive treatment under Drug Medi-Cal. In California, as many as 60% to 75% of adolescents with substance use disorders are estimated to have a co-occurring mental illness. In some cases, substance use may begin as a strategy for self-medicating to manage psychiatric symptoms. Given the need, we are concerned the proposal does not address how the CalAIM changes will provide for the needs of youth. While youth are guaranteed access to substance abuse treatment through the EPSDT benefit, data shows many have difficulty accessing these services. Currently, the American Society of Addiction Medicine’s criteria, which outlines how to uniquely support youth in recovery, is included in the DMC-ODS pilot. As such, we see an opportunity for the DMC-ODS pilot to expand services for young people. However, DMC-ODS is not statewide. DHCS should outline how it will ensure EPSDT-SUD services are available statewide through CalAIM.

Special Programs for Current and Former Foster Youth. We appreciate and support the State’s proposal to seek renewal of the waiver to provide ongoing Medi-Cal until age 26 for out-of-state former foster youth and would welcome additional details on the clarifications being sought related to the Family Urgent Response System (FURS) and the Family First Prevention Services Act (FFPSA).

The state should take the CalAIM waiver opportunity to systemically and sustainably improve Medi-Cal for children and youth, especially after years of poor levels of care and persistent racial and linguistic disparities. Please contact Mike Odeh, Director of Health Policy, at modeh@childrennow.org if you have any questions.

Sincerely,



Ted Lempert
President,
Children Now



May 6, 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
Via Electronic Mail: CalAIMWaiver@dhcs.ca.gov

RE: CalAIM Section 1115 & 1915(b) Waivers

To Whom It May Concern:

In response to your call for public comment, Anthem Blue Cross is pleased to provide feedback and input relating to the following documents:

- Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration
- California Advancing and Innovating Medi-Cal (CalAIM) 1915(b) Waiver Overview April 2021
- Proposed CalAIM Section 1115 Demonstration and Section 1915(B) Waiver Amendment and Renewal Applications

We support and applaud the Department of Health Care Services' (DHCS') ambitious reforms to improve the quality of life and health outcomes of Medi-Cal beneficiaries through CalAIM.

We know that successful programs begin with successful partnerships, and Anthem Blue Cross is fully prepared to support DHCS in its implementation of CalAIM.

Sincerely,



Interim President, CA Medicaid Health Plan
Anthem Blue Cross

1. Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration

Key Section 1115 demonstration initiatives in order to meet the physical, behavioral, developmental, long term services and supports (LTSS), oral health, and health-related social needs of all Medi-Cal beneficiaries

Associated Topic	Section and Page Number	Comment/Question
Services for Justice-Involved Populations 30 Days Pre-Release (effective January 1, 2023) – To ensure continuity of health coverage and care for justice-involved populations—who experience disproportionately higher rates of physical and behavioral health diagnoses—DHCS requests authority to provide targeted Medi-Cal services to eligible justice-involved populations 30 days pre-release. These Medi-Cal services include ECM and limited community-based clinical consultation services provided via telehealth or e-consultation and a 30-day supply of medication for use post-release into the community.	Section 3 – Medi-Cal Five-Year Renewal Request, Services for Justice-Involved Populations 30 Days Pre-Release, Page 19	<p>We suggest expediting the relationship with the Medi-Cal Managed Care Plan (MCP) to prevent individuals from falling through the cracks during the 30- to 60-day period when Medi-Cal eligibility is re-established.</p> <p>In addition, please clarify if this provision includes early enrollment or reinstatement of Medi-Cal benefits, as well as early assignment and hand off to an MCP. To be most effective, we believe it is imperative for DHCS to implement data changes and to facilitate partnerships with jail/prison systems and MCPs.</p>
As discussed in Section 5 below, the independent evaluation of the GPP found that the program has been successful in rewarding and incentivizing value-based, cost-effective care rather than volume of services. For this reason, the State seeks federal approval to continue the GPP using Medicaid DSH and SNCP dollars through the five-year renewal period (ending December 31, 2026).	Section 3.1 – The Global Payment Program, Renewal Request, Page 21	Please provide additional detail regarding which entity determines, facilitates, and monitors the payments.
<p>DHCS is currently negotiating program modifications to take effect in 2021. Pending CMS approval of these modifications, DHCS seeks to continue the following programmatic features using appropriate federal authorities:</p> <ul style="list-style-type: none"> Removal of the limitation on the number of residential treatment episodes that can be reimbursed in a one-year period Clarification of criteria for services requirements (including determination by a licensed provider and treatment post-incarceration) and reimbursement for nonresidential services prior to diagnosis 	Section 3.2 – DMC-ODS, Proposed Improvements to DMC-ODS DHCS Seeks to Establish in 2021, Page 24	To support optimal ECM/In Lieu of Services implementation, we recommend that DHCS play an active role in facilitating communication and data exchange between MCPs and county Substance Use Disorder (SUD) providers. Data privacy is a critical concern related to data sharing, and we recommend that DHCS identifies and addresses any legal impediments towards the exchange of SUD-related information between organizations.

Associated Topic	Section and Page Number	Comment/Question
<ul style="list-style-type: none"> ▪ Clarification of the allowable components of recovery services, describing when and how beneficiaries, including justice-involved individuals, may access recovery services and the availability of recovery services to individuals receiving MAT ▪ Requirement for counties to mandate that all DMC-ODS providers demonstrate they either directly offer or have effective referral mechanisms for MAT 		
<p>In this renewal application, the State seeks authority to extend this important coverage initiative to continue to provide necessary health benefits to low-income pregnant women.</p>	<p>Section 3.4 – Low-Income Pregnant Women, Renewal Request, Page 33</p>	<p>We support extension of this coverage initiative and suggest extending coverage to 12 months post-delivery. Increasingly, data indicate the value of this 12-month post-delivery coverage, including its impact in reducing health disparities.</p>
<p>DHCS is mandating all counties implement an inmate pre-release Medi-Cal application process by January 1, 2023, to ensure all eligible inmates in county jails, including those who are not in suspended status, receive timely access to Medi-Cal services upon release from incarceration.</p>	<p>Section 3.7 – Services for Justice-Involved Populations 30-Days Pre-Release, California Efforts to Support Justice-Involved Populations, Page 37</p>	<p>We recommend a complementary MCP auto assignment process upon enrollment for a smoother transition into MCP services and supports (ECM, for example). We suggest flagging newly released beneficiaries within the 834 enrollment file to make certain the MCP can initiate ECM services immediately upon enrollment. Further, we recommend that DHCS extend the pre-release Medi-Cal application process to eligible justice-involved detainees, including state and federal detainees and juvenile detainees.</p>
<p>California is seeking to implement Medi-Cal coverage 30 days pre-release by January 1, 2023. Recognizing the need for system and operational changes, the State may consider a phased rollout, commencing first with State prisons and counties that elect to opt in to the first phase.</p>	<p>Section 3.7 – Services for Justice-Involved Populations 30-Days Pre-Release, Demonstration Implementation, Page 39</p>	<p>Please clarify if the proposed 2023 implementation of ECM for jail re-entry populations can be revisited to potentially align with this multi-phased approach. MCPs will face challenges in providing ECM services if the 30 days pre-release demonstration is not implemented.</p>
<p>Projected expenditures for CBAS for the period DY 18 through DY 22</p>	<p>Section 7 – Demonstration Financing and Budget Neutrality, Table 10: Projected Expenditures CalAIM</p>	<p>We believe the projected CBAS expenditures for DY 18 through DY 22 do not align with CBAS expenditure trends over the past eight years. We suggest additional review of these projections.</p>

Associated Topic	Section and Page Number	Comment/Question
	Demonstration (Row 4), Page 72	
Projections assume mandatory enrollment of dually eligible beneficiaries statewide as of 1/1/23.	Section 7 – Demonstration Financing and Budget Neutrality, Table 10: Projected Expenditures CalAIM Demonstration (Footnote 2), Page 73	We would like to better understand the basis for these projections. Currently, dually eligible beneficiaries must already enroll with managed care to receive CBAS. If the projections are accurate, we are concerned about capacity. To assure long-term sustainability of the CBAS model and capacity to serve an expanded population, we recommend connecting CBAS to ECM or other alternative models.

2. California Advancing and Innovating Medi-Cal (CalAIM) 1915(b) Waiver Overview April 2021

Framework encompassing broad-based delivery system, program, and payment reform across the Medi-Cal program

Associated Topic	Section and Page Number	Comment/Question
DHCS is also proposing to transition both components of CCI (i.e., Cal MediConnect and mandatory MCMC enrollment and LTSS carve-in) into a statewide aligned enrollment structure, in which dual eligible beneficiaries will enroll in a Medi-Cal MCP and have the option to enroll in a dual eligible special needs plan (D-SNP) operated by the same parent company to allow for greater integration and coordination of care. This will be an important step to achieving integration of long-term services and supports (LTSS) into MCMC for dual eligible beneficiaries in all counties. DHCS plans to begin the transition to aligned enrollment in the seven CCI counties starting in 2023, and will expand this approach statewide by 2025.	Medi-Cal Managed Care, Populations, Page 6	To truly integrate LTSS for dual eligibility beneficiaries, a significant percentage of beneficiaries must be enrolled in a D-SNP under this model. What efforts will DHCS take, or allow MCPs to take, to outreach to and engage beneficiaries to ensure adequate enrollment?
Benefits. Dental services are currently provided through Dental MC plans in two California counties—Sacramento and Los Angeles. In the remaining counties, dental services are available through FFS. While the managed care authority for Dental MC will change, no programmatic changes to Dental MC will be requested in the CalAIM 1915(b) waiver.	Dental Managed Care, Benefits, Page 7	Currently, Dental MC is offered by a limited number of plans, creating challenges for MCPs in effectively providing ECM. For this reason, we recommend that Dental MC be periodically evaluated for effectiveness and clinical outcomes to assist MCPs in evaluating care coordination efforts and identifying gaps in care.

Associated Topic	Section and Page Number	Comment/Question
<p>SMHS are currently provided by 56 county MHPs covering all 58 counties throughout the state, including two joint-county arrangements in Sutter/Yuba and Placer/Sierra. The MHPs are required to provide or arrange for the provision of SMHS to beneficiaries in their counties who meet criteria for services, consistent with beneficiaries’ mental health treatment needs and goals.</p>	<p>Specialty Mental Health Services, Page 8</p>	<p>We recommend adding language in the proposal that requires the MHPs to coordinate and share additional data with the MCPs. This will help ensure a more integrated approach to better serve the population.</p>
<p>Benefits. MHPs will continue to provide the following specialty mental health services in the consolidated 1915(b) waiver:</p> <ul style="list-style-type: none"> Intensive Care Coordination (for beneficiaries under age 21) 	<p>Specialty Mental Health Services, Benefits, Page 9</p>	<p>Children in child welfare/foster care are a target group for ECM, and these children are also eligible for Intensive Care Coordination (ICC) under the Specialty Mental Health Services provided by county MHPs. Both ECM and ICC services have components that significantly overlap and appear to be somewhat duplicative. This includes comprehensive assessment and care planning within the context of multi-system collaboration, engagement of family supports, and linkages to services in and outside of the healthcare system. We request clarification on whether DHCS intends to exempt children in ICC from ECM, or otherwise how the State would recommend that these services be coordinated to avoid duplication and overlap.</p>
<p>Special Programs for Foster Children and Caregivers. As part of the CalAIM 1915(b) waiver, DHCS will also clarify the authority for county mobile response and stabilization teams to provide SMHS services through the Family Urgent Response System (FURS) to current and former foster children and youth and their caregivers. In addition, DHCS will clarify authority for SMHS delivered as part of the Family First Prevention Services Act (FFPSA) requirements for services to children, youth, and families in the child welfare system, including certain FFPSA programs that are limited to counties that opt to provide them.</p>	<p>Specialty Mental Health Services, Special Programs for Foster Children and Caregivers, Page 10</p>	<p>We request clarification on the process by which findings from the Foster Care Model of Care Workgroup will be incorporated into the waiver process. We believe recommendations from this workgroup have implications related to a potential shift to a regional managed care model.</p>
<p>Medi-Cal has long provided coverage of certain SUD treatment benefits through its DMC program, which is authorized through California’s Medicaid State Plan and administered by counties. To improve the SUD delivery system and expand services, the State created the DMC-ODS program under its Medi-Cal 2020</p>	<p>Drug Medi-Cal Organized Delivery System, Page 10</p>	<p>We recommend including language in the proposal that requires the DMC providers to coordinate and share additional data with the MCPs. This will ensure a more integrated approach to better serve the population.</p>

Associated Topic	Section and Page Number	Comment/Question
<p>1115 demonstration authority to expand access to treatment, standardize service delivery across participating counties, and provide a broader continuum of high-quality, evidence-based SUD treatment services.</p>		
<p>In tandem with the consolidated 1915(b) waiver, DHCS will update the DMC-ODS criteria for services to clarify that individuals leaving incarceration are eligible to receive DMC-ODS services if they had at least one SUD diagnosis prior to being incarcerated or during incarceration. The consolidated 1915(b) waiver will also clarify that DMC-ODS assessment and treatment services are reimbursable prior to diagnosis in nonresidential settings (similar to SMHS).</p>	<p>Drug Medi-Cal Organized Delivery System, Population, Page 11</p>	<p>Individuals with an SUD diagnosis and leaving incarceration require timely, seamless care coordination. We recommend that DHCS develops systems to assure individual-level communication between transition coordinators within the correctional setting and MCPs, such that beneficiaries can be engaged in appropriate services and supports immediately upon discharge. Further, we recommend this process be applied to eligible individuals exiting county jails, Department of Corrections facilities, State juvenile facilities, and federal prisons.</p>
<p>For each of the MCMC delivery systems encompassed in the 1915(b) waiver, DHCS will document and maintain data, and report results in these focus areas to CMS. Many of the monitoring activities are tied to existing Medicaid managed care requirements, such as network adequacy validation, programmatic reporting, quality strategy implementation, quality assurance and performance improvement program reviews, and annual external reviews conducted by a qualified organization independent from DHCS and Medi-Cal MCPs.</p>	<p>Federal Authorities Requested Under the 1915(b) Waiver, Monitoring Approach, Page 15</p>	<p>We suggest describing in further detail what, if any, changes are expected to these existing reporting requirements.</p>
<p>MCMC – Mandatory Enrollment of Additional Aid Code Groups and Populations</p> <ul style="list-style-type: none"> ▪ Trafficking and Crime Victims Assistance Program (except beneficiaries with a share of cost) ▪ Individuals participating in accelerated enrollment ▪ Child Health and Disability Prevention infant deeming ▪ Pregnancy-related Medi-Cal (pregnant women only, 138–213 percent FPL citizen/lawfully present) ▪ American Indians and Alaska Natives in non-COHS counties ▪ Beneficiaries with other health care coverage in non-COHS counties 	<p>Attachment 1: Overview of CalAIM 1915(b) Waiver Programs, Program Modification / Improvement for 1915(b) Delivery System (table), Page 18</p>	<p>We request county-level estimates of individuals who will be impacted.</p>

Associated Topic	Section and Page Number	Comment/Question
<ul style="list-style-type: none"> Beneficiaries living in rural zip codes in non-COHS counties 		
<p>MCMC – Mandatory Enrollment of Dual Eligibles All dual and nondual individuals eligible for long-term care services All partial and full dual aid code groups, except share of cost or restricted scope</p>	Attachment 1: Overview of CalAIM 1915(b) Waiver Programs, Program Modification / Improvement for 1915(b) Delivery System (table), Page 19	We request county-level estimates of individuals who will be impacted.
<ul style="list-style-type: none"> Ensure beneficiaries are assessed and provided treatment regardless of the delivery system where they initially request treatment Clarify that beneficiaries may receive nonduplicative, coordinated services in multiple delivery systems 	Attachment 2: Overview of CalAIM Behavioral Health Policies, Summary of Policy Changes (table), Page 20	We request additional detail regarding how DHCS will assist MCPs and other providers in coordinating care across multiple delivery systems. In particular, we are interested in hearing more about the processes DHCS will use to provide MCPs, counties, and other provider organizations with information regarding services received by beneficiaries. The availability of this information is critical in delivering coordinated, appropriate, and non-duplicative services by MCPs and other providers across delivery systems.
<ul style="list-style-type: none"> Develop a standardized transition tool for MHPs and MCPs to use when a beneficiary’s condition changes and they would be better served in the other delivery system 	Attachment 2: Overview of CalAIM Behavioral Health Policies, Summary of Policy Changes (table), Page 21	Our experience is that beneficiary support needs fluctuate between severe and mild/moderate. Rather than repetitively using the transition tool, we suggest building more adequate coordination and CHR/HIE utilization to deliver ongoing co-management.
Criteria 1: The beneficiary has a condition that puts the child or youth at high risk for a mental health disorder due to experiencing trauma, evidenced by any of the following: scoring in the high-risk range on a DHCS-approved trauma screening tool, or involvement in the child welfare system, or experience of homelessness.	Detailed CalAIM Behavioral Health Policy Descriptions, County Mental Health Plan Responsibilities, Criteria 1, Page 25	We request clarification as to whether this criterion means that every child in child welfare/foster care and enrolled in managed care will be receiving mental health services through the county MHPs.

Associated Topic	Section and Page Number	Comment/Question
If the patient has an SUD, the screening tool shall be used to refer to the appropriate SUD treatment system.	Detailed CalAIM Behavioral Health Policy Descriptions, 4. Standardized statewide screening tool, Page 28	We request clarification as to whether sharing a beneficiary's screening tool results with the treating provider will require consent from the beneficiary.
To ensure all county inmates receive timely access to Medi-Cal services upon release from incarceration, DHCS proposes that California mandate the county inmate pre-release Medi-Cal application process by January 2023. Additionally, DHCS proposes mandating that jails and county juvenile facilities implement a process for facilitated referral and linkage from county institution release to county specialty mental health, Drug Medi-Cal, DMC-ODS, and Medi-Cal MCPs when the inmate was receiving behavioral health services while incarcerated, to allow for continuation of behavioral health treatment in the community.	Detailed CalAIM Behavioral Health Policy Descriptions, 7. Facilitated referral and linkage from criminal justice to behavioral health, Page 29	We suggest expediting the relationship with the MCP, to prevent individuals from falling through the cracks during the 30- to 60-day period when Medi-Cal eligibility is re-established.

3. Proposed CalAIM Section 1115 Demonstration and Section 1915(B) Waiver Amendment and Renewal Applications

Notice of intent to submit to 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

Associated Topic	Section and Page Number	Comment/Question
Global Payment Program (GPP) – The GPP provides a pool of funding for value-based payments to participating designated public hospital systems providing care for California's uninsured by allocating federal Disproportionate Share Hospital (DSH) and uncompensated care (UCC) funding. These payments support designated public hospital systems' efforts to provide health care services for the uninsured while promoting the delivery of more cost-effective and higher-value care.	A. Description, Global Payment Program, Page 6	We request clarification as to whether GPP includes the sunseting PRIME and existing QIP program. If so, we request that DHCS consider consolidating these programs into one program for hospitals.

<p>Community-Based Adult Services (CBAS) – CBAS offers services to eligible older adults and adults with disabilities in an outpatient facility-based setting to restore or maintain their optimal capacity for self-care and to delay or prevent institutionalization. California is requesting technical changes as part of this Section 1115 demonstration renewal to align with MCP contract changes, Medi-Cal Provider Manual updates, and provider enrollment requirements, and to clarify both eligibility and medical necessity criteria.</p>	<p>A. Description, Community-Based Adult Services (CBAS), Page 7</p>	<p>We request additional details regarding proposed MCP contract changes related to CBAS. For instance, is DHCS considering changes in contract requirements that provide MCPs greater program flexibility or are such changes creating additional program stringency?</p>
<p>Providing Access and Transforming Health (PATH) Supports – As California implements the CalAIM initiative statewide, the State is requesting expenditure authority to support services and capacity building, including payments for supports, infrastructure, interventions, and services to complement the array of care that will be authorized in the consolidated 1915(b) waiver delivery system. This expenditure authority will support California’s efforts to shift delivery systems in furtherance of its objectives to advance the coordination and delivery of quality care for all Medi-Cal beneficiaries. California also is requesting federal funding of DSHPs to support CalAIM implementation, including efforts to strengthen the effectiveness of Medi-Cal in addressing the significant gaps in health outcomes across beneficiaries based on race and ethnicity.</p>	<p>IV. Summary of New Medi-Cal Program Features to Be Included in the CalAIM Section 1115 Demonstration, Providing Access and Transforming Health (PATH) Supports, Page 8</p>	<p>We request clarification as to whether PATH provides an MCP incentive structure or exists as a separate and additional pool of funds. In addition, we request detail about any overlap or intersection between these potential approaches.</p>



Community Health Centers

- Administration, Finance, and Human Resources
1275 Eighth Street
Arcata, CA 95521
(707) 826-8633
- Administration
670 Ninth Street, Suite 203
Arcata, CA 95521
(707) 826-8633
- Billing
1385 Eighth Street
Arcata, CA 95521
(707) 826-8642
- Burre Dental Center
Mobile Dental Services
959 Myrtle Avenue
Eureka, CA 95501
- Del Norte Community Health Center
550 East Washington Boulevard
Crescent City, CA 95531
- Eureka Community Health & Wellness Center
2200 Tydd Street
Eureka, CA 95501
- Ferndale Community Health Center
638 Main Street (PO Box 1157)
Ferndale, CA 95536
- Fortuna Community Health Center
3750 Rohnerville Road
Fortuna, CA 95540
- Humboldt Open Door Clinic
770 Tenth Street
Arcata, CA 95521
- McKinleyville Community Health Center
1644 Central Avenue
McKinleyville, CA 95519
- Mobile Health Services/ Telehealth & Visiting Specialists Center
2426 Buhne Street
Eureka, CA 95501
- NorthCountry Clinic
785 18th Street
Arcata, CA 95521
- NorthCountry Prenatal Services
3800 Janes Road, Suite 101
Arcata, CA 95521
- Redwood Community Health Center
2350 Buhne Street
Eureka, CA 95501
- Willow Creek Community Health Center
38883 Highway 299 (PO Box 726)
Willow Creek, CA 95573
- Member Services
550 E Washington Blvd, Suite 100
Crescent City, CA 95531

963 Myrtle Ave
Eureka, CA 95501

May 5th, 2021

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:

Open Door Community Health Centers (ODCHC) 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, ODCHC 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.

ODCHC is an FQHC that cares for Medi-Cal and uninsured patients in Humboldt and Del Norte. 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 a network of 24 independent and chain pharmacies

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows ODCHC 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, ODCHC annually saves an estimated sixteen million dollars through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow ODCHC 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, ODCHC 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.

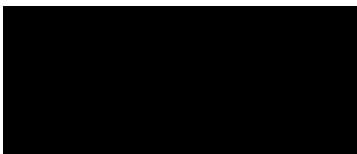
Yet, Medi-Cal Rx will impede our and other FQHCs’ ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which 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 ODHC incorporates by reference into this letter. ODHC 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, ODHC 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 ODHC 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, ODHC looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,



Tory Starr, MSN, PHN, RN
Chief Executive Officer
Open Door Community Health Centers



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>.

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	Hill Country Health & Wellness Center	San Ysidro Health
Clinicas de Salud del Pueblo	Imperial Beach Community Clinic	Shasta Community Health Center
Community Health Centers of the Central Coast	La Maestra Family Clinic	South of Market Health Center
Desert AIDS Project	MCHC Health Centers	TrueCare
Family Health Centers of San Diego	Mission Area Health Associates	United Health Centers of the San Joaquin Valley
Gardner Family Health Network	Omni Family Health	Vista Community Clinic
Golden Valley Health Centers	Open Door Community Health Centers	WellSpace Health
HealthRIGHT 360	Ravenswood Family Health Network	Central California Partnership for Health (Affiliate Support Organization)
	San Francisco Community Health Center	

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Teresa DeCaro, Acting Director
April 16, 2021
Page 2

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

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 Waiver¹

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 care². 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 them⁴. 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

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 fund⁶. 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. 14⁷. 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 dispensing 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 Notice⁸. However, the state’s Legislative Analyst’s office explicitly stated that Medi-Cal Rx would directly affect FQHC funding and patient care coordination⁹. 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 Rx¹⁰. 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 dollars¹¹. 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 billion¹². 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

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/mceestimates/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 years¹⁴. 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
PARTNER
DIRECT DIAL (916) 491-3024
DIRECT FAX (916) 491-3079
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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**.

Judith Cash, Director
March 18, 2021
Page 3

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
<u>Audiological Services</u>	<u>Audiology Services</u>	<u>Audiological services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
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 ⁷⁶
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)	<u>Service is not covered under the State Plan EPSDT</u>	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.	<u>X</u>	<u>X</u>	<u>X⁹ X⁶X⁴</u>	<u>X</u>	<u>X</u>	<u>X</u>

**Attachment N
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Certified Family nurse-Nurse practitioner-Prac titioner	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
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**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
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	<u>EPSDT</u>	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)	<u>EPSDT</u>	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

**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
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)		<p>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.</p> <p>CBAS Unbundled Services: Component parts of CBAS center services delivered outside of centers, under certain conditions, as specified in paragraph 95.</p>	X	X	X	<u>X</u>	<u>X</u>	<u>X</u>
Comprehensive Perinatal Services	Extended Services for Pregnant Women-Pregnancy Related and Postpartum Services	Comprehensive perinatal services means obstetrical, psychosocial, nutrition, and health education services, and related case coordination provided by or under the personal supervision of a physician during pregnancy and 60 days following delivery.	X	X	X	X	X	X

**Attachment N
Capitated Benefits Provided in Managed Care**

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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 <u>administered in-office</u> , 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 <u>EPSDT Supplemental Services</u>	EPSDT	<u>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.</u> Preliminary evaluation to help identify potential health issues.	X²⁶	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷
Erectile Sexual Dysfunction Drugs		FDA-approved drugs that are may be prescribed for a male <u>or female sexual dysfunction are non-benefits of the program.</u> patient experiences an inability or difficulty getting or keeping an erection as a result of a physical problem.						

**Attachment N
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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 ^B	X ^B	X ^B	X ^B	X ^B	X ^B
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

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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.	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷
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

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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

**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
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			

**Attachment N
Capitated Benefits Provided in Managed Care**

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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.	<u>X</u>	<u>X</u>	X	<u>X</u>	<u>X</u>	<u>X</u>
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 <u>contract</u> .	X	X	X	X	X	X

**Attachment N
Capitated Benefits Provided in Managed Care**

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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

**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 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

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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

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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

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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.						

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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	X⁵ X^{3,965}	X⁵ X^{3,596}	X ⁵³	X⁵ X^{3,5}	X⁵ X^{3,5}	X⁵ 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	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>

**Attachment N
Capitated Benefits Provided in Managed Care**

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		<u>beneficiaries people who do not have another way to get to their appointment.</u>						
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	<p>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:</p> <ul style="list-style-type: none"> • 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**

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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

**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
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 ^{9/14} X ^{65/14}	X ^{9/14} X ^{65/14}	X ^{9/14} X ^{65/14}			
Pharmaceutical Services and Prescribed Drugs <u>(effective Jan 1 – Mar 31, 2024)</u> 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
<u>Pharmaceutical Services and Prescribed Drugs (effective Apr 1, 2021 onward)</u>	<u>Pharmaceutical Services and Prescribed Drugs</u>	<p><u>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.</u></p> <p><u>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).</u></p> <p>Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and</p>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>

**Attachment N
Capitated Benefits Provided in Managed Care**

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		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 <u>the same</u> prior authorization <u>procedures that govern physicians</u> , 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.	X⁴	X⁴	X⁴	X⁴	X⁴	X⁴
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 Orthotic 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, 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	X⁸	X	X	X
Rehabilitation Center Outpatient Services	Rehabilitative Services	A facility providing therapy and training for rehabilitation <u>on an outpatient basis</u> . 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

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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 equipment and drugs.	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ 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 ⁷	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 ⁷⁶
Specialty Mental Health 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

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<u>Speech Pathology</u>	<u>Speech Pathology</u>	<u>Speech pathology services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
State Supported Services		State funded abortion services that are provided through a secondary contract.	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
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 <u>and</u> Services-	Targeted Case Management	<u>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.</u> 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						

Attachment N
Capitated Benefits Provided in Managed Care

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		<p>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.</p>						
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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 GenCal Health.~~

⁴ ~~Not covered by GenCal~~ Covered by GenCal 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.~~

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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).

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

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

~~⁹⁻⁶⁵Services 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.~~

~~¹⁰⁻⁷⁶Benefit coverage is limited to only beneficiaries under 21 years of age for services rendered pursuant to EPSDT program requirements.~~

~~¹¹⁻⁸⁻⁷Health 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.~~

Attachment N

Capitated Benefits Provided in Managed Care

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⁸The 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.

⁹California 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 sender name and address]

[Redacted]

[Redacted]

Attachment N Updates ...
119 KB

Attachment N Updates ...
104 KB

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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

[REDACTED]

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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.

*****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

CONFIDENTIALITY NOTICE: This e-mail and any attachments may contain information which is confidential, sensitive, privileged, proprietary or otherwise protected by law. The information is solely intended for the named recipients, other authorized individuals, or a person responsible for delivering it to the authorized recipients. If you are not an authorized recipient of this message, you are not permitted to read, print, retain, copy or disseminate this message or any part of it. If you have received this e-mail in error, please notify the sender immediately by return e-mail and delete it from your e-mail inbox, including your deleted items folder.

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.



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

1 HANSON BRIDGETT LLP
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9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

15
16 COMMUNITY HEALTH CENTER
ALLIANCE FOR PATIENT ACCESS, et
17 al.,

18 Plaintiffs,

19 v.

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

22 Defendants.
23

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

24
25 I, Francisco Castillon, declare as follows:

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

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

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

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

12 4. In order to comply with applicable State and Federal law relating to the
13 340B program OFH has registered each of our FQHC sites that dispenses drugs to Medi-
14 Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B
15 drugs to our Medi-Cal patients.

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

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

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

27 ///

28 ///

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

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

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

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

22 12. If the Medi-Cal Rx Transition became effective on April 1, 2021,
23 approximately seventy percent of our prescriptions would be filled through Medi-Cal's
24 340B-specific fee-for-service reimbursement schedule. This will require changes to our
25 current operations, which may include discontinuing home delivery of drugs to those
26 unable to come to the clinic for health reasons or due to a lack of transportation.
27 Additionally, we would need to discontinue stocking of more expensive medications.

28 ///

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

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

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

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

1 provided primary care services to 131,449 unduplicated patients, and had 588,936
2 patient visits (encounters). The distribution of OFH patients as a percentage of poverty
3 guidelines is 62,160 patients (47.29%) at 100 percent and below the federal poverty
4 level; 10,102 patients (7.69%) at 101 to 150 percent of the federal poverty level; 4,009
5 patients (3.05%) at 151 to 200 percent of the federal poverty level; 2,433 patients
6 (1.85%) at over 200 percent of the federal poverty level; and 52,745 patients (40.13%)
7 whose percent of the federal poverty level is unknown.

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

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

14 19. As reported on our UDS report, with respect to OFH visits involving patients
15 with two or more diseases/diagnoses, the most common diseases/diagnoses involved
16 were: Diabetes Mellitus = 37,494 visits, Overweight and Obesity = 48,295, Hypertension
17 = 52,168, and Heart Disease = 4,747. In addition, the most common visits provided for
18 mental health conditions and substance disorders were: anxiety disorder/PTSD = 37,001,
19 depression and mood disorders = 39,324, and other mental disorders (excluding drug or
20 alcohol dependence) = 22,011.

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

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

7 21. OFH's current 340B prescription drug program includes five (5) onsite and
 8 eighty (80) contract pharmacy sites. From January 1, 2020 through September 30, 2020,
 9 OFH's in-house pharmacies filled 228,791 prescriptions, 26,861 of which were
 10 prescriptions filled for uninsured patients. OFH's 80 contract pharmacies filled nearly
 11 10,000 prescriptions, of which over 10 percent were dispensed for uninsured patients.

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

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

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

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

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

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

8 25. OFH estimates 340B savings generated from our pharmacies through the
9 340B Drug Pricing Program account for about 20 percent of our direct patient care
10 staffing expenses.

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

26 ///

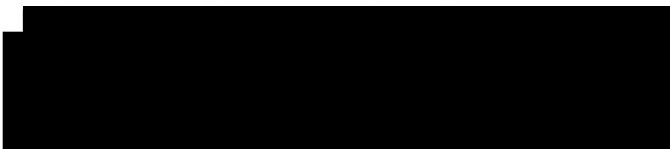
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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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

A large black rectangular redaction box covers the signature area of the document.

Francisco Castillon

Exhibit C
to letter dated 4/16/2021

1 HANSON BRIDGETT LLP
KATHRYN E. DOI, SBN 121979
2 ANDREW W. STROUD, SBN 126475
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9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12

13

UNITED STATES DISTRICT COURT

14

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

15

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

18

Plaintiffs,

19

v.

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

22

Defendants.

23

24

25 I, C. Dean Germano, declare as follows:

26

1. I am the Chief Executive Officer ("CEO") of Shasta Community Health

27

Center ("SCHC") and have been in this position since 1992. I am a past Board President

28

of the California Primary Care Association ("CPCA") and am currently Board Emeritus

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

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

14 2. As CEO of SCHC, I am responsible for overseeing care to 40,000
15 unduplicated patients, providing over 130,000 visits a year in a multi-specialty type
16 practice that includes mental health and dental. Over 92% of SCHC's patients live below
17 200% of the federal poverty line. I also have oversight of our 340B Program. For many
18 years, the savings that SCHC has retained through the discounted drug purchase prices
19 available through the 340B program has been used to benefit our patients through such
20 things as the passing of the 340B price to our uninsured and underinsured patients,
21 allowing us to charge many sliding fee patients no more than \$10 for prescriptions at our
22 contract pharmacies, and providing services such as transportation assistance, covering
23 a significant portion of lab costs for sliding fee patients, and covering patient education
24 services and gap funding for departments that are not profitable, such as telemedicine.
25 In 2019, SCHC's 340B Medi-Cal savings totaled \$1.79 million. The Medi-Cal transition to
26 managed care would result in a loss of these savings and would force SCHC to make
27 cuts to these programs that will have a negative impact on patient care and service to our
28 community.

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

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

12 5. In connection with establishing the SPP, in the fall of 2019, the Department
13 and CPCA asked community health centers to report their projected loss of 340B savings
14 to the State. According to CPCA, 109 community health centers submitted data to the
15 State and 91 submitted data to CPCA and the State. The total amount of lost savings
16 reported by the community health centers that responded to the data request was
17 \$105 million. CPCA staff and the CPCA board also appointed a “Solutions Team” to
18 work with the Department regarding implementation of the SPP. I was one of the people
19 appointed to the Solutions Team.

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

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

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

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

6 9. Ultimately, the SPP was adopted in the Budget Trailer Bill, and codified as
7 California Welfare & Institutions Code § 14105.467, which became effective on June 29,
8 2020. This legislation requires the Department to "establish, implement, and maintain a
9 supplemental payment pool for nonhospital 340B community clinics, subject to an
10 appropriation by the Legislature." Qualifying FQHCs are to receive fee-for-service-based
11 supplemental payments from a fixed-amount payment pool to compensate them for their
12 loss of 340B program revenue.

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

19 11. Section 14105.467 also requires the Department to establish a stakeholder
20 process that "shall be utilized to develop and implement the methodology for distribution
21 of supplemental pool payments to qualifying nonhospital 340B community clinics."
22 Section 14105.467 further requires the Department to conduct at least three meetings
23 with stakeholders and to finalize the methodology for distribution no later than October 1,
24 2020.

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

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

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

3 (c) The SPP would be simple to administer.

4 (d) The SPP will be renewed annually.

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

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

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

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

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

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

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

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

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

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

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

-7-

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

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

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

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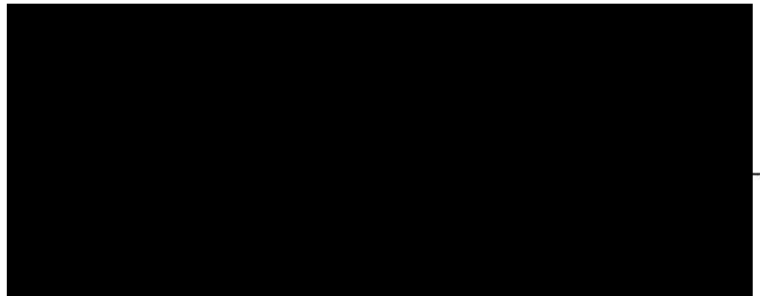
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1 down the chain relating to the provision of services, including the benefits available to
2 the Medi-Cal beneficiaries who will receive those services.

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

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



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Exhibit D
to letter dated 4/16/2021

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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

15
16 COMMUNITY HEALTH CENTER
ALLIANCE FOR PATIENT ACCESS, et
17 al.,

18 Plaintiffs,

19 v.

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

22 Defendants.
23

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**

24 I, Ricardo Roman, declare as follows:

25 1. I am the Chief Financial Officer ("CFO") at Family Health Centers of San
26 Diego ("FHCS") and have held this role since September 2010. As CFO, I report
27 directly to the Chief Executive Officer ("CEO") and am responsible for leading and
28

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

8 2. FHCS D is a Federally Qualified Health Center ("FQHC") that receives
9 federal grant funding under Section 330 of the Public Health Service Act. FHCS D meets
10 all current statutory requirements under Section 330 of the Public Health Service Act.
11 FHCS D has served the medically underserved communities of San Diego County since
12 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health
13 Center, the flagship clinic of FHCS D. FHCS D has since transformed into the tenth
14 largest health center in the country (47 service delivery sites), providing care to over
15 149,000 patients each year, of whom 90 percent are low income (under 200% of Federal
16 Poverty Level) and 31 percent are uninsured. FHCS D serves all patients regardless of
17 their ability to pay.

18 3. FHCS D provides pharmaceutical services primarily through one hundred
19 and eighty one (181) 340B contract pharmacies.

20 4. In order to comply with applicable State and Federal law relating to the
21 340B program, FHCS D has registered each of our FQHC sites that dispenses drugs to
22 Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only
23 340B drugs to our Medi-Cal fee-for-service patients.

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

1 paid at “actual acquisition cost” plus a \$10.05 or \$13.20 dispensing fee.

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

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

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

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

22

23 Clinical Service	Number of Patients	Percent of Patients	Number of Visits	Percent of Visits
24 Medical (Primary Care)	126,178	84.54%	457,021	50.73%
25 Dental	24,344	16.31%	70,816	7.86%
26 Mental Health	18,819	12.61%	110,624	12.28%
27 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 FHCS D 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, FHCS D’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 FHCS D 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%

1	Race		
2	Asian	9,506	6.37%
3	Native Hawaiian/Other Pacific Islander	1,090	.73%
4	Black/African American	13,331	8.93%
5	American Indian/Alaska Native	839	.56%
6	White	91,968	61.62%
7	More than 1 Race	6,249	4.19%
8	Race Unreported/Refused	26,261	17.60%
9	Ethnicity		
10	Hispanic/Latino	81,076	54.33%
11	Non-Hispanic	56,032	37.54%
12	Ethnicity Unreported/Refused	12,136	8.13%
13	Medical Conditions		
14	Hypertension	23,482	15.73%
15	Diabetes	13,015	8.72%
16	Asthma	7,025	4.71%
17	Symptomatic/Asymptomatic HIV	1,361	.91%
18	Prenatal Care Patients		
19	Number of Patients	3,650	100.00%
20	Number of Patients who Delivered	2,017	55.26%
21	Chronic Disease Management		
22	Use of Appropriate Meds for Asthma	1,127	93.70%
23	Statin Therapy for Prevention & Treatment of Cardiovascular Disease	13,663	78.70%
24	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	2,245	89.67%
25	Controlling High Blood Pressure	21,886	69.74%
26	Diabetes: Controlling Hemoglobin A1c	12,656	64.08%
27	% of Patients Seen for Follow-up within 90 days of first ever HIV diagnosis	46	86.96%

28 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.” FHCS D’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, FHCS D’s 340B onsite pharmacy and contract pharmacy

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

- 6 • Affordable Patient Medication & Pharmacy Programs
- 7 • HIV and Hep C Patient Screening and Care Management
- 8 • Expanded Patient Vision Services
- 9 • Increased Access to Mobile Medical & Mental Health Services
- 10 • Expanded Older Adult Patient Services
- 11 • Critical Workforce Development Initiatives
- 12 • Expanded Clinical Patient Services
- 13 • Patient Weight Management Program
- 14 • Expanded Patient Health Education
- 15 • Urgent Care Services
- 16 • Patient Clinical Care Coordination/Patient Case Management
- 17 • Expanded Patient Specialty Services
- 18 • Patient Quality Improvement Staff and Programs
- 19 • Clinical Computer Upgrades
- 20 • Clinical Infrastructure Upgrades
- 21 • Patient Substance Abuse and MAT Programs
- 22 • Clinical Lab and Point of Care Testing Upgrades
- 23 • Expanded Podiatry Services
- 24 • Patient Security Control
- 25 • PHI Security and Server Upgrades

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

28

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

8 15. FHCS D's MCO patient population accounts for approximately 71 percent of

9 the 340B savings achieved through FHCS D's onsite pharmacy and contract pharmacy

10 programs. From July 1, 2020 to June 30, 2021 (annualized), the FHCS D 340B pharmacy

11 programs are anticipated to generate gross revenues of \$39,107,192 with net program

12 savings (gross revenues minus program and drug replenishment costs) of \$17,256,644.

13 This is based on estimates of filling 709,156 prescriptions (annualized) or 59,096

14 pharmacy claims per month. The estimated loss in net 340B benefits due to the Medi-

15 Cal pharmacy program transition will be \$12,164,687 (71 percent of total net 340B

16 Program savings). These lost savings will have a negative impact on access, targeted

17 patient clinical disease state programs, and enabling services for the most vulnerable

18 patients. As a result, an unnecessary adverse impact will occur in such important quality

19 and cost related indicators including: unnecessary emergency room/urgent care

20 utilization, increased hospital admissions, increases in diabetes complications rates,

21 lower health screening rates, and lower improvement of disease management outcomes.

22 16. The 340B Drug Pricing Program requires drug manufacturers to provide

23 discounted pharmaceuticals to health centers and other covered entities – which makes

24 prescription drugs affordable for all FQHC patients, including the uninsured and

25 underinsured. In addition, the savings retained by FHCS D allow it to continue to serve

26 more patients and to increase comprehensive services at no cost to the taxpayer.

27 Because of the action taken by California's Governor to eliminate 340B savings, patient

28 services and programs described above are at risk of being reduced significantly or

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

14 17. FHCSO is also at the heart of the battle against the COVID-19 pandemic in
15 San Diego County. As the largest community clinic organization serving the area,
16 FHCSO's clinics are located in already disadvantaged communities and those hardest hit
17 by the pandemic. As evidenced by the positivity rates seen at FHCSO, health center
18 patients carry more COVID-19 burden than the general population. Since the pandemic
19 onset, FHCSO has performed 35,213 COVID-19 PCR tests with a 16.9% overall test
20 positivity rate. Despite that high positivity over many months, each week in November
21 and December 2020, our test positivity continued to climb to a current rate of 28.5%,
22 more than double California's current test positivity rate of 12.2%. In short, FHCSO and
23 FQHCs across the state are at ground zero of the COVID-19 pandemic. Eliminating the
24 savings realized through the current 340B structure would be devastating to our ability to
25 continue to care for a population with such high test positivity rates. As we near 2021, the
26 drain on FHCSO resources has made it increasingly difficult to maintain quality
27 healthcare for the communities we serve. With high levels of virus in the community, our
28

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

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

12 19. FHCS D has other concerns about the CSOSR process, as well. For
13 example, as part of the CSOSR process, a health center with multiple sites is required to
14 submit a home office cost report in addition to a cost report for each site that is seeking a
15 change to its rate based on a change in the scope of its services. 340B drug costs
16 associated with a health center's contract pharmacy arrangements are not included in the
17 reimbursable costs of the health center because the contract pharmacy (such as a
18 Walgreen's or CVS or corner drug store) incurs all of the costs associated with managing
19 and dispensing the drugs, with the exception of the payment for the replenishment of the
20 drugs, which is paid for by the health center. In connection with an FHCS D CSOSR that
21 is currently under consideration by DHCS, DHCS is proposing to treat FHCS D's 340B
22 drug costs as a non-reimbursable cost center and to allocate an amount of FHCS D's total
23 overhead costs to the non-reimbursable cost center based on the proportion of overall
24 costs represented by the "costs" of the 340B drugs. This proposed adjustment to the
25 home office cost report will result in lower rates for the sites that are undergoing the
26 CSOSR because a disproportionate amount of home office costs will be allocated to the
27 340B drug costs and away from sites that actually use and benefit from the costs

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

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

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

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Ricardo Roman

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Exhibit E
to letter dated 4/16/2021

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17 Attorneys for Plaintiffs
 18 COMMUNITY HEALTH CENTER ALLIANCE
 19 FOR PATIENT ACCESS, ET AL.

20 **UNITED STATES DISTRICT COURT**
 21 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

22 COMMUNITY HEALTH CENTER
 23 ALLIANCE FOR PATIENT ACCESS, et
 24 al.,

25 Plaintiffs,

26 v.

27 WILLIAM LIGHTBOURNE, Director of the
 28 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

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

5 2. DAP was founded in 1984 by a group of community volunteers in the face
 6 of the AIDS crisis. Since that time, DAP has been named one of the "Top 20 HIV/AIDS
 7 Charities" and has expanded its mission to other disenfranchised members of the
 8 Coachella Valley community. Today, DAP is a FQHC that serves over 7,000 active
 9 clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS. The
 10 majority of DAP's clients are low-income, with more than 75 percent of the immediate
 11 population living under 200 percent of the Federal Poverty Level. DAP receives federal
 12 grant funding under Section 330 of the Public Health Service Act. DAP meets all current
 13 statutory requirements under Section 330 of the Public Health Service Act. DAP also is a
 14 340B-eligible Ryan White Part A (RWI) grantee provider organization.

15 3. According to the most recent DAP Uniform Data System ("UDS") report
 16 submitted to the federal Health Resources and Services Administration ("HRSA") for
 17 2019, DAP conducted clinic visits with the following distribution of services for the 7,487
 18 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%

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

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

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3 7. The purpose of the 340B Program is to enable covered entities “to stretch
4 scarce federal resources as far as possible, reaching more eligible patients and providing
5 more comprehensive services.” DAP’s participation in the 340B Program allows the
6 organization to stretch scarce resources to meet the needs of the medically underserved
7 residents of the Coachella Valley and surrounding communities. This includes the most
8 vulnerable high-risk populations (e.g., uninsured, underinsured, HIV/AIDS patients).
9 Specifically, as a Ryan White/ HIV/ FQHC provider, DAP’s population is heavily weighted
10 (over 33%) with Ryan White clients. DAP also is a Hepatitis Center of Excellence that
11 provides medication therapy to a number of patients diagnosed with Hepatitis C. Under
12 federal law, regulation, and program guidance, grantee programs are expected to
13 reinvest 340B net savings directly back into services provided to the organization’s
14 patient populations. In 2018 and 2019, DAP’s Medi-Cal 340B claims from 340B contract
15 pharmacies were estimated to be 10,300 and 9,300 respectively. DAP’s Medi-Cal 340B
16 contract pharmacy program recognized a net program savings (gross revenues less
17 program and drug replenishments costs) of approximately \$3,200,000 and \$3,050,000 in
18 2018 and 2019, respectively. DAP utilized these net 340B funds to:

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

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

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

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

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

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

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

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

13 Executed this 16th day of December 2020, in Palm Springs, California.

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David Brinkman

Exhibit F
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Kelvin Vu, declare as follows:

25 1. I am currently a family physician at Open Door Community Health Centers
26 ("Open Door"), where I have worked for the last ten years. I also currently serve as Chief
27 Medical Officer at Open Door. I received my medical training from Western University
28 and completed my Family Medicine Residency at the University of California, Davis

DECLARATION OF DR. KELVIN VU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

1 Medical Center, where I also served as Chief Resident in my final year. As a family
2 physician, I regularly interact with patients, prescribe medications, and ensure my
3 patients are receiving their medications and following the treatment regimens. As the
4 Chief Medical Officer, I also receive reports from the other physicians about the provision
5 of services to their patients, including concerns about challenges and suggestions for
6 improving services. The majority of Open Door's patients are Medi-Cal beneficiaries who
7 are members of a Medi-Cal managed care plan ("MCP"). I have personal knowledge of
8 the facts set forth herein, and if called to do so, could and would testify competently
9 thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition
10 to the Motion for a Preliminary Injunction.

11 2. Open Door is a Federally Qualified Health Center that receives federal
12 grant funds under Section 330 of the Public Health Services Act. Open Door is
13 committed to providing excellent health care and health education to medically
14 underserved patients in the Humboldt and Del Norte Counties, two rural counties in the
15 far northwest region of Northern California along the coast. Open Door currently
16 operates twelve community health centers across both counties, serving more than
17 55,000 patients each year while employing nearly 700 members of the community.

18 3. Humboldt and Del Norte Counties are predominately rural, and tend to rank
19 near the bottom for health outcomes among California counties. Like many rural areas,
20 our patients struggle with widespread problems of poverty, opioid use disorder, lack of
21 health education, lack of reliable housing and transportation, and numerous other socio-
22 economic barriers to health care that directly affect their well-being in the short and the
23 long term. As a physician who has worked in this community for ten years, I am well-
24 aware that these socio-economic problems often cause my patients to forego necessary
25 medical treatments in order to focus on other urgent aspects of their lives, such as going
26 to work to support their families, or using their limited incomes to buy food or pay rent
27 instead of paying for their prescribed medications.

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1 4. Open Door is committed to meeting our patients where they need us to be.
2 To that end, we operate under a patient-centered medical home model (“Medical Home”)
3 that allows us to coordinate an individual patient’s care across specialties so that we treat
4 the whole person, rather than individual symptoms. As their Medical Home, Open Door
5 proudly serves as a one-stop-shop for all of our patients’ medical needs, as well as their
6 unique needs for accessing transportation assistance, housing, and food. The Medical
7 Home also helps patients follow their medical treatment plans because they do not need
8 to go to multiple facilities – all of their providers are in one place, which greatly improves
9 the patients’ overall health outcomes.

10 5. The Medical Home includes coordination with pharmacy services and the
11 MCP member services team. The ability for me as a prescribing physician to work
12 directly with the MCP and case managers greatly improves my patients’ ability to access
13 necessary treatments. For example, if I prescribe a Lidocaine patch – a non-opioid
14 chronic pain treatment – I will have access to real-time information regarding what the
15 cost will be to the patient, when and if the patient is able to pick up the patch, or if the
16 patch is not covered by the patient’s plan. If the Lidocaine patch is not available for some
17 reason, I am able to find out immediately and make same-day adjustments to the
18 treatment plan so that my patient’s needs are met. This is just one concrete example of
19 how the pharmacy benefit’s inclusion in managed care facilitates medical services for
20 both doctors and patients, leading to better care and outcomes for the most vulnerable,
21 medically underserved people in California.

22 6. The inclusion of the pharmacy benefit in managed care also enables me to
23 tailor my treatment plan to the patient’s needs. With the pharmacy and medical benefits
24 linked, the current managed care model allows me to see and track if my patients are
25 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
26 returning for medical follow-ups on time. This information is critical to creating a
27 treatment plan for my patients, tracking their progress and condition, and scheduling
28 necessary follow-up appointments.

1 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
2 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
3 This will directly undermine Open Door's Medical Home model and my ability to treat my
4 patients effectively. For example, disconnecting pharmacy services from medical
5 services will require our patients to take multiple trips to receive their care and their
6 medication. For most of my patients, this is not simply one more errand in their day – it is
7 an insurmountable barrier because they do not have access to reliable transportation to
8 make multiple trips, or they cannot take additional time from work during the day, or they
9 need to be home to take care of children or other family members.

10 8. Additionally, Medi-Cal Rx will fundamentally alter the way I and other Medi-
11 Cal providers at FQHCs will be able to treat our patients. For example, I will no longer
12 have access to real-time information as to the availability of medications or my patients'
13 adherence to the treatment plan. Using the example of the Lidocaine patch discussed
14 above, under the Medi-Cal Rx fee-for-service model, I would prescribe the patch and my
15 patient would have to make a separate trip to a pharmacy to get it. However, if that
16 pharmacy does not have it in stock or the pharmacist needs prior authorization, I will no
17 longer be notified as part of managed care and will not necessarily be advised that my
18 patient was unable to pick up their prescription. Because of the type of patients I work
19 with and the challenges they face in making multiple trips to different healthcare
20 providers, there is a high likelihood that my patient would forego the treatment altogether.
21 I would not discover the problem until months later in a follow-up visit with my patient, at
22 which point their condition and pain has worsened because they could not access the
23 treatment I prescribed.

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1 9. It is also my understanding that Medi-Cal Rx will also change Open Door's
2 and other FQHCs' reimbursement for drugs purchased under the federal 340B drug
3 discount program. I am gravely concerned that the proposed fee-for-service
4 reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would
5 not cover the cost of providing necessary pharmacy services to my patients.

6 10. In addition, the savings and reimbursement Open Door receives from the
7 340B program go directly to providing additional, much-needed services for our patients that
8 are not otherwise reimbursed by Medi-Cal. One key example is Open Door's Medication
9 Assistance ("MAT") Program. MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid use disorder to overcome and manage their addiction. The drug is very
12 expensive, so without 340B pricing, our patients would not be able to receive it at all.
13 Additionally, MAT includes support groups that help patients maintain sobriety, which
14 requires efforts from case managers and member services staff. However, these
15 counseling services are not reimbursable by the Medi-Cal program, and are instead
16 directly funded by 340B revenue and savings. Without services like our MAT Program,
17 Open Door's patients will be denied access to a highly effective treatment option that can
18 help them get away from opiates and improve their overall lifestyle.

19 11. Based on my experience as a family physician at an FQHC, I believe that
20 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
21 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
22 as how those patients access their Medi-Cal benefits. I am greatly concerned that
23 removing the pharmacy benefit from managed care will directly prevent Open Door's
24 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
25 their unique and varied needs. Additionally, the loss of 340B revenue will force Open
26 Door to cut off critical resources for patients who are struggling with opioid use disorder
27 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
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Paramvir Sidhu, declare as follows:

25 1. I am currently a family physician at Family Health Care Network ("FHCN"),
26 where I have worked for the last ten years. I also currently serve as Chief Clinical Officer
27 at Family Health Care Network. I received my medical training in India and completed
28 my residency in family medicine at the Riverside Community Medical Center, Riverside,

DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

1 California. As a family physician, I regularly interact with patients, prescribe medications,
2 and ensure my patients are receiving their medications and following the treatment
3 regimens. As the Chief Clinical Officer, I also receive reports from the other physicians
4 about the provision of services to their patients, including concerns about challenges and
5 suggestions for improving services. The majority of FHCN patients are Medi-Cal
6 beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). Although
7 FHCN is not a named plaintiff in this action, it is an affiliate of the Community Health
8 Center Alliance for Patient Access. I have personal knowledge of the facts set forth
9 herein, and if called to do so, could and would testify competently thereto. I make this
10 declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a
11 Preliminary Injunction.

12 2. FHCN is a Federally Qualified Health Center ("FQHC") that receives federal
13 grant funds under Section 330 of the Public Health Services Act. FHCN is committed to
14 providing excellent health care and health education to medically underserved patients in
15 the Tulare, Kings and Fresno Counties, three rural counties in the San Joaquin Valley of
16 Central California. FHCN currently operates forty-one (41) community health centers
17 across these counties, serving more than 221,000 patients each year while employing
18 nearly 1,500 members of the community.

19 3. The patients we serve from Tulare, Kings and Fresno counties are
20 predominately from rural communities, and tend to rank near the bottom for health
21 outcomes among California counties. Our patients struggle with widespread problems of
22 poverty, lack of health education, lack of reliable housing and transportation, and
23 numerous other socio-economic barriers to health care that directly affect their well-being
24 in the short and the long term. A large majority of our patients are Seasonal and Migrant
25 farmworkers who suffer from severe health care disparities. As a physician who has
26 worked in this community for ten years, I am well aware that these socio-economic
27 problems often cause my patients to forego necessary medical care in order to focus on
28 other urgent aspects of their lives. These patients have to choose between utilizing their

1 limited resources to either buy food or pay rent to support their families, or pay for their
2 prescribed medications.

3 4. FHCN is committed to meeting our patient's needs and provide access to
4 quality medical care to everyone. We are Joint Commission Accredited clinics and we
5 operate under a patient-centric medical home model ("Medical Home") that allows us to
6 coordinate an individual patient's care across specialties so that we treat the whole
7 person, rather than individual symptoms. As their Medical Home, FHCN proudly serves
8 as a one-stop-shop for all of our patients' medical needs, as well as their unique needs
9 for accessing transportation assistance, housing, and food and connect the patients with
10 resources in the communities. The Medical Home also helps patients follow their medical
11 treatment plans because they do not need to go to multiple facilities – all of their
12 providers are in one place, which greatly improves the patients' overall health outcomes.

13 5. A part of the Medical Home also includes pharmaceutical services for our
14 patients. Having pharmacies in our health centers and medications under the 340B
15 program allows me as a prescribing physician to work directly with the pharmacists and
16 greatly improve my patients' ability to access necessary treatments. For example, if I
17 prescribe Insulin– a lifesaving treatment for diabetes – I will have access to real-time
18 information as to when and if the patient is able to pick up the medication at a very
19 affordable price. If the Insulin is not available for some reason or not covered by the
20 patient's plan, the pharmacist is able to call and inform me and provide alternatives to the
21 medication. This allows me to make same-day adjustments to the treatment plan and
22 patient leaves the visit with medications. Relatedly, our in-house pharmacists have
23 access to a patient's Electronic Health Record, allowing them to track prescription
24 dosages and types, which enhances patient safety. For example, our pharmacist can
25 see and verify the weight of a pediatric patient who is prescribed antibiotics for an
26 infection, verify the dosage calculation, and consult with me prior to the patient leaving
27 the health center. Another example would be the pharmacist reviewing the medical
28 record and noting additional medications or supplements listed in the patient's medication

1 list that could have contraindications when taken with the prescribed medication. Again,
2 this can be discussed with me before the patient leaves the health center. These are just
3 a few concrete examples of how the pharmacy benefit's inclusion in managed care
4 facilitates medical services for both doctors and patients, leading to better care and
5 outcomes for the most vulnerable, medically underserved people in California.

6 6. The inclusion of the pharmacy benefit in managed care also enables me to
7 tailor my treatment plan to the patient's needs. First, with the pharmacy and medical
8 benefits linked, the current managed care model allows me to see if my patients are
9 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
10 returning for medical follow-ups on time. This information is critical to creating a
11 treatment plan for my patients, tracking their progress and condition, and scheduling
12 necessary follow-up appointments. Second, the 340B savings allow us to operate a
13 robust in-house pharmacy program, including a Director of Pharmacy who sits on our
14 Medical Director Team. This coordination allows us to create a formulary for our
15 pharmacy specific to the clinical needs of our patient population and at the lowest
16 acquisition price possible, benefiting our patients both clinically and financially. Without
17 the 340B program, this cross-collaboration and comprehensive care management will not
18 be possible, as the dramatic cuts that would need to be made to our in-house pharmacies
19 would no longer allow us to have a Director of Pharmacy, and pharmacists would no
20 longer be able to dedicate time to comprehensive care management.

21 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
22 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
23 This will directly undermine FHCN's Medical Home model and my ability to treat my
24 patients effectively. For example, disconnecting pharmacy services from medical
25 services will require our patients to take multiple trips to receive their care and their
26 medication. For most of my patients, this is not simply one more errand in their day – it is
27 an insurmountable barrier because they don't have access to reliable transportation to
28 make multiple trips, or they cannot take additional time from work during the day, or they

1 need to be home to take care of children or other family members.

2 8. It is also my understanding that Medi-Cal Rx will also change FHCN's and
3 other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount
4 program. I am gravely concerned that the proposed fee-for-service reimbursement,
5 actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the
6 cost of providing necessary pharmacy services to my patients. It will also impact our
7 ability to provide other benefits that are significant to our patients. For instance, we
8 currently have an extensive patient transportation program that provides door-to-door
9 service from a patient's home to the health center, which we would need to be scaled
10 back or eliminated if we no longer received revenue from the 340B program.
11 Additionally, we will have to increase the nominal fee offered to uninsured patients on our
12 pharmacy sliding fee scale, which will increase the costs for patients who cannot afford
13 higher out-of-pocket expenses for medical care. Such a change could result in uninsured
14 patients forgoing prescriptions, leading to worse health outcomes.

15 9. Medi-Cal Rx will also fundamentally alter the way I and other Medi-Cal
16 providers at FQHCs will be able to treat our patients. For example, FHCN has a Diabetic
17 clinic where the goal is to provide coordinated diabetic care to patients. This includes the
18 patient getting education about diabetes from health educators, necessary screenings
19 and immunizations, and behavioral-health counseling. These services are in addition to
20 medical care and treatment the physicians provide during the same (single) visit for the
21 patient. Using the example of the Insulin discussed above, under the Medi-Cal Rx fee-
22 for-service model, I would have to prescribe the Insulin and my patient would have to
23 make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it
24 in stock, the cost is too high, or the pharmacist needs prior authorization, I will not be
25 notified immediately that my patient was unable to pick up their prescription. Because of
26 the type of patients I work with and the challenges they face in making multiple trips to
27 different healthcare providers, there is a high likelihood that my patient would forego the
28 treatment altogether. I would not discover the problem until months later in a follow-up

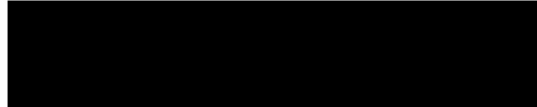
1 visit with my patient, at which point their condition has worsened and severe
2 complications developed because they could not access the treatment I prescribed, or
3 the supportive Diabetic clinic services. The result for that patient is deteriorated clinical
4 outcomes and, most likely, costly trips to the emergency room paid for by the Medi-Cal
5 program for a Medi-Cal beneficiary.

6 10. In addition, the savings and reimbursement FHCN receives from the 340B
7 program go directly to providing additional, much-needed services for our patients that are
8 not otherwise reimbursed by Medi-Cal. One key example is FHCN's Medication
9 Assistance Program ("MAT"). MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid addiction to overcome and manage their addiction. The drug is very expensive, so
12 without 340B pricing, our patients would not be able to receive it at all. Additionally, the
13 MAT clinic includes counseling that help patients maintain sobriety, which requires efforts
14 from Behavioral Health and member services staff. However, some of these ancillary
15 services provided in the MAT clinic as well as the above mentioned Diabetic clinic are not
16 reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue
17 and savings. Without programs like MAT, FHCN's patients will be denied access to a
18 highly effective treatment option that can help them get away from opiates and improve
19 their overall lifestyle.

20 11. Based on my experience as a family physician at an FQHC, I believe that
21 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
22 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
23 as how those patients access their Medi-Cal benefits. I am greatly concerned that
24 removing the pharmacy benefit from managed care will directly interfere with FHCN's
25 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
26 their unique and varied needs. Additionally, the loss of 340B revenue will force FHCN to
27 cut off critical resources for patients who are struggling with opioid addiction and other
28 chronic conditions like Diabetes.

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

3 Executed on this 5 day of February, 2021, in VISALIA, California.
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8 DR. PARAMVIR SIDHU
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Exhibit H
to letter dated 4/16/2021

1 2HANSON BRIDGETT LLP
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 2 ANDREW W. STROUD, SBN 126475
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 3 Sacramento, California 95814
 Telephone: (916) 442-3333
 4 Facsimile: (916) 442-2348
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 5 astroud@hansonbridgett.com

6 REGINA M. BOYLE, SBN 164181
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 8 Sacramento, CA 95816-9479
 Telephone: (916) 930-0930
 9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
 COMMUNITY HEALTH CENTER ALLIANCE
 11 FOR PATIENT ACCESS, ET AL.

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UNITED STATES DISTRICT COURT

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EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

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Plaintiffs,

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v.

20 WILLIAM LIGHTBOURNE, Director of the
 California Department of Health Care
 21 Services; CALIFORNIA DEPARTMENT
 OF HEALTH CARE SERVICES,
 22

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Defendants.

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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

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I, Fran Butler-Cohen, declare:

25

1. I am the Chief Executive Officer ("CEO") at Family Health Centers San

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Diego ("FHCS D") and have held this role since 1986. I have reviewed the data and

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associated outcomes relevant to the impact of Medi-Cal Rx on FHCS D in connection with

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the preparation of this declaration. I have personal knowledge of the facts set forth

1 herein, and if called to do so, could and would testify competently thereto. I make this
2 declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

3 2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives
4 federal grant funding under Section 330 of the Public Health Services Act. FHCSD has
5 served the medically underserved communities of San Diego County since 1970, with the
6 transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's
7 flagship clinic. FHCSD has since transformed into the tenth largest health center in the
8 country, providing care to over 149,000 patients each year, of whom 90 percent are low
9 income and 31 percent are uninsured. FHCSD serves all patients regardless of their
10 ability to pay.

11 3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020,
12 FHCSD has provided free COVID-19 testing to as many patients as the staff can
13 manage. During this time, demand for FHCSD services has skyrocketed. To try to meet
14 our patients' testing needs, FHCSD has purchased additional lab equipment and
15 increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid
16 testing and notification systems to quickly identify patients with COVID-19 and reduce
17 community spread. Additionally, we have set up a separate obstetrics clinic for mothers
18 who have tested positive for COVID-19. These steps have proven necessary, since,
19 among the patients we serve, the COVID positivity rate in the second week of January
20 2021 was 35 percent, more than double the average statewide rate for the same time
21 period.

22 4. In an effort to take care of patients and to avoid sending them to hospitals –
23 which currently cannot handle an additional influx of patients – FHCSD has also ramped
24 up its ability to care for the sickest, non-emergent patients. Instead, we have started
25 Monoclonal Antibody administration for the sickest, non-emergent patients at one of our
26 clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as
27 soon as possible.

28 ///

1 5. Despite the heroic efforts of our health care workers – who have shouldered
2 the burden of coming to work every day risking their own health and the health of their
3 families – FHCS D staff is stretched beyond its limits and is struggling to continue. We
4 currently have seventy (70) members of our team out of work due to COVID, which hurts
5 FHCS D’s ability to meet patients’ needs and county demands. We have started an
6 emergency child care program to keep our workers on the job when they have no other
7 childcare options. We have also started an Employee Food Pantry Program so that
8 employees who have lost income can feed their families.

9 6. Now, with the development of a COVID-19 vaccine, San Diego County is
10 asking FHCS D to submit information regarding how many vaccinations we could
11 administer to the general public, which requires me and the FHCS D staff to study
12 guidance from the Centers for Disease Control and the Department of Defense to
13 implement massive public vaccination events, in addition to juggling the current
14 emergency needs of our patients and community.

15 7. Simultaneously, FHCS D is still required to commit time to fielding
16 government audits and meet with the State and Managed Care Organizations on metric
17 performance. In addition, FHCS D is currently in the beginning stages of a random federal
18 340B audit that has already taken several hundred hours of staff time in preparation and
19 document submission. At the same time, the Health Resources and Services
20 Administration is requesting capital funding grantees submit previously unrequired data
21 and qualitative information to help them design future grant programs. Moreover,
22 FHCS D has had to make significant modifications to contract pharmacy arrangements to
23 ensure our patients receive affordable medications due to the attack on the 340B
24 program by pharmaceutical manufacturers. All of this comes against the backdrop of the
25 State of California awarding a contract valued at approximately \$80 million annually to a
26 for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by
27 Centene, a publicly traded NYSE corporation worth \$76 billion for \$2.2 billion dollars to
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1 facilitate the state in their plan that will remove hundreds of millions of dollars from the
2 state's health care safety-net.

3 8. It is unconscionable that during this time of perpetual crisis, when our staff
4 and other healthcare workers have sacrificed so much to serve the communities that
5 need them most, FHCS and other FQHCs are required to prepare and plan for Medi-
6 Cal Rx, which will result in drastic funding reductions due to changes in reimbursement.
7 Additionally, the loss of 340B funding that helps stretch our resources to expand
8 healthcare access will further reduce staff and desperately needed health services.

9 9. Although the "effective" date of Medi-Cal Rx has been moved to April 1,
10 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring
11 health centers to adjust our conduct in a number of ways. Examples of some of the
12 activities FHCS has had to undertake in anticipation of the "go live" date for Medi-Cal
13 Rx include:

- 14 • A complete budget review and assessment of programs currently
15 funded through 340B savings, including the potential for lay-offs,
16 elimination of support programs, and reduction in hours and types of
17 services provided to our patients.
- 18 • Meetings with vendors that currently support in-house pharmacy
19 operations to ensure systems remain compliant following full
20 implementation.
- 21 • Subscribe to and dedicate staff time to monitor, review and bring
22 forward issues noted in regular updates from the Medi-Cal Rx
23 Subscription Service
- 24 • Secure Provider Portal access and enroll approximately 250
25 prescribing providers into the provider portal, necessitating hundreds
26 of hours of administrative staff time.

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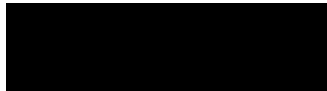
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1 patients who have suffered the most throughout the COVID-19 emergency will also bear
2 the burden of the Medi-Cal Rx initiative's consequences.

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

5 Executed this 20th day of January, 2021, at San Diego, California.

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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](#)
2. [Updates to the List of Covered Enteral Nutrition Products](#)
3. [Medi-Cal Provider Training Schedule](#)
4. [Prescriber Phone Campaign](#)
5. [Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey](#)
6. [Pharmacy Provider Self-Attestation Period Begins April 2021](#)
7. [Portal Registration](#)

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 SabaSM 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.

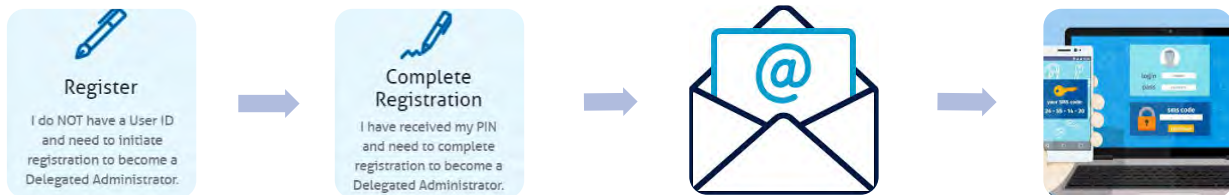
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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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Dear Honorable Colleagues:

I write in response to comments on “CalAIM Section 1115 & 1915(b) Waivers” documents, with a particular emphasis on the impact of the CalAIM proposed policies for children and youth. I am a medical provider in California’s safety net system, and an oral health advocate and disparities researcher. I would also like to reference “Implementing High Quality Primary Care: Rebuilding the Foundation of Health Care”, a report released this week from the National Academies of Sciences, Engineering, and Medicine, which I helped co-author.
<https://www.nationalacademies.org/our-work/implementing-high-quality-primary-care>

As a provider, I have seen the benefit of Medi-Cal to support health in children and youth. Still, I would support stronger mechanisms to promote preventive care, especially for marginalized populations. One important step toward that end would be to enhance Medi-Cal managed care authority. Some of the work I have been able to promote in the state was tied to reminding systems that Medi-Cal could audit on certain measures, but I once had a system decline because they said they had not ever been penalized from an audit. Of note, I would like to highlight the importance of supporting enhanced care management (something my local MCMC said they don’t have the money to do).

On a related note, more support needs to be given to coordination and financing of dental services. We know that money invested in early prevention of oral disease prevents hundred-fold costs later. Still, many medical providers have trouble finding dental providers who will accept Denti-Cal. Moreover, the fact that health plans are required to make dental assessments and referrals for their patients, there is no auditing of this, and no incentive for medical and dental providers to use an electronic health record that communicates, so it is not audited, and thus not enforced. Los Angeles and San Mateo are two regions where pilots showed this type of sharing benefits patients. This is an opportune time for DCHS to support these changes statewide. In addition, , transitioning the Dental Transformation Initiative will be important to sustain the gains achieved and diffuse innovative good practices for adaptation.

I am grateful that DHCS has proposed including trauma as eligibility for Specialty Mental Health services. Now we just need more mental health providers, as my patients have been told they have to wait over a year for access to care, which is getting even worse with the pandemic.

Last, underpinning all of this is the impact of Social Determinants of Health. It is essential to identify and manage member health risk and health needs of SDOH, ideally through team-based, whole-person care approaches. Related to this is to facilitate Medi-Cal to be more consistent and seamless by increasing alignment across delivery systems, reducing complexity and increasing flexibility-the majority of my patients lose coverage for at least some part of the year. Overall care can be improved by emphasizing quality outcomes, especially those supporting preventive care; reduce health inequities; and foster delivery system transformation and innovation via value-based initiatives, system modernization, and payment reform (including for team-based care).

It is encouraging for those of use tired at the front line to think the state could take the CalAIM waiver opportunity to systemically and sustainably improve Medi-Cal for children and youth, especially after years of poor levels of care and persistent racial and linguistic disparities. Now is the time to ameliorate these challenges!

Thank you for your time and work on these important initiatives and in incorporating stakeholder feedback. Please do not hesitate to contact me with any questions.

Sincerely,

Susan A. Fisher-Owens, MD, MPH ([my pronouns](#): she/her/hers)
Clinical Professor of Pediatrics
Clinical Professor of Preventive and Restorative Dental Sciences
University of California, San Francisco

Informatics Director, Pediatrics, Primary Care and Public Health Integration
Clinical Informaticist, PRIME/QIP
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Susan.Fisher-Owens@ucsf.edu



May 5, 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:

Vista Community Clinic (VCC) 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, VCC 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.

Vista Community Clinic is an FQHC that cares for Medi-Cal and uninsured patients in San Diego, Riverside, and Orange 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 our two VCC pharmacies and 107 contract pharmacy locations.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows VCC 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, Vista Community Clinic annually saves an estimated \$3.7M through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow VCC 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, VCC 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. Vista Community Clinic incorporates by reference the CHCAPA public comment letter into this letter. VCC 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, Vista Community Clinic urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS’ consideration. Doing so will enable VCC 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. Vista Community Clinic looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,



Fernando Sañudo, MPH
Chief Executive Officer

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>.

To whom it may concern:

My name is Daniel Mistak, and I am Director of Health Care Initiatives for Justice-Involved Populations at COCHS. COCHS is a philanthropically funded 501(c)(3) headquartered in California that aims to improve connections between community health systems and correctional settings. Many of the adults that we see started on their path to adult incarceration because of unmet behavioral health needs in their childhood. The CalAIM 1115 and 1915(b) waivers hold great potential for stopping the intergenerational trauma that results in justice involvement, but only if it is implemented to its fullest potential. I have three main concerns regarding implementations.

1. Resist pathologizing adversity—as evidenced by proposed tools to “screen in for a high risk score” for ongoing services. We must honor the wisdom and intelligence of low income communities to determine their own definition of medical necessity. Any positive screen, and more importantly, any request for support from a beneficiary should qualify a child for services and support.
2. Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan—or if such a tool is to be used it must only be used during the course of treatment and treatment can not be stopped or interrupted until or if there is a transition in care.
3. Clarify unanswered questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

Resolving these issues will not only make an improved system for the youth, it will be a step in the right direction to undo the way in which failures in the youth behavioral health programming leads to entanglement with the justice system.

Sincerely,
Daniel Mistak

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Daniel Mistak
Director of Health Care Initiatives for Justice-Involved Populations
Community Oriented Correctional Health Services
808-765-9428

May 06, 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:

GARDNER HEALTH SERVICES [GHS] 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, **GHS** 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.

GHS is an FQHC that cares for Medi-Cal and uninsured patients in San Jose/Santa Clara 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 13 sites and/or locations..

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows **GHS** 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, **GHS** annually saves an estimated \$800k through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow **GHS** to provide vital services to more patients. These benefits are not available to FQHCs when reimbursed for pharmacy on a FFS basis. As a result of the current managed care system, **GHS** 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. **GHS** incorporates by reference the CHCAPA public comment letter into this letter. **GHS** 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, **GHS** 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 **GHS** 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. **Gardner Health Services** looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,



✓ Reynaldo S. Espinoza
Chief Executive Officer
Gardner Health Services, Inc.
160 E. Virginia Street, Suite 100
San Jose, CA 95112
(408) 938-2172

Encl.

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>.

CalAim Comments from Institute on Aging

Institute on Aging (IOA) appreciates DHCS' interest in receiving comments and feedback from organizations with experience in delivering the types of services and supports contemplated in the ambitious CalAIM proposal. IOA has been a partner to local governments and health plans in the delivery of ILOS-like services and ECM-like care management for more than ten years and has gained an intimate understanding through that experience of how these services can be most efficient, effective and impactful. Our programs have primarily been focused on de-institutionalization by either migrating individuals out of long-term care settings or avoiding long-term care stays for those at high risk of an admission. Our experience includes:

- Community Living Fund program in San Francisco County
- Community Care Settings Pilot in San Mateo County
- Nursing Home Diversions, Transitions and Care Coordination Program in Santa Clara County (part of Whole Person Care)
- Operation of waiver programs such as HCBA, CCT, ALW throughout the state
- Community living program development in the Inland Empire and San Diego County

We've organized our feedback in the following Key Performance Indicator categories that we believe will impact a successful implementation of CalAIM's mission and goals.

KPI #1: Shifting from a primarily institutional long-term care system to a value-based home & community-based system of care

- ❖ Recommendation: Don't be afraid of opening up Pandora's Box. Yes, there will be some level of a 'woodwork effect' which will lead to more individuals receiving home & community-based services than in the past. That's ok. That's a desirable change that aligns with most Californians preferences. If we collectively reach a point where the 'problem' of unnecessary long-term care institutionalization appears to be resolved (as measured by inability to identify individuals who could successfully transition to a community setting), not only will that be a 'success' but it will also offer an opportunity to evaluate new ways to segment the population into high and low risk categories.
- ❖ Apply the lessons of value-based care to the LTSS environment in a meaningful way. If we value timeliness, person-centered-ness, and longevity in the community for instance, tie financial performance metrics to them. Align those incentives at the MCP and ECM/ILOS provider level. Especially in the first couple years prior to more robust long-term care risk sharing structures.
- ❖ Encourage / incentivize MCPs to pay market rates. There is no reason Medi-Cal rates have to / or should be considered below market. If anything, the complexity of the population along with regulatory requirements should actually warrant rates that are leading the market.

KPI #2: Ensuring individuals receiving services under CalAim receive high quality, well coordinated, person-centered care

- ❖ Not all care management programs are created equal, and there are significant differences in outcomes that result. IOA is proud of our top-tier care management model that has been highly successful in sustaining community living for complex individuals. Enabling and sustaining community living for the complex individuals requires significant staff investment in each case, including face-to-face visits, collaboration with stakeholders, care planning, service coordination, administrative tasks and ongoing monitoring. Low caseloads enable this work and multiple disciplines including MSWs, Occupational Therapists, and Nurses are needed to holistically assess and best care for members in the community. In many cases this represents 6-9 months of work before an individual can be stepped down to less

intensive care management. IOA would encourage DHCS to consider the ways in which care management programs are differentiated, including potentially tiering services to ensure that adequate investments are made in high-intensity care management rather than a 'race to the bottom' where programs compete solely on price.

- ❖ ECM providers often specialize in serving distinct target populations which should not dissuade MCPs from selecting multiple ECM providers. Should a "one size fits all" approach be preferred by MCPs, the direct member impact will be substantial in the quality of care they receive.
- ❖ There should be clear connections between the deployment of ILOS and care management programs such as ECM. Ideally, ILOS & ECM have the most potential impact when offered together. IOA's experience has been that it is necessary for a care manager and the care plan that they help develop to be the driving force behind the use of ILOS to ensure that they are both necessary and effectively utilized. The effectiveness of SNF transitions is largely linked to the ability to flexibly purchase goods and/or services beyond the CCT offerings. While there are some ILOS services being contemplated that may not require connections with ECM, we believe this should be the exception not the norm.
- ❖ Create a clear, robust, connection point to housing resources, specifically actionable housing vouchers and/or rental subsidies. Housing opportunities must reflect the needs of the range of needs of the members served. We recognize the limitations of Medicaid funding directly supporting these resources, but Section 8 vouchers, Senior Housing, Permanent Supportive Housing, and ALW are essential. The reality is that a nursing home placement comes with housing and services, therefore it is less effective to offer a community-based alternative without a pathway for both. Dramatically expand Project 811 vouchers connected to CCT eligibility, seek alternative funding streams to support a flexible subsidy program, enable immediate access to the ALW for timely transitions, tie development resources to providing set-aside units to this population. All of this improves system flow in counties where SNF bed shortages result in unnecessarily extensions of acute care stays.
- ❖ Demand high levels of reporting and accountability from ECM/ILOS providers and MCPs, but compensate them for this work. Invest in best-in-class solutions that develop tools and infrastructure to support high functioning ECM and ILOS providers.
- ❖ Community stakeholder engagement is hugely beneficial to member experience and outcomes, decreases duplication of services, and ensures the most efficient and effective use of limited resources. Often MCPs are less familiar than CBOs are with the range of community resources that are available along with the key players that deliver them; this is an excellent opportunity to leverage the skills of CBOs.

KPI #3: Ensuring ALL Californians have access to CalAim benefits regardless of Zip Code

- ❖ Recommendation: We encourage the department to avoid statewide rate setting methodologies. The costs of doing business for institutional and home & community-based providers is not the same from region to region within the state. Available resources to be considered as part of a payer of last resort model are not consistent across the state, so the 'gap' to fill is different in different regions. Similarly, the viability of a statewide PMPM rate is a function of volume; as a result, it may require additional investment to ensure provider network access in rural or semi-urban settings.
- ❖ Work with MCPs who are nervous about their ability to provide ILOS across their entire population due to initial capacity constraints. Develop milestone progress markers to incentivize building capacity rather than choosing not to offer an ILOS because if I 'offer it to one member', I have to offer it to all'. Recognize that there are potential ECM & ILOS network development provider solutions that can build networks on behalf of MCPs to ease their burden.

KPI #4: MCPs investing in thriving, dynamic networks of LTSS services and deriving ROI and benefits through active long-term care risk sharing and improvements in social determinants of health.

- ❖ ROI calculations should include benefits derived through long-term care cost avoidance as well as population health improvements related to improved social determinants of health risk factors. A robust LTSS system of care will improve Californians health risk factors, benefits that should be realized through the integrated D-SNP model and factored into the long-term economic analysis of CalAIM investments.
- ❖ A thriving, dynamic network of LTSS service providers also prepares the state to serve individuals currently above Medi-Cal financial eligibility thresholds through new cost-sharing approaches to long-term care insurance.
- ❖ Network management and capacity building will be key aspects of a successful ILOS program, as MCPs may not have experience working with ILOS providers and may not have the organizational bandwidth to integrate them fully into existing provider networks. ILOS direct service providers may also not have awareness of CalAIM or the sophistication to work within health plan contracting and billing structures. A network management entity such as a CBO could instead relieve MCPs of that burden while also delivering significant benefits such as ensuring ILOS is the payer of last resort, improving quality, delivering encounter data, performing UM, and implementing procurement and compliance efforts.
- ❖ Network management and capacity building requires significant effort by either the MCP or CBOs (recommended structure) and therefore should be tied to incentives and compensation structures to ensure the work is done efficiently and effectively. This would mean ensuring that there is an administrative cost factored into the payments for services or a separate administrative fee should be contemplated for network development and management in ILOS.
- ❖ While it is certainly understandable that there may be a variety of fiscal and regulatory reasons to limit lifetime costs for recipients of ILOS, hard lifetime caps in individual ILOS categories will negatively impact the most complex service recipients. Care plans for transitions in particular can take many months to plan, implement and monitor the stability of, which requires ongoing investments in services that are likely to exceed the stated \$5,000 maximums. To ensure the sustainability of placements rather than readmissions to institutions, certain services will need the flexibility to exceed those caps such as RCFE services and care management supports.

Once more, we appreciate the opportunity to provide feedback on this important proposal and remain available to answer questions on the above or continue the conversation should it be beneficial to DHCS. Please do not hesitate to reach out to Dustin Harper at dharper@ioaging.org.



Health Services
LOS ANGELES COUNTY

May 6, 2021

**Los Angeles County
Board of Supervisors**

Hilda L. Solis
First District

Holly J. Mitchell
Second District

Sheila Kuehl
Third District

Janice Hahn
Fourth District

Kathryn Barger
Fifth District

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

**RE: Los Angeles County DHS – Comment on DHCS’ CalAIM 1115 and 1915
Waiver Applications**

Submitted via e-mail to: CalAIMWaiver@dhcs.ca.gov

Dear Director Lightbourne:

We appreciate the opportunity to comment on the state’s draft California Advancing and Innovating Medi-Cal (CalAIM) 1115 and 1915 waiver renewal applications. For decades, Medi-Cal demonstration projects have provided critical support to the Los Angeles County (LA County) Department of Health Services (DHS), which includes four acute care hospitals and 26 health centers. Each year, DHS serves more than 750,000 unique patients, the majority of which are Medicaid or uninsured (69% and 18%, respectively). The system also provides health care to youth in the juvenile justice system and adults in the county jails and runs programs to provide health care and housing-related supports for individuals experiencing homelessness.

The programmatic opportunities and core funding offered through the Medi-Cal program, and these waivers, are essential to the ongoing sustainability of a strong public health care system. The need for such a system has never been more apparent than during the COVID-19 pandemic, where DHS provided a disproportionate share of essential public health and health care services to patients who were at high risk for contracting COVID-19 and to the broader community. As we continue to learn from our experience with COVID-19, we must ensure that the public health care system in LA County can continue to support both its core services and the innovative social programs serving the county’s most vulnerable residents that are contemplated as a part of CalAIM.

Expansion of Support for Justice-Involved Population. We appreciate the focus on this population in the draft 1115 application and encourage the state to tailor the current proposals to reflect the range of services available to ensure successful release and reintegration to the community.

The draft 1115 application proposes to cover certain targeted services during the 30 days prior to release from incarceration, specifically Enhanced Care Management (ECM), limited community-based clinical consultation services provided via telehealth or e-consultation, and a 30-day supply of medication for use post-release into the community. This list should be expanded to cover additional targeted services during the 30 days prior to release that are of critical importance to ensuring a successful transition to the community, including:

- Treatment for behavioral health disorders, which can be essential to preventing relapse, overdoses, suicides, hospitalizations, and deaths post-release;
- Treatment for other chronic conditions to help stabilize conditions and prepare for continuing treatment in the community, even if not provided via

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- telemedicine;
- The initiation and administration/provision of drugs prior to release, including drugs to manage chronic diseases such as diabetes and hypertension, as well as stabilizing drugs such as injectable antipsychotics, naloxone, and buprenorphine; and
- Release planning activities.

In addition, while we support the proposal to extend ECM to the pre-release population, we have multiple questions about how it would be implemented that are not addressed in the draft application. For example, the draft application does not clarify whether individuals released from incarceration would continue to be eligible for ECM after release but before they are enrolled in a Managed Care Plan (MCP). To be effective, case management for the re-entry population must be available during the initial transition back into the community when individuals are at the highest risk for poor outcomes. This necessarily occurs before the individual has made their election of a managed care plan. Similarly, we are puzzled by the language in the draft application that indicates, in the context of discussing pre-release ECM, that ECM would be “delivered by Medi-Cal MCPs.” Work done for the pre-release population necessarily must be performed by county correctional health systems, and assigning MCP responsibility for the care is particularly fraught prior to a beneficiary’s enrollment in the plan. County systems need predictable funding if they are to provide ECM to the justice-involved community. Additional information about how the payment and enrollment in ECM would occur are necessary.

Transition of Existing Programs into CalAIM. We appreciate the components of CalAIM that build financial and programmatic support for the state’s most vulnerable residents into Medi-Cal managed care structures. However, we have significant concerns that the transition of existing programs for these populations will reduce options and services currently available, including those currently available through the county-operated Whole Person Care (WPC) pilots. Without strong state directives, managed care plans will almost certainly be cautious in implementing new programs like ECM and In Lieu of Services (ILOS), limiting access to benefits just as the current funding under WPC expires. This backsliding cannot occur.

We acknowledge that the Providing Access and Transforming Health (PATH) Support incentives outlined in the draft application are intended in part to promote a successful transition, and encourage the state to provide additional information so that both managed care plans and other stakeholders, including DHS, can understand what funding will be available and for which programs. Without assurances that the current programs will remain financially viable in CalAIM, DHS will need to prepare for service reductions and potential discontinuation.

It is also critical that the Department of Health Care Services (DHCS) exercise firm oversight over both ECM and ILOS to ensure robust take up and implementation. DHCS should establish simple and concrete criteria for eligibility for both ECM and ILOS, removing managed care plan discretion to deny or narrow these benefits. While we understand there may be a need to phase-in the new programs, managed care plans should be required to ensure populations receiving services through existing programs are seamlessly transitioned as CalAIM begins.

California’s public health care systems require financial support to sustain and strengthen the safety net and prepare for future emergencies. DHS, like all of California’s public health care systems, has been a leading partner in piloting programs and developing the expertise CalAIM will leverage. As local governmental entities with experience treating local indigent populations – including those difficult-to-manage populations other health systems avoid – systems like the DHS are essential to the future success of CalAIM. DHS supports the goals of CalAIM in expanding new services and supports for Medi-Cal beneficiaries; at the same time, its ability to continue delivering ongoing core services and supports are jeopardized by concerns about base funding levels at its hospitals and clinics.

To ensure the stability of all public health care systems during the expansion of services envisioned under CalAIM, it is critical that the state continue to use the 1115 waiver to provide financial support for the more traditional components of these systems, namely the hospitals and clinics. COVID-19 revealed the central role public health care systems play in the health care delivery system and broader public health infrastructure. For instance, during the COVID-19 surge in early 2021, DHS treated nearly twice the percentage of LA County's COVID-19 patients compared to its relative share of LA County's staffed inpatient beds. The importance of having this public safety net is further underscored by the relative scarcity of hospital beds in the state: according to the Kaiser Family Foundation, California has one of the lowest per-capita bed counts in the nation – 1.9 beds per 1,000 compared to a national average of 2.4. It is no exaggeration to say that beds in LA County, and especially at DHS, were stretched to the breaking point during the worst of the crisis in January 2021, and that DHS stepped up in its public role to respond to the dire need, despite the financial implications of shutting down other services to do so. Now, as the county works to put shots in arms and reduce COVID-19 infection rates, DHS is managing pent-up demand and returning to preventive and primary care services that have been deprioritized by Medicaid populations during the crisis.

Maintaining these core public services that meet both mission and budget objectives is a yearly struggle. With over 85% of patients on Medi-Cal or uninsured, DHS has a projected operating deficit for hospital and clinic services in each of the next three fiscal years in the low hundreds of millions of dollars. The closure or reduction in levels of services at DHS facilities could be catastrophic during this recovery period and leave LA County unprepared when the next emergency happens, undermining any vision to expand support to vulnerable communities through CalAIM. To mitigate these financial concerns and ensure future capacity, we urge the state to increase the statewide funds available to public health care systems through PATH by \$500 million (gross), and to make those additional funds available for activities and work conducted by the hospitals and clinics within public health care systems. The opportunity to earn these funds will help financially stabilize DHS and California's other public health care systems, allowing them to maintain existing services for Medi-Cal beneficiaries and uninsured individuals; manage pent-up demand for specialty, primary care, and preventive care services; continue to provide core public health emergency response infrastructure; and undertake the expansions and transitions contemplated by CalAIM.

Overall Support for CalAIM. DHS recognizes that CalAIM is greater than the sum of its parts, and that it is only through the full implementation of the interrelated proposals that we will move towards the vision for a more holistic, streamlined Medi-Cal program with better care for our patients. As the public health care system in LA County, DHS' long-term stability is foundational to the success of CalAIM. The above changes would be significant improvements and must be considered as part of a complete package of proposals that strengthen and preserve safety-net providers in California, along with the proposed continuation and strengthening of the Global Payment Program and the Quality Incentive Pool. We applaud the state's efforts and look forward to continuing to work with the state on the successful implementation of CalAIM.

Sincerely,



Christina R. Ghaly, M.D.
Director

CRG:jjb

- c: Jacey Cooper, State Medicaid Director and Chief Deputy Director, DHCS
- Jacqueline Bender
- Clemens Hong, M.D.
- Allan Wecker



Private
Essential
Access
Community
Hospitals

California's Community Safety Net Hospitals
Essential to Access, Essential to Health

May 3, 2021

Jacey Cooper
Chief Deputy Director Health Care Programs and State Medicaid Director
Department of Health Care Services
1501 Capitol Avenue
Sacramento, CA, 95814

via: CalAIMWaiver@dhcs.ca.gov

RE: Public Comment CalAIM Section 1115 & 1915(b) Waivers

Dear Ms. Cooper,

Thank you for your leadership in developing a comprehensive CalAIM proposal that includes a wide range of services designed to meet the behavioral, developmental, and physical needs of all Medi-Cal members in a more integrated and patient centered fashion. The proposal represents a major step forward in reforming a fragmented delivery system and builds upon the lessons learned from prior pilots. Private Essential Access Community Hospitals (PEACH), the statewide association dedicated to advancing policies and programs that ensure sustainability for California's community safety net hospitals is pleased to comment on the proposal.

PEACH is generally supportive of the three main goals that the CalAIM proposal lays out, which DHCS summarizes as:

1. Identify and manage member risk and need through whole person care approaches and addressing social determinants of health;
2. Move Medi-Cal to a more consistent and seamless system by reducing complexity and increasing flexibility; and
3. Improve quality outcomes, reduce health disparities, and drive delivery system transformation and innovation through value-based initiatives, modernization of systems, and payment reform.

In particular, PEACH appreciates DHCS's recognition of the need for increased care coordination and care management, as evident by the proposed new statewide Enhance Care Management (ECM) benefit. Many Medi-Cal beneficiaries with complex physical or behavioral health conditions are unable to navigate our complex health care system on their own. Moreover, depending on their specific medical, behavioral, and social needs, beneficiaries may require services from multiple delivery systems and already receive some level of care coordination. Medi-Cal managed care plans' (MCPs) ability to implement patient-centered coordination of care will be critical to the overall success of CalAIM. We also urge DHCS to increase oversight of the Medi-Cal MCPs and their Subcontractors to ensure that not only are basic obligations are being met, but that the additional layers of benefits and requirements contained in the California Advancing and Innovating Medi-Cal are being achieved.



In addition, PEACH is supportive of the In Lieu of Services (ILOS) benefit, especially as it pertains in efforts to reduce many of the health disparities due to homelessness. PEACH hospitals serve the highest number of homeless individuals amongst private hospitals, and acutely understand the need to address social determinants of health at their source – which the ILOS proposal seeks to do.

PEACH hospitals are deeply involved in these types of supports already and have been for decades. As hospitals that treat over 80% of patients enrolled in either Medi-Cal or Medicare, we believe that community safety net hospitals and their partners are well positioned to participate with health plans in a standardized ECM/ILOS benefit. We also look forward to partnering with plans as they seek to extend these benefits to members.

PEACH urges DHCS to look at ways to help standardize the definitions, criteria, reporting requirements and network adequacy requirements for Medi-Cal MCPs as they implement this new ECM and ILOS benefit-as currently each plan appears to have significant latitude to select patient populations and criteria which can lead to significant confusion amongst beneficiaries and the provider community.

PEACH also urges DHCS to clarify the scope of eligible ECM Providers and to specify that private providers are indeed qualified and appropriate. While the CalAIM proposal does not exclude any group, we do believe Health Plans should be encouraged to work with their private safety net partners as these new benefits are rolled out.

Full Integration Plans – Estimated for no earlier than 2027

Given the current complexity of the Medi-Cal System, PEACH appreciates the inclusion of ECM/ILOS services as a covered benefit in Medi-Cal Managed Care. However, the creation of these benefits further highlights the problems of the current fragmentation in the Medi-Cal delivery system. We request that DHCS to do the necessary work to pull together stakeholders interested in piloting a full Integration Plan as we believe that the ECM/ILOS and other attempts at coordinating care that the department is seeking to make could be greatly simplified if there was one entity in charge of managing all of a Medi-Cal member's needs. We would encourage a deliberate rollout in specific regions, with additional engagement from all interested entities.

Behavioral Health Payment Reform

As a fundamental principle with proposed changes from a CPE financing mechanism to an IGT mechanism, PEACH requests DHCS to only implement the proposed changes in a way that ensures the change from CPEs to peer grouped reimbursement rates will result in greater investment in this important area. PEACH hospitals treat 65% of inpatient behavioral health and substance use patients in the safety net, and base payments from mental health plans often do not come close to covering the cost of care. While we concur that transitioning to an IGT based payment structure will offer county mental health plans additional flexibilities, we encourage DHCS to use this flexibility to also address the long-standing problem of underpayment to providers and encourage DHCS and the Specialty Mental Health plans to place additional emphasis on use of alternative programs like preventative services such outpatient partial hospitalization programs offered by several PEACH member hospitals.

Transplant/Long Term Care Carve-In

In today's complex Medi-Cal managed care delivery system, several levels of risk are assigned and reassigned across a broad range of providers and health plans. Ultimately the State of California must be



responsible for the Medi-Cal population. PEACH cautions DHCS to avoid the development of a model that threatens the financial viability of any one of the parties/segments of care. The state should be the stop-gap or hedge undue/outlier risk so as to preserve the delicate safety net the Medi-Cal members, and to avoid unintended consequences that simply shift risk that could result in bankruptcy, closure, loss of access, and overall deterioration of the Medi-Cal health care delivery system.

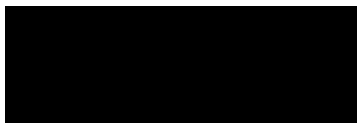
Indirect Impact on Supplemental Payments

While not specifically addressed in the CalAim proposal, increased responsibilities of health plans to cover previously 'carved-out' services and increased mandatory enrollment of certain populations will likely have the impact of reducing Medi-Cal fee-for-service (FFS) federal upper payment limit (UPL) room and supplemental payments made to private hospitals. The current gap that exists between the UPL and current payments, including base payments and crucially important supplemental payments made to private, community safety net hospitals (including the Private Disproportionate Share Hospital (DSH) replacement payments, Private Hospital Supplemental Fund payments and Hospital Quality Assurance Fee Payments), is critically important to support the services provided to Medi-Cal beneficiaries. DHCS must ensure that any potential loss in FFS UPL room for private hospitals is accounted for in equitable supplemental managed care payments made available to private hospitals as more of the population is enrolled in MCPs.

For homeless and other socially complex populations, PEACH encourages DHCS to incorporate adjustments for socially complexity into payment models to account for the increased risk and financial burden not already addressed in medical acuity-based payment approaches – especially for private safety net hospitals that do not receive renumeration for the additional costs/resources required to care for this population. This includes Medi-Cal FFS where many of the presumptively eligible homeless beneficiaries will continue to reside.

Thank you in advance for your consideration of our comments. PEACH looks forward to further engagement with DHCS as it continues working on the CalAIM proposal.

Sincerely,



Anne McLeod
President & CEO
Private Essential Access Community Hospitals

May 6, 2021

To: California Department of Health Care Services (DHCS) staff
 Re: Cal AIM Section 1115 & 1915(b) Waivers
 From: First 5 LA

First 5 LA is an independent public agency with the goal of supporting the safe and healthy development of young children. In partnership with others, First 5 LA works to strengthen families, communities, and systems of services and supports so all children in Los Angeles County enter kindergarten ready to succeed in school and life. We thank DHCS for the opportunity to provide feedback on its Cal AIM 1115 Demonstration and 1915(b) waiver proposals. Nearly 60 percent of California children under the age of 5-years old receive care through Medi-Cal. As such, updating the state’s federal waivers and reforming the program through the California Advancing and Innovating Medi-Cal (Cal AIM) effort represent uniquely powerful opportunities to support child health and promote family well-being.

To build a Medi-Cal system that truly strengthens the Whole Child and Whole Family, the department, through the state’s updated waivers and Cal AIM, should:

- **Serve children ages prenatal to 5-years old as a special population.** During the earliest years of life, 90 percent of brain development occurs and millions of new neural connections form each second. When a developmental concern emerges, children can recover from missed milestones, attain needed skills and return to optimal development, so long as the delay is identified and treated early enough. Interventions that occur too late, or not at all however, can lead delays to persist and become disabilities that carry life-long adverse impacts on health and quality of life. To support optimal health and developmental outcomes, **infants and toddlers should receive presumptive eligibility for Medi-Cal services**, rather than waiting for deficits to accumulate and reach particular thresholds before they can receive certain care. This includes not requiring a given Adverse Childhood Experiences (ACEs) score to access services.
- **Promote an approach to Medi-Cal that centers on prevention,** especially through the statewide adoption of evidence-based prevention models for pregnant women and families with young children. A universal system of voluntary family strengthening services, with home visitation at its center, is the best avenue for promoting prevention and early intervention, as well as quickly connecting at-risk children and families to supports. Such a universal system should promote model choice in home visiting, emphasizing family responsiveness and that not one, single approach or program model can effectively serve every family. Overall, DHCS should **make home visitation a covered benefit for all families on Medi-Cal.** In order to close current race-based disparities in utilization of Medi-Cal services, DHCS should also prioritize family access to community health workers, doulas and Promotoras that offer language- and culturally-appropriate care.
- **Implement a guaranteed income pilot program for pregnant women and new mothers served by Medi-Cal.** Economic security is foundational to child success, and

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family stability is impossible achieve without the income and resources necessary to feed, clothe and house the family. The supports California currently provides are neither sufficient to promote family stability and lift children out of poverty, nor to break the continuing cycle of intergenerational poverty families often experience. **A targeted guaranteed income pilot that provides direct income supports to pregnant women and new mothers on Med-Cal** would help alleviate the worst impacts of economic instability. Such an approach has already shown success in supporting families: basic income pilots in Jackson, Mississippi and Stockton, California, for example, helped recipients cover daily expenses, purchase school supplies for their children, and access healthier food options. Furthermore, direct financial payments to families through the federal Coronavirus Aid, Relief, and Economic Security (CARES) Act and American Rescue Plan helped reduce the national poverty rate and increase economic growth.

More broadly, First 5 LA remains concerned that the department is requiring Managed Care Plans (MCPs) to take on many new responsibilities through Cal AIM even as they have been unable to meet current requirements. The federal EPSDT benefit, for example, mandates all young children served by Medi-Cal receive a suite of preventative health services. Based on DHCS's own audit from 2019, this is not currently occurring. Children of color are most likely to miss out, which is especially concerning because children from minority backgrounds face elevated risks for development delays as well. Nearly 90 percent of children in the state who receive Medi-Cal care do so through managed care, so focusing on MCP performance, by implementing both incentives *and* accountability measures, will help ensure families have access to vital preventative care. We further ask that DHCS provide adequate oversight and technical assistance to ensure plans come into compliance with existing EPSDT requirements, even as they take on expanded roles required by Cal AIM and the related Medi-Cal waivers.

Thank you again for the opportunity to provide feedback. If we can be of further assistance, please contact Andrew Olenick, Policy Analyst, at Aolenick@First5LA.org.



NORTHEASTERN RURAL HEALTH CLINICS

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:

Northeastern Rural Health Clinics 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, Northeastern Rural Health Clinics 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.

Northeastern Rural Health Clinics is an FQHC that cares for Medi-Cal and uninsured patients in Lassen 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 four outside pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Northeastern Rural Health Clinics 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.

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Fax: 530-252-1340

Northeastern Health
1850 Spring Ride Dr.
Susanville, CA 96130
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Westwood Family Practice
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NORTHEASTERN RURAL HEALTH CLINICS, INC.

Additionally, Northeastern Rural Health Clinics annually saves approximately \$800,000 through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Northeastern Rural Health Clinics 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, Northeastern Rural Health Clinics 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. Northeastern Rural Health Clinics incorporates by reference the CHCAPA public comment letter into this letter. Northeastern Rural Health Clinics 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, Northeastern Rural Health Clinics urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the

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>.

Administration Phone: 530-251-1525 Fax: 530-252-1340	Northeastern Health 1850 Spring Ride Dr. Susanville, CA 96130 Phone: 251-5000 Fax: 530-252-1340	Westwood Family Practice 209 Birch Street Westwood, CA 96137 Phone: 530-256-3152 Fax: 530-256-2061
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NORTHEASTERN RURAL HEALTH CLINICS, INC.

Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable Northeastern Rural Health Clinics 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. Northeastern Rural Health Clinics looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

Michael Schaub, CEO
Northeastern Rural Health Clinics

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I am writing to provide support for the CalAIM 1115 Demonstration and waiver to improve oral health integration. This is long overdue and all aspects of the system need to be integrated, from payment, to care delivery to technology.

Thank you,

Elizabeth Mertz, PhD, MA

Professor, Preventive and Restorative Dental Sciences

Faculty, Healthforce Center

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May 6, 2021

Will Lightbourne, Director
Jacey Cooper, State Medicaid Director and Chief Deputy Director of Health Care
California Department of Healthcare Services
1501 Capitol Avenue, MS 0000
P.O. Box 997413
Sacramento, California 95899

Submitted via email to CalAIM@dhcs.ca.gov

Subject: Feedback on CalAIM and the 1115 Demonstration and 1915(b) Waiver

Thank you for the opportunity to provide feedback on the updated CalAIM proposal as well as the 1115 Demonstration and 1915(b) Waiver. The California Children's Trust (CCT) and the California Alliance of Child and Family Services (The Alliance) continue to support the broad goals outlined in the updated proposal. As with most large-scale systems transformations, much of the impact of these initiatives is not felt by providers and consumers until the details of an initiative's implementation are developed. Below we offer comments, some suggestions, and questions for the department that we feel are critical to answer as the state begins to shape the structure of the MediCal system of the future.

No Wrong Door:

While there is progress in advancing the relationship between MCPs and MHPs and their shared role in providing children's mental health services in either system, the creation of tools to determine the system in which services should be provided adds an administrative burden and creates a barrier to access.

The 1915(b) waiver overview (p. 27/60) emphasizes a "No Wrong Door" approach to mental health services stating: "*DHCS proposes to ensure that beneficiaries receive the care they need, no matter how they enter the system.*" The paragraphs immediately following this declaration outline multiple screening processes and the creation of four new screening tools -- two for persons seeking services for the first time (one for those under 21 and one for those over 21) and two additional age-designated tools to screen individuals transitioning between MCP and MHP services. The concept of a "no wrong door" means when you enter the door, you are served. It does not mean you are screened and sent elsewhere.

When youth or their families reach out to access behavioral health services in the public system, it has likely taken them significant emotional and psychological effort just to reach out for help. To create any additional “doors” that have to be opened to get treatment will more often than not result in them retreating from help they need.

Further, DHCS states (p. 20/60) it intends to “*streamline and simplify assessment and documentation requirements.*” The creation of four new digital screening tools will not simplify the process. They will be layered into the state’s siloed mental health system -- a system that already loses more than 40% of clinician time to documentation.

Fiscal Structure is Paramount to Success:

The 1915(b) waiver proposes moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT)—which could increase federal revenue for counties and open up the possibility of claiming against non-federal dollars already being spent in other child-serving systems. However, there are multiple unanswered questions that prohibit us from fully evaluating the proposal. We appreciate that DHCS has listened to our concerns and pledged to address them (including modeling at the local MHP level) in advance of implementation in July 2022. Following are the questions that we see as critical to the design of the waiver:

1. Will the IGT mechanism expose MHPs to an Upper Payment Limit (UPL) calculation? We understand that the MHPs cannot be paid more than the state would pay under the state plan, which outlines the reimbursement process as it currently exists. How will this change under IGT?
2. What will the process be for setting rates? Given that rates will need to be approved by CMS, and that prior years’ cost reports will likely be used as a benchmark for determining rates under IGT, it seems imperative that a design for proposing and testing rates prior to full implementation will be essential. We would also request clarity on what efforts the state will make to ensure that there is guidance provided for MHPs on rate setting for community based organizations (CBOs). This will ensure that the payment reform efforts are felt throughout the system of care.
3. Has DHCS done a comparison of the CPT Schedule to County Cost Reports? Changing from the use of HCPCS codes to CPT codes, which create more specificity but are also not bundled as many HCPCS codes are, is one of the many significant components of the CalAIM effort. As with rate processes, the need to compare the proposed CPT Schedule with the current County Cost Reports will be critical in order to ensure that the system is adequately funded.
4. MHP’s play a number of roles outside their Pre-Paid Inpatient Health Plan (PIHP) status. Many of these roles are defined/required in Welfare and Institutions Code and other health and safety codes. How will these other functions be accounted for (e.g. detainee health, 5150 management and regulation, MHSA administration and compliance)?

5. How will the separate Federal Financial Participation (FFP) programs be handled in the shift? There are four FFP programs in the state cost report:
- Administrative
 - Utilization Review/Quality Assurance (UR/QA)
 - Mental Health MediCal Administrative Activities (MAA)
 - Direct Services

No detail is provided in the proposal about these additional service and billing codes that MHPs (and in some cases, CBOs) utilize in performing MediCal program activities. These help to fund the infrastructure and administration of the system, so understanding how these will be managed within the structure of IGT is essential.

Medical Necessity:

A core objective of CalAIM in addressing high-need individuals should be intervention early in the lives of Medi-Cal enrollees to mitigate the onset of conditions in the first place. By identifying emerging risks early in a child’s life and following up with appropriate, coordinated, and timely care and support services, Medi-Cal can contribute to setting a child’s life on a course of health and wellbeing by preventing or mitigating conditions in adulthood. For example, health systems should proactively nurture healthy relationships and resilience of young children and their families, and identify and address developmental, social-emotional, behavioral, and other related issues at the earliest stages, before they spiral into long-term, high-cost needs. *The system must shift from a diagnosis-driven system to an approach that reflects an understanding of the impact of trauma and the social determinants of health on long-term health and mental health outcomes for children and youth.*

The list of conditions on pages 24 and 25 of the proposal miss the essence of DHCS’s previous articulated statement: *“If your condition produces debilitating symptoms or side effects, then it is considered medically necessary.”* The range of circumstances that could lead someone to feel debilitated is so vast and personal, no screening tool could calculate a score. The mere act of a beneficiary seeking help should be all that is needed to deem a mental health service necessary. Beneficiaries should be able to determine whether their experiences rise to the level of needing support without the use of a rigid and often re-traumatizing screening tool.

We suggest the following changes to criteria 1 on page 25:

“Criteria 1: The beneficiary has a condition that puts the child or youth at high risk for a current or future mental health disorder due to experiencing trauma or adversity, evidenced by any of the following: beneficiary or caregiver declaration of need, or positive screen on ACES, or involvement or risk of involvement in the child welfare system, or experience or risk of homelessness.”

We also recommend clarifying that the reference to “involvement in the child welfare system” includes children currently or formerly involved in the child welfare system *or at risk of involvement*.

Criteria 2 as proposed is over complicated, lacks specificity for key definitions like “significant impairment,” and is likely to lead to confusion. While not the Department’s intent, the inclusion of the phrase “impairment level” could lead to some children being wrongfully denied SMHS as has occurred in the past. Instead, we recommend the following language be adopted:

*Criteria 2A: The beneficiary must have at least one of the following:
A reasonable probability of significant deterioration in an important area of life functioning, or
A reasonable probability a child will not progress developmentally as appropriate, or
Requires mental health services that are not included within the mental health benefits that managed care plans are required to provide.*

We believe the above options will allow for a broad-based understanding by providers on how to determine need. Additionally, under criteria 2, when services are provided based on a suspected mental disorder, the DHCS proposal does not define if a diagnosis must be ultimately given and if so what timeframe it must be given within. We recommend that a mental health diagnosis not be required for children to continue receiving services.

Workforce:

The waivers do not address the workforce diversity or shortage problem we have in our public behavioral health system. In light of California’s behavioral health workforce shortage crisis, expanding our supply of behavioral health workers must be a top priority. We urge DHCS to keep this goal in mind when implementing CalAIM.

Medi-Cal’s unlicensed mental health provider categories such as Mental Health Rehabilitation Specialists and Other Qualified Providers, for example, offer effective mechanisms for expanding California’s behavioral health workforce. We should be expanding in particular the roles of peer support specialists, community health workers (promotores), and traditional healers. Studies demonstrate that the use of these workers in comprehensive mental health or substance abuse treatment programs helps reduce client hospitalization, improve client functioning, increase client satisfaction, alleviate depression, and diversify the workforce. Not to mention, they actually reflect the communities we are serving in California.

In addition, The Peer Support Specialist certification program authorized by SB 803, is currently structured as a county option and therefore access to these evidence-based services for parents and families will be mixed. We recommend making access to Peer Support Specialists a statewide benefit for all Medi-Cal families so that families impacted by mental health issues in a parent or child have access to this evidence-based and culturally-responsive service. Finally, investing in the state Youth Crisis Hotlines, which train and utilize peer volunteers also makes sense as they serve as a both a trusted support system and a valuable workforce pipeline (volunteers often pursue counseling and other support careers).

Drug Medi-Cal Organized Delivery System for Enrollees Under 21:

The 1915(b) Waiver Overview states that “beneficiaries under age 21 are currently, and will remain, eligible to receive DMC-ODS services without a diagnosis. Under the Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) mandate, beneficiaries under the age of 21 are eligible to receive all appropriate and medically necessary services needed to correct or ameliorate health conditions that are coverable under Section 1905(a) Medicaid authority. Nothing in the DMC-ODS overrides any EPSDT requirements. Counties are responsible for the provision of services pursuant to the EPSDT mandate”. We applaud DHCS’s confirmation that beneficiaries under the age of 21 are eligible for DMC-ODS services under EPSDT. We urge DHCS to ensure a youth-centered service delivery model and that eligible EPSDT services include outreach, screening, assessment, care coordination, family/caregiver education and support groups, mentoring, recreational therapies, and clinical supervision in addition to the current service delivery system being offered under the existing Waiver. While youth will now be guaranteed access to needed substance use disorder treatment services through the EPSDT benefit, we urge DHCS to develop accountability measures to ensure that EPSDT-eligible DMC services are available and offered consistently and in alignment to the intent of CalAIM at a statewide level.

The addition of Contingency Management services will add great value to the service delivery toolbox of DMC-ODS providers in achieving positive health outcomes. As a newly included evidence-based practice, we recommend that DHCS work with counties to provide dedicated funding for training providers in the utilization of Contingency Management and that youth Contingency Management services be tailored to youth needs and with clear protocols on definitions and feasible youth-centered target behaviors that will be reinforced.

We appreciate the proposal’s inclusion of the American Society of Addiction Medicine’s 0.5 within the Drug Medi-Cal Waiver as we believe prevention is an important piece of the continuum of care. However, as stated above, we would like to see more specificity on how youth can receive treatment under Drug Medi-Cal. In California, as many as 60% to 75% of adolescents with substance use disorders are estimated to have a co-occurring mental illness. In some cases, substance use may begin as a strategy for self-medicating to manage psychiatric symptoms. Given the need, we are concerned the proposal does not address how the CalAIM changes will provide for the needs of youth. While youth are guaranteed access to substance abuse treatment through the EPSDT benefit, data shows many have difficulty accessing these services. Currently, the American Society of Addiction Medicine’s criteria, which outlines how to uniquely support youth in recovery, is included in the DMC-ODS pilot. As such, we see an opportunity for the DMC-ODS pilot to expand services for young people. However, DMC-ODS is not statewide. DHCS should outline how it will ensure EPSDT-SUD services are available statewide through CalAIM.

We are supportive of DHCS’s proposal to remove existing limitations on residential length-of-stay for SUD treatment services. Particularly, we were heartened to see this portion of the proposal:

Residential length-of-stay should be determined based on the individual's condition, medical necessity, and treatment needs. Given that the two-episode limit is inconsistent with the clinical understanding of relapse and recovery from SUDs, DHCS proposed in the 12-month extension request to remove this limitation and base treatment on medical necessity.² DHCS will further propose that there be no distinction between adults and adolescents for these particular requirements, CalAIM page 95.

We believe that linking length of stay to client needs is more appropriate.

Foundational MCP Oversight and Accountability:

The enormous changes that DHCS is proposing require a stronger level of oversight and accountability driven by DHCS when historically there has been a poor track record in overseeing the existing MCP contracts with demonstrably stagnant or declining progress on many children's indicators. We find it concerning that there is very little explicit discussion in the CalAIM proposal regarding DHCS' plans for additional managed care oversight and accountability. The upcoming re-procurement process is an important opportunity to reset MCP requirements and expectations regarding network adequacy, timely access to care, language access requirements, quality improvement and the reduction of health disparities. Performance measures and improvements should be more directly tied to plan financing, namely their capitation payments. *It will be critical to track and report on how managed care plans engage with traditional safety net providers, and how they meet the new demands the state has specified regarding population health and the social determinants of health.*

In addition, DHCS must require greater accountability and transparency from both MCPs and County Mental Health Plans (MHP) to meet the federal entitlement to behavioral health care under EPSDT. The MCP contracts should clarify that the MCP remains responsible for the provision of all medically necessary mental health services and has a case management and care coordination obligation to communicate with the County Mental Health Plan to ensure the member can access needed care without delay.

Enhanced Care Management and In Lieu of Services:

CCT and the Alliance support the core concept that Medi-Cal managed care plans and the public behavioral health plans including community-based agencies should more closely align and enter into contracts to better manage care for beneficiaries across delivery systems. We support the continuation and evolution of Whole Person Care pilots with additional Medicaid match for those services otherwise not matchable. We recommend, however, that the proposal do more to compel public behavioral health and MCP collaboration, particularly as it relates to the state's goal to target SED/SMI and SUD populations.

Given the prominent role case management plays in public behavioral health systems, and the fact that ECM would be a required benefit across the state, we believe that, at a minimum, the public behavioral health system should be core, required partners in implementing the ECM benefit which would touch public behavioral health clients. This could take the form of a requirement on MCPs to develop their population health management strategy with county and community-based partners. In fact, we are supportive of this portion of the proposal which calls

out the importance of MCPs contracting with the public behavioral health system and to provide a rationale if they do not:

If a plan proposes to keep some level of enhanced care management in-house instead of contracting with direct providers, the plan will need to demonstrate to the state that their enhanced care management benefit is appropriately community-based and provide a rationale for not contracting with existing WPC and HHP providers, CalAIM proposal page 48.

Given this existing expertise, the public behavioral health system should be provided with a first right of refusal to contract for ECM services for individuals with SED/SMI and SUD needs.

Further, the current criteria for participation in ECM as proposed is narrow and omits important categories of children and youth in need of ECM. DHCS should expand the criteria and include “proxy” criteria, such as school-related criteria, to identify eligible children. The MCP Enhanced Care Management and In Lieu of Services Contract template provisions should include community health workers in the list of provider types serving in child-serving systems of care.

Our primary concern with the ILOS proposal that we continue to raise has to do with the matching of services to target populations. In our experience providing housing supports, transitions in and out of incarceration, and managing transitions from other acute settings, including locked facilities, and in working with homeless populations, the benefits cannot and should not be limited in terms of the intensity, frequency, or duration if they are to be successfully applied in addressing the social determinants of health. Given the lack of available affordable housing options for very low-income individuals for example, combined with the relatively low education and employment levels for our county behavioral health clients, we believe the limited housing benefits envisioned under ILOS are not well targeted at high-risk beneficiaries.

Population Health Management:

CCT and the Alliance support CalAIM’s Population Health Management proposal to require health plans to conduct assessments for new members and for all members annually. We believe these plan-wide assessments can play a critical role in identifying youth with key risk factors for emerging mental health conditions. We recommend that plans be required to include in these assessments several questions concerning key Social Determinants of Health (SDOH). If the assessment indicates the youth and/or the family is experiencing one or more of these SDOH, the plan should be responsible for ensuring the family is linked with a community-based provider that is qualified to both provide a more thorough assessment and to ensure the youth receives appropriate and coordinated follow-up care.

The Alliance and CCT also support CalAIM’s Population Health Management proposal to require health plans to conduct assessments for new members and for all members annually. We applaud CalAIM’s requirement that these assessments gather SDOH, including “access to basic needs such as education, food, clothing, household goods, etc.”; “[h]ousing and housing instability assessment”; and “[u]se of community-based services and supports”. We

recommend in particular that plans be required to gather data reflecting economic distress and a youth's potential exposure to trauma, such as the following questions from the Whole Child Assessment: "On average, how difficult was it for your family to meet expenses for basic needs like food, clothing, and housing in the last year?"; and "Do you feel your child is difficult to take care of?"

We also support the requirement that plans identify members with "emerging risk" factors and provide those members case management services, including ensuring a "family-centered approach by identification of [a] member's circle of support or caregivers"; and "[d]eveloping relationships with local community organizations to implement social determinant interventions (e.g. housing supports, nutritional classes, etc.)". The Alliance and CCT believe it is critical that plans are required not only to identify members who should receive more thorough follow-up assessments, but also to ensure members actually receive those evaluations and any recommended follow-up interventions.

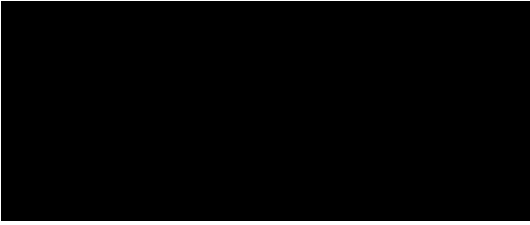
Documentation:

We remain unclear on the timeline and execution of documentation streamlining as outlined on page 26 of the CalAIM waiver overview. We reiterate our request that DHCS identify overzealous documentation requirements on counties and community-based organizations. In order for the system to be the most cost effective and streamlined and the focus to be truly on the beneficiary, this must be addressed. We understand that there are discussions and workgroups developed, we will continue to advocate for movement in this area both in documentation and administrative processes until we can identify tangible changes. Below are a few examples of burdensome requirements:

- Site certification: this process is required for any site where a provider is serving beneficiaries, even if their records are not stored on site (e.g., school site). A fire clearance and documentation of adequate space should meet the needed requirement, rather than full site reviews.
- Credentialing of staff: each MHP does this differently, with some requiring up to 10 years of addresses, work history, and a significant amount of detailed information, even if staff are already licensed with a state board. This type of additional burden is an example of requirements with MHPs that do not currently exist when contracting with MCPs.
- Clinical paperwork: statewide documentation standards need to be put in place during this process, and assurances provided to MHPs that they will not be audited outside of these required documents. The audit tool must match the actual documents and updates completed in sync between the DHCS program and audit divisions.

We appreciate this opportunity to provide comments on the department's CalAIM waiver proposals and urge the department to include our recommendations to prioritize the health and wellbeing of California's Medi-Cal children. If you have any questions, please contact Chris Stoner-Mertz at chris@cacfs.org or Alex Briscoe at alex@cachildrentrust.org.

Sincerely,



Christine Stoner-Mertz, CEO
California Alliance of Child and Family Services
chris@cacfs.org | 916-956-0693



Alex Briscoe, Principal
California Children's Trust
alex@cachildrenstrust.org | 415-629-8142



May 5, 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:

Neighborhood Healthcare (Neighborhood) 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, Neighborhood 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.

Neighborhood Healthcare is an FQHC that cares for Medi-Cal and uninsured patients in San Diego and Riverside 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 an in-house pharmacy and contracted pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Neighborhood 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, Neighborhood annually saves valuable dollars through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Neighborhood 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, Neighborhood 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. Neighborhood incorporates by reference the CHCAPA public comment letter into this letter. Neighborhood 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, Neighborhood Healthcare 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 Neighborhood and DHCS to “work

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.)

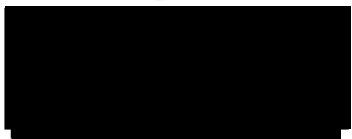
² Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: <https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program>.



in partnership to provide individuals access to affordable healthcare, including prescription drugs” as now-Secretary Becerra described.

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

Sincerely,



Rakesh Patel, M.D.

CEO

Encl.

¹ 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>.

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
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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	Hill Country Health & Wellness Center	San Ysidro Health
Clinicas de Salud del Pueblo	Imperial Beach Community Clinic	Shasta Community Health Center
Community Health Centers of the Central Coast	La Maestra Family Clinic	South of Market Health Center
Desert AIDS Project	MCHC Health Centers	TrueCare
Family Health Centers of San Diego	Mission Area Health Associates	United Health Centers of the San Joaquin Valley
Gardner Family Health Network	Omni Family Health	Vista Community Clinic
Golden Valley Health Centers	Open Door Community Health Centers	WellSpace Health
HealthRIGHT 360	Ravenswood Family Health Network	Central California Partnership for Health (Affiliate Support Organization)
	San Francisco Community Health Center	

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Teresa DeCaro, Acting Director
April 16, 2021
Page 2

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

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 Waiver¹

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 care². 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 them⁴. 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

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 fund⁶. 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. 14⁷. 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 dispensing 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 Notice⁸. However, the state’s Legislative Analyst’s office explicitly stated that Medi-Cal Rx would directly affect FQHC funding and patient care coordination⁹. 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 Rx¹⁰. 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 dollars¹¹. 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 billion¹². 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

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/mceestimates/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 years¹⁴. 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
PARTNER
DIRECT DIAL (916) 491-3024
DIRECT FAX (916) 491-3079
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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**.

Judith Cash, Director
March 18, 2021
Page 3

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
<u>Audiological Services</u>	<u>Audiology Services</u>	<u>Audiological services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
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 ⁷⁶
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)	<u>Service is not covered under the State Plan EPSDT</u>	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.	<u>X</u>	<u>X</u>	<u>X⁹ X⁶X⁴</u>	<u>X</u>	<u>X</u>	<u>X</u>

**Attachment N
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Certified Family nurse-Nurse practitioner-Prac titioner	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
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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
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	<u>EPSDT</u>	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)	<u>EPSDT</u>	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

**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
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)		<p>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.</p> <p>CBAS Unbundled Services: Component parts of CBAS center services delivered outside of centers, under certain conditions, as specified in paragraph 95.</p>	X	X	X	<u>X</u>	<u>X</u>	<u>X</u>
Comprehensive Perinatal Services	Extended Services for Pregnant Women- Pregnancy Related and Postpartum Services	Comprehensive perinatal services means obstetrical, psychosocial, nutrition, and health education services, and related case coordination provided by or under the personal supervision of a physician during pregnancy and 60 days following delivery.	X	X	X	X	X	X

**Attachment N
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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 <u>administered in-office</u> , 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 <u>EPSDT Supplement al Services</u>	EPSDT	<u>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.</u> Preliminary evaluation to help identify potential health issues.	X²⁶	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷
<u>Erectile Sexual Dysfunction Drugs</u>		FDA-approved drugs that <u>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.</u>						

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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 ^B	X ^B	X ^B	X ^B	X ^B	X ^B
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

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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.	X⁴⁴X⁸⁷	X⁴⁴X⁸⁷	X⁴⁴X⁸⁷	X⁴⁴X⁸⁷	X⁴⁴X⁸⁷	X⁴⁴X⁸⁷
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

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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

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
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 <u>(Jan 1 – Mar 31, 2021)</u> Prior to April 1, 2021		Human Immunodeficiency Virus and AIDS drugs that are listed in the Medi-Cal Provider Manual			X ⁵			

**Attachment N
Capitated Benefits Provided in Managed Care**

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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.	<u>X</u>	<u>X</u>	X	<u>X</u>	<u>X</u>	<u>X</u>
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 <u>contract</u> .	X	X	X	X	X	X

**Attachment N
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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.	X⁵X³	X⁵X³	X	X⁵X³	X⁵X³	X⁵X³

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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**

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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

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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

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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	X⁵X^{3,965}	X⁵X^{3,596}	X⁵³	X⁵X^{3,5}	X⁵X^{3,5}	X⁵X^{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>

**Attachment N
Capitated Benefits Provided in Managed Care**

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		<u>beneficiaries people who do not have another way to get to their appointment.</u>						
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

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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	<p>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:</p> <ul style="list-style-type: none"> • 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

**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
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.	X⁹X⁶⁵₁₄	X⁹X⁶⁵₁₄	X⁹X⁶⁵₁₄			
Pharmaceutical Services and Prescribed Drugs <u>(effective Jan 1 – Mar 31, 2024)</u> 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
<u>Pharmaceutical Services and Prescribed Drugs (effective Apr 1, 2021 onward)</u>	<u>Pharmaceutical Services and Prescribed Drugs</u>	<p>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.</p> <p><u>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).</u></p> <p>Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and</p>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>

**Attachment N
Capitated Benefits Provided in Managed Care**

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		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 <u>the same</u> prior authorization <u>procedures that govern physicians</u> , 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.	X⁴	X⁴	X⁴	X⁴	X⁴	X⁴
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 Orthotic 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, 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	X⁸	X	X	X
Rehabilitation Center Outpatient Services	Rehabilitative Services	A facility providing therapy and training for rehabilitation <u>on an outpatient basis</u> . 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

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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 equipment and drugs.	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ 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 ⁷	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 ⁷⁶
Specialty Mental Health 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

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<u>Speech Pathology</u>	<u>Speech Pathology</u>	<u>Speech pathology services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
State Supported Services		State funded abortion services that are provided through a secondary contract.	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
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 <u>and</u> Services-	Targeted Case Management	<u>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.</u> 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						

Attachment N
Capitated Benefits Provided in Managed Care

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		<p>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.</p>						
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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 GenCal Health.~~

⁴ ~~Not covered by GenCal~~ Covered by GenCal 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.~~

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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).

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

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

~~⁹⁻⁶⁵Services 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.~~

~~¹⁰⁻⁷⁶Benefit coverage is limited to only beneficiaries under 21 years of age for services rendered pursuant to EPSDT program requirements.~~

~~¹¹⁻⁸⁻⁷Health 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.~~

Attachment N
Capitated Benefits Provided in Managed Care

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⁸The 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.

⁹California 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 Name]
[Redacted Email]
[Redacted Address]

[Redacted]

[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

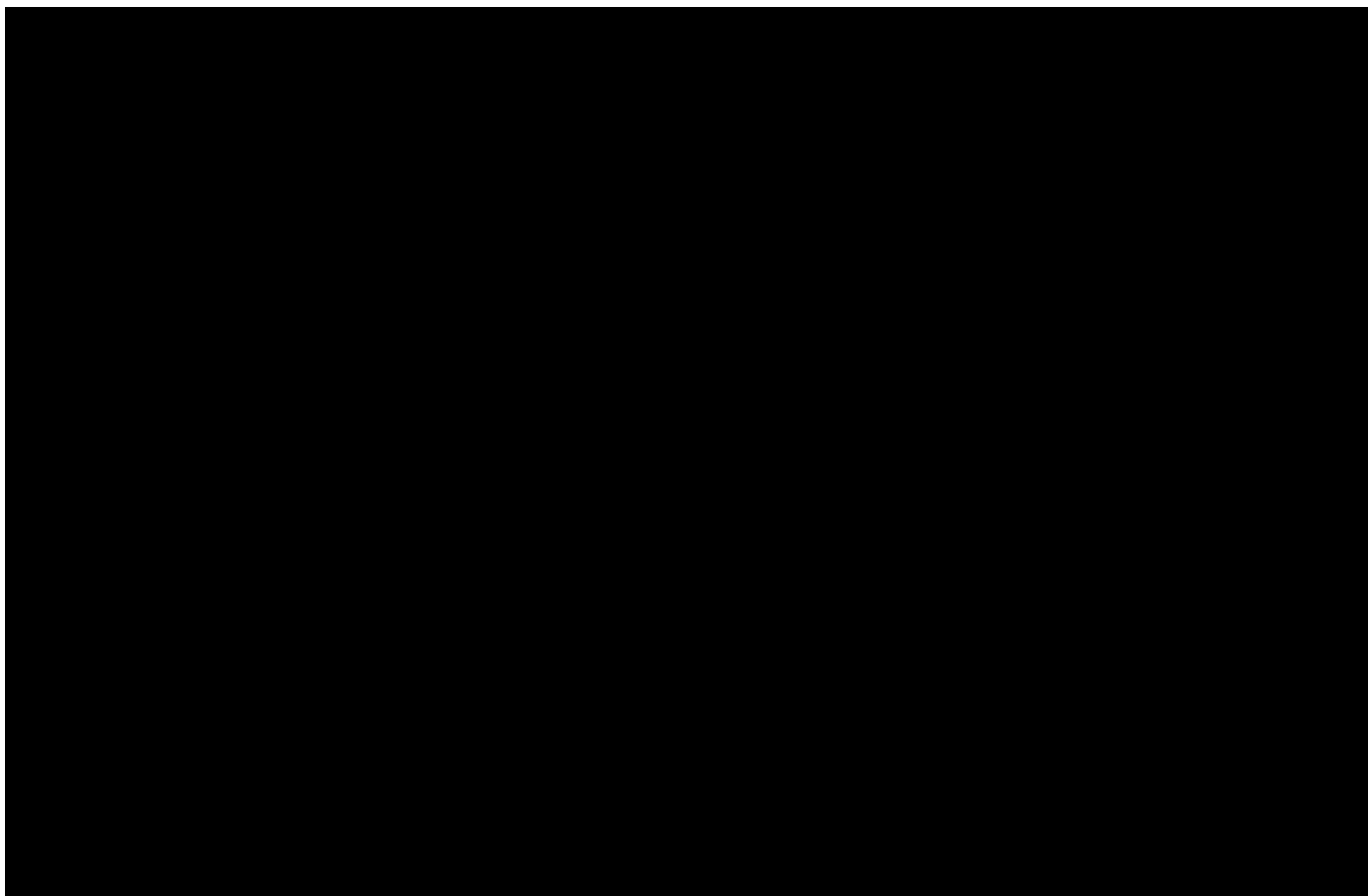


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Exhibit C

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



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[Redacted text block]

[Redacted text block]

[Redacted text block]

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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

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

CONFIDENTIALITY NOTICE: This e-mail and any attachments may contain information which is confidential, sensitive, privileged, proprietary or otherwise protected by law. The information is solely intended for the named recipients, other authorized individuals, or a person responsible for delivering it to the authorized recipients. If you are not an authorized recipient of this message, you are not permitted to read, print, retain, copy or disseminate this message or any part of it. If you have received this e-mail in error, please notify the sender immediately by return e-mail and delete it from your e-mail inbox, including your deleted items folder.

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.



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

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

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services, CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES.
22

23 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

24
25 I, Francisco Castillon, declare as follows:

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

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

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

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

12 4. In order to comply with applicable State and Federal law relating to the
13 340B program OFH has registered each of our FQHC sites that dispenses drugs to Medi-
14 Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B
15 drugs to our Medi-Cal patients.

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

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

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

27 ///

28 ///

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

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

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

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

22 12. If the Medi-Cal Rx Transition became effective on April 1, 2021,
23 approximately seventy percent of our prescriptions would be filled through Medi-Cal's
24 340B-specific fee-for-service reimbursement schedule. This will require changes to our
25 current operations, which may include discontinuing home delivery of drugs to those
26 unable to come to the clinic for health reasons or due to a lack of transportation.
27 Additionally, we would need to discontinue stocking of more expensive medications.

28 ///

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

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

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

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

1 provided primary care services to 131,449 unduplicated patients, and had 588,936
2 patient visits (encounters). The distribution of OFH patients as a percentage of poverty
3 guidelines is 62,160 patients (47.29%) at 100 percent and below the federal poverty
4 level; 10,102 patients (7.69%) at 101 to 150 percent of the federal poverty level; 4,009
5 patients (3.05%) at 151 to 200 percent of the federal poverty level; 2,433 patients
6 (1.85%) at over 200 percent of the federal poverty level; and 52,745 patients (40.13%)
7 whose percent of the federal poverty level is unknown.

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

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

14 19. As reported on our UDS report, with respect to OFH visits involving patients
15 with two or more diseases/diagnoses, the most common diseases/diagnoses involved
16 were: Diabetes Mellitus = 37,494 visits, Overweight and Obesity = 48,295, Hypertension
17 = 52,168, and Heart Disease = 4,747. In addition, the most common visits provided for
18 mental health conditions and substance disorders were: anxiety disorder/PTSD = 37,001,
19 depression and mood disorders = 39,324, and other mental disorders (excluding drug or
20 alcohol dependence) = 22,011.

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

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

7 21. OFH's current 340B prescription drug program includes five (5) onsite and
 8 eighty (80) contract pharmacy sites. From January 1, 2020 through September 30, 2020,
 9 OFH's in-house pharmacies filled 228,791 prescriptions, 26,861 of which were
 10 prescriptions filled for uninsured patients. OFH's 80 contract pharmacies filled nearly
 11 10,000 prescriptions, of which over 10 percent were dispensed for uninsured patients.

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

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

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

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

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

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

8 25. OFH estimates 340B savings generated from our pharmacies through the
9 340B Drug Pricing Program account for about 20 percent of our direct patient care
10 staffing expenses.

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

26 ///

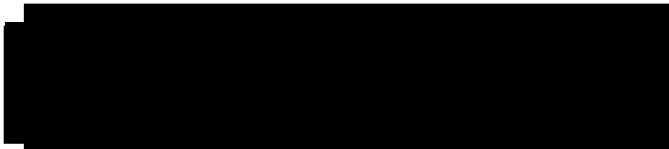
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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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



Francisco Castillon

Exhibit C
to letter dated 4/16/2021

1 HANSON BRIDGETT LLP
KATHRYN E. DOI, SBN 121979
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6 REGINA M. BOYLE, SBN 164181
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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12

13

UNITED STATES DISTRICT COURT

14

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

15

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

18

Plaintiffs,

19

v.

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

22

Defendants.

23

24

25

I, C. Dean Germano, declare as follows:

26

1. I am the Chief Executive Officer ("CEO") of Shasta Community Health

27

Center ("SCHC") and have been in this position since 1992. I am a past Board President

28

of the California Primary Care Association ("CPCA") and am currently Board Emeritus

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

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

14 2. As CEO of SCHC, I am responsible for overseeing care to 40,000
15 unduplicated patients, providing over 130,000 visits a year in a multi-specialty type
16 practice that includes mental health and dental. Over 92% of SCHC's patients live below
17 200% of the federal poverty line. I also have oversight of our 340B Program. For many
18 years, the savings that SCHC has retained through the discounted drug purchase prices
19 available through the 340B program has been used to benefit our patients through such
20 things as the passing of the 340B price to our uninsured and underinsured patients,
21 allowing us to charge many sliding fee patients no more than \$10 for prescriptions at our
22 contract pharmacies, and providing services such as transportation assistance, covering
23 a significant portion of lab costs for sliding fee patients, and covering patient education
24 services and gap funding for departments that are not profitable, such as telemedicine.
25 In 2019, SCHC's 340B Medi-Cal savings totaled \$1.79 million. The Medi-Cal transition to
26 managed care would result in a loss of these savings and would force SCHC to make
27 cuts to these programs that will have a negative impact on patient care and service to our
28 community.

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

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

12 5. In connection with establishing the SPP, in the fall of 2019, the Department
13 and CPCA asked community health centers to report their projected loss of 340B savings
14 to the State. According to CPCA, 109 community health centers submitted data to the
15 State and 91 submitted data to CPCA and the State. The total amount of lost savings
16 reported by the community health centers that responded to the data request was
17 \$105 million. CPCA staff and the CPCA board also appointed a “Solutions Team” to
18 work with the Department regarding implementation of the SPP. I was one of the people
19 appointed to the Solutions Team.

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

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

28 ///

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

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

6 9. Ultimately, the SPP was adopted in the Budget Trailer Bill, and codified as
7 California Welfare & Institutions Code § 14105.467, which became effective on June 29,
8 2020. This legislation requires the Department to "establish, implement, and maintain a
9 supplemental payment pool for nonhospital 340B community clinics, subject to an
10 appropriation by the Legislature." Qualifying FQHCs are to receive fee-for-service-based
11 supplemental payments from a fixed-amount payment pool to compensate them for their
12 loss of 340B program revenue.

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

19 11. Section 14105.467 also requires the Department to establish a stakeholder
20 process that "shall be utilized to develop and implement the methodology for distribution
21 of supplemental pool payments to qualifying nonhospital 340B community clinics."
22 Section 14105.467 further requires the Department to conduct at least three meetings
23 with stakeholders and to finalize the methodology for distribution no later than October 1,
24 2020.

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

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

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

3 (c) The SPP would be simple to administer.

4 (d) The SPP will be renewed annually.

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

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

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

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

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

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

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

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

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

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

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

-7-

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

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

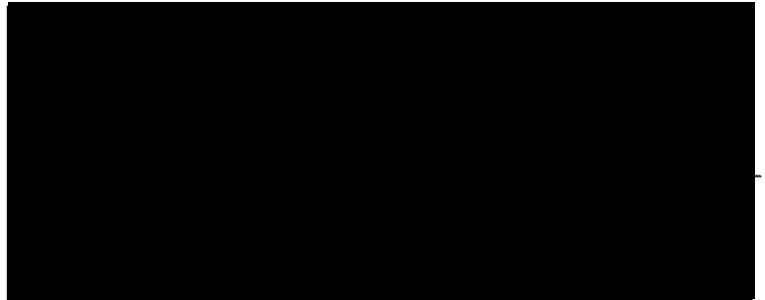
8 20. In my capacity as CEO of SCHC I am also a member of the Board of
9 Directors of Partnership Health Plan of California (“PHP”), a non-profit community based
10 health care organization that contracts with the State to administer Medi-Cal benefits
11 through local care providers, as the Shasta County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

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

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

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



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Exhibit D
to letter dated 4/16/2021

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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

15
16 COMMUNITY HEALTH CENTER
ALLIANCE FOR PATIENT ACCESS, et
17 al.,

18 Plaintiffs,

19 v.

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

22 Defendants.
23

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**

24 I, Ricardo Roman, declare as follows:

25 1. I am the Chief Financial Officer ("CFO") at Family Health Centers of San
26 Diego ("FHCS D") and have held this role since September 2010. As CFO, I report
27 directly to the Chief Executive Officer ("CEO") and am responsible for leading and
28

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

8 2. FHCSO is a Federally Qualified Health Center ("FQHC") that receives
9 federal grant funding under Section 330 of the Public Health Service Act. FHCSO meets
10 all current statutory requirements under Section 330 of the Public Health Service Act.
11 FHCSO has served the medically underserved communities of San Diego County since
12 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health
13 Center, the flagship clinic of FHCSO. FHCSO has since transformed into the tenth
14 largest health center in the country (47 service delivery sites), providing care to over
15 149,000 patients each year, of whom 90 percent are low income (under 200% of Federal
16 Poverty Level) and 31 percent are uninsured. FHCSO serves all patients regardless of
17 their ability to pay.

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

20 4. In order to comply with applicable State and Federal law relating to the
21 340B program, FHCSO has registered each of our FQHC sites that dispenses drugs to
22 Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only
23 340B drugs to our Medi-Cal fee-for-service patients.

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

1 paid at “actual acquisition cost” plus a \$10.05 or \$13.20 dispensing fee.

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

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

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

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

22

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 FHCS D 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, FHCS D’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 FHCS D 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%

1	Race		
2	Asian	9,506	6.37%
3	Native Hawaiian/Other Pacific Islander	1,090	.73%
4	Black/African American	13,331	8.93%
5	American Indian/Alaska Native	839	.56%
6	White	91,968	61.62%
7	More than 1 Race	6,249	4.19%
8	Race Unreported/Refused	26,261	17.60%
9	Ethnicity		
10	Hispanic/Latino	81,076	54.33%
11	Non-Hispanic	56,032	37.54%
12	Ethnicity Unreported/Refused	12,136	8.13%
13	Medical Conditions		
14	Hypertension	23,482	15.73%
15	Diabetes	13,015	8.72%
16	Asthma	7,025	4.71%
17	Symptomatic/Asymptomatic HIV	1,361	.91%
18	Prenatal Care Patients		
19	Number of Patients	3,650	100.00%
20	Number of Patients who Delivered	2,017	55.26%
21	Chronic Disease Management		
22	Use of Appropriate Meds for Asthma	1,127	93.70%
23	Statin Therapy for Prevention & Treatment of Cardiovascular Disease	13,663	78.70%
24	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	2,245	89.67%
25	Controlling High Blood Pressure	21,886	69.74%
26	Diabetes: Controlling Hemoglobin A1c	12,656	64.08%
27	% 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.” FHCS D’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, FHCS D’s 340B onsite pharmacy and contract pharmacy

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

- 6 • Affordable Patient Medication & Pharmacy Programs
- 7 • HIV and Hep C Patient Screening and Care Management
- 8 • Expanded Patient Vision Services
- 9 • Increased Access to Mobile Medical & Mental Health Services
- 10 • Expanded Older Adult Patient Services
- 11 • Critical Workforce Development Initiatives
- 12 • Expanded Clinical Patient Services
- 13 • Patient Weight Management Program
- 14 • Expanded Patient Health Education
- 15 • Urgent Care Services
- 16 • Patient Clinical Care Coordination/Patient Case Management
- 17 • Expanded Patient Specialty Services
- 18 • Patient Quality Improvement Staff and Programs
- 19 • Clinical Computer Upgrades
- 20 • Clinical Infrastructure Upgrades
- 21 • Patient Substance Abuse and MAT Programs
- 22 • Clinical Lab and Point of Care Testing Upgrades
- 23 • Expanded Podiatry Services
- 24 • Patient Security Control
- 25 • PHI Security and Server Upgrades

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

28

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

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

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

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

14 17. FHCSO is also at the heart of the battle against the COVID-19 pandemic in
15 San Diego County. As the largest community clinic organization serving the area,
16 FHCSO's clinics are located in already disadvantaged communities and those hardest hit
17 by the pandemic. As evidenced by the positivity rates seen at FHCSO, health center
18 patients carry more COVID-19 burden than the general population. Since the pandemic
19 onset, FHCSO has performed 35,213 COVID-19 PCR tests with a 16.9% overall test
20 positivity rate. Despite that high positivity over many months, each week in November
21 and December 2020, our test positivity continued to climb to a current rate of 28.5%,
22 more than double California's current test positivity rate of 12.2%. In short, FHCSO and
23 FQHCs across the state are at ground zero of the COVID-19 pandemic. Eliminating the
24 savings realized through the current 340B structure would be devastating to our ability to
25 continue to care for a population with such high test positivity rates. As we near 2021, the
26 drain on FHCSO resources has made it increasingly difficult to maintain quality
27 healthcare for the communities we serve. With high levels of virus in the community, our
28

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

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

12 19. FHCS D has other concerns about the CSOSR process, as well. For
13 example, as part of the CSOSR process, a health center with multiple sites is required to
14 submit a home office cost report in addition to a cost report for each site that is seeking a
15 change to its rate based on a change in the scope of its services. 340B drug costs
16 associated with a health center's contract pharmacy arrangements are not included in the
17 reimbursable costs of the health center because the contract pharmacy (such as a
18 Walgreen's or CVS or corner drug store) incurs all of the costs associated with managing
19 and dispensing the drugs, with the exception of the payment for the replenishment of the
20 drugs, which is paid for by the health center. In connection with an FHCS D CSOSR that
21 is currently under consideration by DHCS, DHCS is proposing to treat FHCS D's 340B
22 drug costs as a non-reimbursable cost center and to allocate an amount of FHCS D's total
23 overhead costs to the non-reimbursable cost center based on the proportion of overall
24 costs represented by the "costs" of the 340B drugs. This proposed adjustment to the
25 home office cost report will result in lower rates for the sites that are undergoing the
26 CSOSR because a disproportionate amount of home office costs will be allocated to the
27 340B drug costs and away from sites that actually use and benefit from the costs

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

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

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

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Ricardo Roman

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Exhibit E
to letter dated 4/16/2021

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17 Attorneys for Plaintiffs
 18 COMMUNITY HEALTH CENTER ALLIANCE
 19 FOR PATIENT ACCESS, ET AL.

20 **UNITED STATES DISTRICT COURT**
 21 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

22 COMMUNITY HEALTH CENTER
 23 ALLIANCE FOR PATIENT ACCESS, et
 24 al.,

25 Plaintiffs,

26 v.

27 WILLIAM LIGHTBOURNE, Director of the
 28 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

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

5 2. DAP was founded in 1984 by a group of community volunteers in the face
 6 of the AIDS crisis. Since that time, DAP has been named one of the "Top 20 HIV/AIDS
 7 Charities" and has expanded its mission to other disenfranchised members of the
 8 Coachella Valley community. Today, DAP is a FQHC that serves over 7,000 active
 9 clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS. The
 10 majority of DAP's clients are low-income, with more than 75 percent of the immediate
 11 population living under 200 percent of the Federal Poverty Level. DAP receives federal
 12 grant funding under Section 330 of the Public Health Service Act. DAP meets all current
 13 statutory requirements under Section 330 of the Public Health Service Act. DAP also is a
 14 340B-eligible Ryan White Part A (RWI) grantee provider organization.

15 3. According to the most recent DAP Uniform Data System ("UDS") report
 16 submitted to the federal Health Resources and Services Administration ("HRSA") for
 17 2019, DAP conducted clinic visits with the following distribution of services for the 7,487
 18 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%

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

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

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

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

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

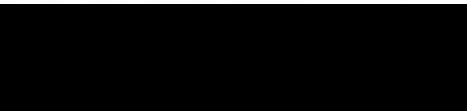
17 9. The 340B Drug Pricing Program requires drug manufacturers to provide
18 discounted pharmaceuticals to health centers and other covered entities – which makes
19 prescription drugs affordable for all FQHC patients, including the uninsured and
20 underinsured. In addition, the savings retained by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

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

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

13 Executed this 16th day of December 2020, in Palm Springs, California.

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David Brinkman

Exhibit F
to letter dated 4/16/2021

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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Kelvin Vu, declare as follows:

25 1. I am currently a family physician at Open Door Community Health Centers
26 ("Open Door"), where I have worked for the last ten years. I also currently serve as Chief
27 Medical Officer at Open Door. I received my medical training from Western University
28 and completed my Family Medicine Residency at the University of California, Davis

1 Medical Center, where I also served as Chief Resident in my final year. As a family
2 physician, I regularly interact with patients, prescribe medications, and ensure my
3 patients are receiving their medications and following the treatment regimens. As the
4 Chief Medical Officer, I also receive reports from the other physicians about the provision
5 of services to their patients, including concerns about challenges and suggestions for
6 improving services. The majority of Open Door's patients are Medi-Cal beneficiaries who
7 are members of a Medi-Cal managed care plan ("MCP"). I have personal knowledge of
8 the facts set forth herein, and if called to do so, could and would testify competently
9 thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition
10 to the Motion for a Preliminary Injunction.

11 2. Open Door is a Federally Qualified Health Center that receives federal
12 grant funds under Section 330 of the Public Health Services Act. Open Door is
13 committed to providing excellent health care and health education to medically
14 underserved patients in the Humboldt and Del Norte Counties, two rural counties in the
15 far northwest region of Northern California along the coast. Open Door currently
16 operates twelve community health centers across both counties, serving more than
17 55,000 patients each year while employing nearly 700 members of the community.

18 3. Humboldt and Del Norte Counties are predominately rural, and tend to rank
19 near the bottom for health outcomes among California counties. Like many rural areas,
20 our patients struggle with widespread problems of poverty, opioid use disorder, lack of
21 health education, lack of reliable housing and transportation, and numerous other socio-
22 economic barriers to health care that directly affect their well-being in the short and the
23 long term. As a physician who has worked in this community for ten years, I am well-
24 aware that these socio-economic problems often cause my patients to forego necessary
25 medical treatments in order to focus on other urgent aspects of their lives, such as going
26 to work to support their families, or using their limited incomes to buy food or pay rent
27 instead of paying for their prescribed medications.

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1 4. Open Door is committed to meeting our patients where they need us to be.
2 To that end, we operate under a patient-centered medical home model (“Medical Home”)
3 that allows us to coordinate an individual patient’s care across specialties so that we treat
4 the whole person, rather than individual symptoms. As their Medical Home, Open Door
5 proudly serves as a one-stop-shop for all of our patients’ medical needs, as well as their
6 unique needs for accessing transportation assistance, housing, and food. The Medical
7 Home also helps patients follow their medical treatment plans because they do not need
8 to go to multiple facilities – all of their providers are in one place, which greatly improves
9 the patients’ overall health outcomes.

10 5. The Medical Home includes coordination with pharmacy services and the
11 MCP member services team. The ability for me as a prescribing physician to work
12 directly with the MCP and case managers greatly improves my patients’ ability to access
13 necessary treatments. For example, if I prescribe a Lidocaine patch – a non-opioid
14 chronic pain treatment – I will have access to real-time information regarding what the
15 cost will be to the patient, when and if the patient is able to pick up the patch, or if the
16 patch is not covered by the patient’s plan. If the Lidocaine patch is not available for some
17 reason, I am able to find out immediately and make same-day adjustments to the
18 treatment plan so that my patient’s needs are met. This is just one concrete example of
19 how the pharmacy benefit’s inclusion in managed care facilitates medical services for
20 both doctors and patients, leading to better care and outcomes for the most vulnerable,
21 medically underserved people in California.

22 6. The inclusion of the pharmacy benefit in managed care also enables me to
23 tailor my treatment plan to the patient’s needs. With the pharmacy and medical benefits
24 linked, the current managed care model allows me to see and track if my patients are
25 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
26 returning for medical follow-ups on time. This information is critical to creating a
27 treatment plan for my patients, tracking their progress and condition, and scheduling
28 necessary follow-up appointments.

1 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
2 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
3 This will directly undermine Open Door's Medical Home model and my ability to treat my
4 patients effectively. For example, disconnecting pharmacy services from medical
5 services will require our patients to take multiple trips to receive their care and their
6 medication. For most of my patients, this is not simply one more errand in their day – it is
7 an insurmountable barrier because they do not have access to reliable transportation to
8 make multiple trips, or they cannot take additional time from work during the day, or they
9 need to be home to take care of children or other family members.

10 8. Additionally, Medi-Cal Rx will fundamentally alter the way I and other Medi-
11 Cal providers at FQHCs will be able to treat our patients. For example, I will no longer
12 have access to real-time information as to the availability of medications or my patients'
13 adherence to the treatment plan. Using the example of the Lidocaine patch discussed
14 above, under the Medi-Cal Rx fee-for-service model, I would prescribe the patch and my
15 patient would have to make a separate trip to a pharmacy to get it. However, if that
16 pharmacy does not have it in stock or the pharmacist needs prior authorization, I will no
17 longer be notified as part of managed care and will not necessarily be advised that my
18 patient was unable to pick up their prescription. Because of the type of patients I work
19 with and the challenges they face in making multiple trips to different healthcare
20 providers, there is a high likelihood that my patient would forego the treatment altogether.
21 I would not discover the problem until months later in a follow-up visit with my patient, at
22 which point their condition and pain has worsened because they could not access the
23 treatment I prescribed.

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1 9. It is also my understanding that Medi-Cal Rx will also change Open Door's
2 and other FQHCs' reimbursement for drugs purchased under the federal 340B drug
3 discount program. I am gravely concerned that the proposed fee-for-service
4 reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would
5 not cover the cost of providing necessary pharmacy services to my patients.

6 10. In addition, the savings and reimbursement Open Door receives from the
7 340B program go directly to providing additional, much-needed services for our patients that
8 are not otherwise reimbursed by Medi-Cal. One key example is Open Door's Medication
9 Assistance ("MAT") Program. MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid use disorder to overcome and manage their addiction. The drug is very
12 expensive, so without 340B pricing, our patients would not be able to receive it at all.
13 Additionally, MAT includes support groups that help patients maintain sobriety, which
14 requires efforts from case managers and member services staff. However, these
15 counseling services are not reimbursable by the Medi-Cal program, and are instead
16 directly funded by 340B revenue and savings. Without services like our MAT Program,
17 Open Door's patients will be denied access to a highly effective treatment option that can
18 help them get away from opiates and improve their overall lifestyle.

19 11. Based on my experience as a family physician at an FQHC, I believe that
20 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
21 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
22 as how those patients access their Medi-Cal benefits. I am greatly concerned that
23 removing the pharmacy benefit from managed care will directly prevent Open Door's
24 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
25 their unique and varied needs. Additionally, the loss of 340B revenue will force Open
26 Door to cut off critical resources for patients who are struggling with opioid use disorder
27 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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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Paramvir Sidhu, declare as follows:

25 1. I am currently a family physician at Family Health Care Network ("FHCN"),
26 where I have worked for the last ten years. I also currently serve as Chief Clinical Officer
27 at Family Health Care Network. I received my medical training in India and completed
28 my residency in family medicine at the Riverside Community Medical Center, Riverside,

1 California. As a family physician, I regularly interact with patients, prescribe medications,
2 and ensure my patients are receiving their medications and following the treatment
3 regimens. As the Chief Clinical Officer, I also receive reports from the other physicians
4 about the provision of services to their patients, including concerns about challenges and
5 suggestions for improving services. The majority of FHCN patients are Medi-Cal
6 beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). Although
7 FHCN is not a named plaintiff in this action, it is an affiliate of the Community Health
8 Center Alliance for Patient Access. I have personal knowledge of the facts set forth
9 herein, and if called to do so, could and would testify competently thereto. I make this
10 declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a
11 Preliminary Injunction.

12 2. FHCN is a Federally Qualified Health Center ("FQHC") that receives federal
13 grant funds under Section 330 of the Public Health Services Act. FHCN is committed to
14 providing excellent health care and health education to medically underserved patients in
15 the Tulare, Kings and Fresno Counties, three rural counties in the San Joaquin Valley of
16 Central California. FHCN currently operates forty-one (41) community health centers
17 across these counties, serving more than 221,000 patients each year while employing
18 nearly 1,500 members of the community.

19 3. The patients we serve from Tulare, Kings and Fresno counties are
20 predominately from rural communities, and tend to rank near the bottom for health
21 outcomes among California counties. Our patients struggle with widespread problems of
22 poverty, lack of health education, lack of reliable housing and transportation, and
23 numerous other socio-economic barriers to health care that directly affect their well-being
24 in the short and the long term. A large majority of our patients are Seasonal and Migrant
25 farmworkers who suffer from severe health care disparities. As a physician who has
26 worked in this community for ten years, I am well aware that these socio-economic
27 problems often cause my patients to forego necessary medical care in order to focus on
28 other urgent aspects of their lives. These patients have to choose between utilizing their

1 limited resources to either buy food or pay rent to support their families, or pay for their
2 prescribed medications.

3 4. FHCN is committed to meeting our patient's needs and provide access to
4 quality medical care to everyone. We are Joint Commission Accredited clinics and we
5 operate under a patient-centric medical home model ("Medical Home") that allows us to
6 coordinate an individual patient's care across specialties so that we treat the whole
7 person, rather than individual symptoms. As their Medical Home, FHCN proudly serves
8 as a one-stop-shop for all of our patients' medical needs, as well as their unique needs
9 for accessing transportation assistance, housing, and food and connect the patients with
10 resources in the communities. The Medical Home also helps patients follow their medical
11 treatment plans because they do not need to go to multiple facilities – all of their
12 providers are in one place, which greatly improves the patients' overall health outcomes.

13 5. A part of the Medical Home also includes pharmaceutical services for our
14 patients. Having pharmacies in our health centers and medications under the 340B
15 program allows me as a prescribing physician to work directly with the pharmacists and
16 greatly improve my patients' ability to access necessary treatments. For example, if I
17 prescribe Insulin– a lifesaving treatment for diabetes – I will have access to real-time
18 information as to when and if the patient is able to pick up the medication at a very
19 affordable price. If the Insulin is not available for some reason or not covered by the
20 patient's plan, the pharmacist is able to call and inform me and provide alternatives to the
21 medication. This allows me to make same-day adjustments to the treatment plan and
22 patient leaves the visit with medications. Relatedly, our in-house pharmacists have
23 access to a patient's Electronic Health Record, allowing them to track prescription
24 dosages and types, which enhances patient safety. For example, our pharmacist can
25 see and verify the weight of a pediatric patient who is prescribed antibiotics for an
26 infection, verify the dosage calculation, and consult with me prior to the patient leaving
27 the health center. Another example would be the pharmacist reviewing the medical
28 record and noting additional medications or supplements listed in the patient's medication

1 list that could have contraindications when taken with the prescribed medication. Again,
2 this can be discussed with me before the patient leaves the health center. These are just
3 a few concrete examples of how the pharmacy benefit's inclusion in managed care
4 facilitates medical services for both doctors and patients, leading to better care and
5 outcomes for the most vulnerable, medically underserved people in California.

6 6. The inclusion of the pharmacy benefit in managed care also enables me to
7 tailor my treatment plan to the patient's needs. First, with the pharmacy and medical
8 benefits linked, the current managed care model allows me to see if my patients are
9 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
10 returning for medical follow-ups on time. This information is critical to creating a
11 treatment plan for my patients, tracking their progress and condition, and scheduling
12 necessary follow-up appointments. Second, the 340B savings allow us to operate a
13 robust in-house pharmacy program, including a Director of Pharmacy who sits on our
14 Medical Director Team. This coordination allows us to create a formulary for our
15 pharmacy specific to the clinical needs of our patient population and at the lowest
16 acquisition price possible, benefiting our patients both clinically and financially. Without
17 the 340B program, this cross-collaboration and comprehensive care management will not
18 be possible, as the dramatic cuts that would need to be made to our in-house pharmacies
19 would no longer allow us to have a Director of Pharmacy, and pharmacists would no
20 longer be able to dedicate time to comprehensive care management.

21 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
22 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
23 This will directly undermine FHCN's Medical Home model and my ability to treat my
24 patients effectively. For example, disconnecting pharmacy services from medical
25 services will require our patients to take multiple trips to receive their care and their
26 medication. For most of my patients, this is not simply one more errand in their day – it is
27 an insurmountable barrier because they don't have access to reliable transportation to
28 make multiple trips, or they cannot take additional time from work during the day, or they

1 need to be home to take care of children or other family members.

2 8. It is also my understanding that Medi-Cal Rx will also change FHCN's and
3 other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount
4 program. I am gravely concerned that the proposed fee-for-service reimbursement,
5 actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the
6 cost of providing necessary pharmacy services to my patients. It will also impact our
7 ability to provide other benefits that are significant to our patients. For instance, we
8 currently have an extensive patient transportation program that provides door-to-door
9 service from a patient's home to the health center, which we would need to be scaled
10 back or eliminated if we no longer received revenue from the 340B program.
11 Additionally, we will have to increase the nominal fee offered to uninsured patients on our
12 pharmacy sliding fee scale, which will increase the costs for patients who cannot afford
13 higher out-of-pocket expenses for medical care. Such a change could result in uninsured
14 patients forgoing prescriptions, leading to worse health outcomes.

15 9. Medi-Cal Rx will also fundamentally alter the way I and other Medi-Cal
16 providers at FQHCs will be able to treat our patients. For example, FHCN has a Diabetic
17 clinic where the goal is to provide coordinated diabetic care to patients. This includes the
18 patient getting education about diabetes from health educators, necessary screenings
19 and immunizations, and behavioral-health counseling. These services are in addition to
20 medical care and treatment the physicians provide during the same (single) visit for the
21 patient. Using the example of the Insulin discussed above, under the Medi-Cal Rx fee-
22 for-service model, I would have to prescribe the Insulin and my patient would have to
23 make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it
24 in stock, the cost is too high, or the pharmacist needs prior authorization, I will not be
25 notified immediately that my patient was unable to pick up their prescription. Because of
26 the type of patients I work with and the challenges they face in making multiple trips to
27 different healthcare providers, there is a high likelihood that my patient would forego the
28 treatment altogether. I would not discover the problem until months later in a follow-up

1 visit with my patient, at which point their condition has worsened and severe
2 complications developed because they could not access the treatment I prescribed, or
3 the supportive Diabetic clinic services. The result for that patient is deteriorated clinical
4 outcomes and, most likely, costly trips to the emergency room paid for by the Medi-Cal
5 program for a Medi-Cal beneficiary.

6 10. In addition, the savings and reimbursement FHCN receives from the 340B
7 program go directly to providing additional, much-needed services for our patients that are
8 not otherwise reimbursed by Medi-Cal. One key example is FHCN's Medication
9 Assistance Program ("MAT"). MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid addiction to overcome and manage their addiction. The drug is very expensive, so
12 without 340B pricing, our patients would not be able to receive it at all. Additionally, the
13 MAT clinic includes counseling that help patients maintain sobriety, which requires efforts
14 from Behavioral Health and member services staff. However, some of these ancillary
15 services provided in the MAT clinic as well as the above mentioned Diabetic clinic are not
16 reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue
17 and savings. Without programs like MAT, FHCN's patients will be denied access to a
18 highly effective treatment option that can help them get away from opiates and improve
19 their overall lifestyle.

20 11. Based on my experience as a family physician at an FQHC, I believe that
21 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
22 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
23 as how those patients access their Medi-Cal benefits. I am greatly concerned that
24 removing the pharmacy benefit from managed care will directly interfere with FHCN's
25 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
26 their unique and varied needs. Additionally, the loss of 340B revenue will force FHCN to
27 cut off critical resources for patients who are struggling with opioid addiction and other
28 chronic conditions like Diabetes.

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

3 Executed on this 5 day of February, 2021, in VISALIA, California.
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8 DR. PARAMVIR SIDHU
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Exhibit H
to letter dated 4/16/2021

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 9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
 COMMUNITY HEALTH CENTER ALLIANCE
 11 FOR PATIENT ACCESS, ET AL.

12

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UNITED STATES DISTRICT COURT

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EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

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v.

20 WILLIAM LIGHTBOURNE, Director of the
 California Department of Health Care
 Services; CALIFORNIA DEPARTMENT
 21 OF HEALTH CARE SERVICES,
 22

Defendants.

23

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

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I, Fran Butler-Cohen, declare:

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1. I am the Chief Executive Officer ("CEO") at Family Health Centers San

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Diego ("FHCS D") and have held this role since 1986. I have reviewed the data and

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associated outcomes relevant to the impact of Medi-Cal Rx on FHCS D in connection with

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the preparation of this declaration. I have personal knowledge of the facts set forth

1 herein, and if called to do so, could and would testify competently thereto. I make this
2 declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

3 2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives
4 federal grant funding under Section 330 of the Public Health Services Act. FHCSD has
5 served the medically underserved communities of San Diego County since 1970, with the
6 transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's
7 flagship clinic. FHCSD has since transformed into the tenth largest health center in the
8 country, providing care to over 149,000 patients each year, of whom 90 percent are low
9 income and 31 percent are uninsured. FHCSD serves all patients regardless of their
10 ability to pay.

11 3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020,
12 FHCSD has provided free COVID-19 testing to as many patients as the staff can
13 manage. During this time, demand for FHCSD services has skyrocketed. To try to meet
14 our patients' testing needs, FHCSD has purchased additional lab equipment and
15 increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid
16 testing and notification systems to quickly identify patients with COVID-19 and reduce
17 community spread. Additionally, we have set up a separate obstetrics clinic for mothers
18 who have tested positive for COVID-19. These steps have proven necessary, since,
19 among the patients we serve, the COVID positivity rate in the second week of January
20 2021 was 35 percent, more than double the average statewide rate for the same time
21 period.

22 4. In an effort to take care of patients and to avoid sending them to hospitals –
23 which currently cannot handle an additional influx of patients – FHCSD has also ramped
24 up its ability to care for the sickest, non-emergent patients. Instead, we have started
25 Monoclonal Antibody administration for the sickest, non-emergent patients at one of our
26 clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as
27 soon as possible.

28 ///

1 5. Despite the heroic efforts of our health care workers – who have shouldered
2 the burden of coming to work every day risking their own health and the health of their
3 families – FHCS D staff is stretched beyond its limits and is struggling to continue. We
4 currently have seventy (70) members of our team out of work due to COVID, which hurts
5 FHCS D’s ability to meet patients’ needs and county demands. We have started an
6 emergency child care program to keep our workers on the job when they have no other
7 childcare options. We have also started an Employee Food Pantry Program so that
8 employees who have lost income can feed their families.

9 6. Now, with the development of a COVID-19 vaccine, San Diego County is
10 asking FHCS D to submit information regarding how many vaccinations we could
11 administer to the general public, which requires me and the FHCS D staff to study
12 guidance from the Centers for Disease Control and the Department of Defense to
13 implement massive public vaccination events, in addition to juggling the current
14 emergency needs of our patients and community.

15 7. Simultaneously, FHCS D is still required to commit time to fielding
16 government audits and meet with the State and Managed Care Organizations on metric
17 performance. In addition, FHCS D is currently in the beginning stages of a random federal
18 340B audit that has already taken several hundred hours of staff time in preparation and
19 document submission. At the same time, the Health Resources and Services
20 Administration is requesting capital funding grantees submit previously unrequired data
21 and qualitative information to help them design future grant programs. Moreover,
22 FHCS D has had to make significant modifications to contract pharmacy arrangements to
23 ensure our patients receive affordable medications due to the attack on the 340B
24 program by pharmaceutical manufacturers. All of this comes against the backdrop of the
25 State of California awarding a contract valued at approximately \$80 million annually to a
26 for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by
27 Centene, a publicly traded NYSE corporation worth \$76 billion for \$2.2 billion dollars to
28 ///

1 facilitate the state in their plan that will remove hundreds of millions of dollars from the
2 state's health care safety-net.

3 8. It is unconscionable that during this time of perpetual crisis, when our staff
4 and other healthcare workers have sacrificed so much to serve the communities that
5 need them most, FHCS and other FQHCs are required to prepare and plan for Medi-
6 Cal Rx, which will result in drastic funding reductions due to changes in reimbursement.
7 Additionally, the loss of 340B funding that helps stretch our resources to expand
8 healthcare access will further reduce staff and desperately needed health services.

9 9. Although the "effective" date of Medi-Cal Rx has been moved to April 1,
10 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring
11 health centers to adjust our conduct in a number of ways. Examples of some of the
12 activities FHCS has had to undertake in anticipation of the "go live" date for Medi-Cal
13 Rx include:

- 14 • A complete budget review and assessment of programs currently
15 funded through 340B savings, including the potential for lay-offs,
16 elimination of support programs, and reduction in hours and types of
17 services provided to our patients.
- 18 • Meetings with vendors that currently support in-house pharmacy
19 operations to ensure systems remain compliant following full
20 implementation.
- 21 • Subscribe to and dedicate staff time to monitor, review and bring
22 forward issues noted in regular updates from the Medi-Cal Rx
23 Subscription Service
- 24 • Secure Provider Portal access and enroll approximately 250
25 prescribing providers into the provider portal, necessitating hundreds
26 of hours of administrative staff time.

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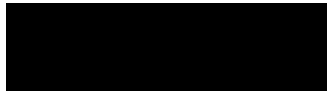
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1 patients who have suffered the most throughout the COVID-19 emergency will also bear
2 the burden of the Medi-Cal Rx initiative's consequences.

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

5 Executed this 20th day of January, 2021, at San Diego, California.

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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](#)
2. [Updates to the List of Covered Enteral Nutrition Products](#)
3. [Medi-Cal Provider Training Schedule](#)
4. [Prescriber Phone Campaign](#)
5. [Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey](#)
6. [Pharmacy Provider Self-Attestation Period Begins April 2021](#)
7. [Portal Registration](#)

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 SabaSM 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.

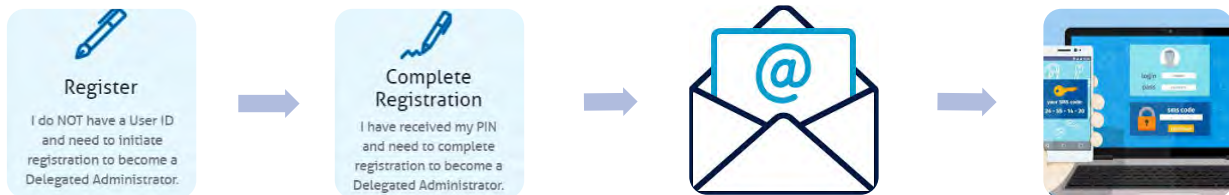
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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 6, 2021

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

Submitted via email to CalAIMWaiver@dhcs.ca.gov

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

Dear Director Lightbourne,

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

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

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

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

Comments

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

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

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

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

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

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

The Cal AIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although we recognize a statewide need to enhance access to both sets of services in a coordinated manner, we see several issues that need to be addressed in order to ensure that counties are prepared to adequately meet the demand for services and patients/families can be assured they are receiving the highest quality of care. Most notably, we are concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs are consolidated. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, 2017/18 External Quality Review Organization (EQRO) reported that several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care. Thus, while Northeastern Rural Health Clinics agrees that the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure access to timely and quality SMH/SUD services.

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

Northeastern Rural Health Clinics is pleased to see the inclusion of Enhanced Care Management and In-lieu-of Services in the Cal AIM proposal as well as the Administration's commitment to ensure adequate funding is allocated for these services in this year's budget. However, to ensure successful implementation of these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to work together. We are encouraged by the inclusion of the Providing Access and Transforming Health Supports, which is necessary to transition existing services

and build up capacity, including payments for new staffing and infrastructure. Supports are also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care.

We are concerned with several program elements that might impact their current operation and infrastructure, namely implementation of a new care management system and process, new care referral process or new claim submission process, new patient assignment process and other. Yet more is needed. Therefore, we respectfully ask DHCS to ensure ample resources and support available to ECM and ILOS providers.

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

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

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

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

Again, Northeastern Rural Health Clinics appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Michael Schaub, CEO, at 530-251-1424, or by email at mschaub@northeasternhealth.org.

Sincerely,

Michael Schaub, CEO
Northeastern Rural Health Clinics



May 6, 2021

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

Submitted via email to CalAIMWaiver@dhcs.ca.gov

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

Dear Director Lightbourne,

On behalf of California's 1,370 community clinics and health centers (CHCs) and the 7.2 million patients they serve, the California Primary Care Association (CPCA) appreciates the opportunity to comment on the proposed CalAIM Section 1115 Section 1915(b) Waiver Amendment and Renewal Applications.

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

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

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

Comments

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

We are aware of the time and investment the state committed to the design and vision of Medi-Cal Rx. However, providers and health plans have systems in place today that ensure pharmacy access for Medi-Cal beneficiaries. Delaying the transition at the last minute, as was done in December 2020 and again in April 2021, will undermine already strained delivery systems and further confuse and worry

Medi-Cal beneficiaries. To that end, we ask DHCS to continue to delay the pharmacy transition to ensure no disruption in pharmaceutical access and guarantee patient access to their current pharmacy through the COVID-19 pandemic. Recognizing the rapidly evolving pandemic response, as well as the current challenges and unknown resolution to conflict concerns with the project's contractor vendor, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

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

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

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

The Cal AIM proposal will integrate county mental health plans and Drug Medi-Cal Organized Delivery Systems into a single behavioral health plan. Although we recognize a statewide need to enhance access to both sets of services in a coordinated manner, we see several issues that need to be addressed in order to ensure that counties are prepared to adequately meet the demand for services and patients/families can be assured they are receiving the highest quality of care. Most notably, we are concerned with how the state will hold county behavioral health plans accountable for performance with managed care responsibilities, especially when the administration of two discrete programs are consolidated. Recent statewide audits of SMH plans found that counties were deficient in meeting quality and timely access goals. In fact, 2017/18 External Quality Review Organization (EQRO) reported that several SMH plans did not have performance improvement plans, functioning quality improvement committees, and failed to meet culture-specific and community defined best practices for communities, perpetuating ongoing disparities in access and care. Thus, while CPCA agrees that the integration of SMH/SUD into specialty behavioral health is necessary, there must be necessary safeguards to ensure access to timely and quality SMH/SUD services.

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

CPCA is pleased to see the inclusion of Enhanced Care Management and In-lieu-of Services in the Cal AIM proposal as well as the Administration's commitment to ensure adequate funding is allocated for these services in this year's budget. However, to ensure successful implementation of these elements, it

is important that community-based organizations, including health centers, have the tools and resources needed to work together. We are encouraged by the inclusion of the Providing Access and Transforming Health Supports (PATHS), which is necessary to transition existing services and build up capacity, including payments for new staffing and infrastructure. Supports are also needed to guarantee data exchange, establish payment relationships, measure value and outcomes, and ensure that beneficiaries remain at the center of care. Currently, DHCS is working with two consulting firms to provide technical assistance to counties and Medi-Cal managed care plans, yet there has been no public announcement on DHCS intent or plan to provide technical assistance to community providers.

We are concerned with several program elements that might impact current operation and infrastructure, namely implementation of a new care management system and process, new care referral process or new claim submission process, new patient assignment process and other. Significant support for providers is needed to ensure successful implementation of CalAIM. Therefore, we respectfully ask DHCS to ensure ample resources and support available to community providers who are considering or sign on to participate in the ECM and ILOS programs.

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

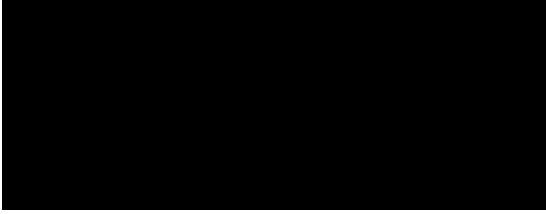
While we appreciate the opportunities to comment on the 1115 and 1915(b) waivers and expect DHCS will release other policy changes for public comment in the future, we would like to underscore the importance of gathering and incorporating stakeholder input into final policies. Specifically, we request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

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

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

Again, CPCA appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes. If you have any questions, please contact Trong Le at tle@cpcpa.org.

Sincerely,



Andie Martinez Patterson
Senior Vice President
California Primary Care Association



May 5, 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:

Vista Community Clinic (VCC) 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, VCC 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.

Vista Community Clinic is an FQHC that cares for Medi-Cal and uninsured patients in San Diego, Riverside, and Orange 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 our two VCC pharmacies and 107 contract pharmacy locations.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows VCC 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, Vista Community Clinic annually saves an estimated \$3.7M through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow VCC 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, VCC 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.

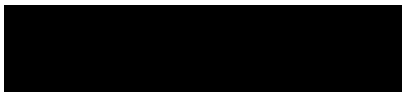
Yet, Medi-Cal Rx will impede our and other FQHCs’ ability to provide these critical services to patients. The proposed FFS reimbursement, compounded by the loss of 340B savings, will force FQHCs to reduce services. This directly undermines the whole-person care approach and the purpose of Medi-Cal, which 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. Vista Community Clinic incorporates by reference the CHCAPA public comment letter into this letter. VCC 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, Vista Community Clinic urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS’ consideration. Doing so will enable VCC 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. Vista Community Clinic looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,



Fernando Sañudo, MPH
Chief Executive Officer

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>.

To: Will Lightbourne, Director, California Department of Health Care Services
From: Susan Gallagher, MMPA, Executive Director
Date: May 6, 2021
Subject: California Advancing and Innovating Medi-Cal (CalAIM): Behavioral Health

On behalf of Cal Voices (formerly known as Mental Health America of Northern California) and the consumers we serve, I offer the following comments on the California Department of Health Care Services' (DHCS) California Advancing and Innovating Medi-Cal (CalAIM).

Cal Voices is dedicated to improving the lives of residents in the diverse communities of California through advocacy, education, research, and culturally relevant services. In all of our programs, Cal Voices works with individuals and families with mental health challenges to promote wellness and recovery, prevention, and improved access to services and support. Cal Voices staff strive to provide peer services that foster recovery, reduce stigma and discrimination, and improve cultural competency through self-help, education, and culturally relevant research. For over 70 years, Cal Voices has provided mental health consumers with culturally-affirming peer support services, assistance in navigating various human service agencies, and advocacy for consumer-oriented public mental health policies.

Cal Voices applauds DHCS' goals of CalAIM, including the goal to improve the delivery of quality Medi-Cal behavioral health services for Californians, regardless of age, culture, and geographic location. We also support DHCS' goal to consolidate Medi-Cal managed care programs (Medi-Cal Managed Care, Specialty Mental Health Services under the County Mental Health Plans, and the Drug Medi-Cal Organized Delivery System) under the same authority, which will hopefully decrease the fragmentation of the current system of care.

Of general concern is the lack of detail for each proposal. The old adage holds true: *the devil is in the details*. For example, "Enhanced Care Management" and "In Lieu of Services" are identified as key elements throughout CalAIM but are not defined, and are listed as optional. Given DHCS's history of lack of authentic engagement with consumers, family members, and private providers who provide the vast majority of behavioral health supports and services in the state, Cal Voices, and those we represent, are concerned that the "new" system will continue to include bureaucratic barriers to care, thereby failing to achieve the vision that is presented in the plan. Therefore, DHCS must actively engage non-governmental stakeholders as equal partners in fleshing out the details for all elements of the plan and for on-going monitoring and improvement to the system of care.

A second general concern is the limited reference to cultural competency. Apart from the introduction of cultural health care workers and natural healers (a service limited to Native American healers providing substance abuse services) there are little, if any, elements that address cultural diversity and disparity in mental health services. For example, LGBTQ older adults are at high risk of abuse from in-home caregivers, who are often under paid and from cultures that hold anti-LGBTQ beliefs.

Additionally, the CalAIM proposal is lacking focus on recovery/wellness oriented care. Principles in keeping with SAMHSA “Bringing Recovery Oriented Services to Scale” should be embedded in all elements of CalAIM (found at <https://www.samhsa.gov/brss-tacs/about>) and California should take advantage of SAMHSA technical assistance to meet these goals.

The remainder of this memo will address what we see as the primary strengths and challenges of each section of the renewal request:

“No Wrong Door”

Strength: CalAIM proposes a “no wrong door” philosophy to ensure individuals receive services prior to a diagnosis, including preventative services, regardless of which part of the system they first present.

Challenge: Coordination between service sectors is currently poor or non-existent, depending on the location. DHCS has long required an MOU between the MMCP and the County MHPs which has included a requirement to describe methods of coordination of care, but DHCS has failed to monitor the compliance with this requirement, let alone the quality of any MOUs submitted.

Two additional barriers to the vision of “no wrong door” currently exist and need to be addressed: 1) separate provider networks and funding levels of the mental health and substance use systems; and 2) inability to access services when an individual is outside of their county of residence.

Recommendation:

1. DHCS should strengthen the detailed requirements of the MOU between the MMCPs and MHP as well as contracts with each to accomplish the goals of “no wrong door”, seamless transitions, and timely access to all medically necessary services, including preventive services.
2. DHCS should create a Behavioral Health Accountability Commission comprised of non-governmental stakeholders including adult and youth consumers, family members, private/non-profit providers, legal advocates, and other stakeholders to assist in monitoring the quality and accuracy of MOUs and contract compliance, as well as to provide recommendations for program and system improvement to DHCS and the legislature.
3. Clarify that substance use/abuse services can be provided directly from, or in coordination with, the mental health provider, as medically necessary and within the scope of practice of the provider.
4. Develop a system of care that allows for “out of county/network” care when a beneficiary is outside of their county of residence and experiences a behavioral health need.

Changes to Behavioral Health Medical Necessity Criteria

Strength: CalAIM attempts to address many of the primary barriers individuals face when attempting to access needed mental health services: outdated “Medical Necessity Criteria”, streamline assessment and documentation requirements, and ensure auditing processes with increasing access to quality and timely mental health services.

Challenges: Details of how DHCS will accomplish these goals are lacking. Historically, DHCS, County MHP, and many throughout the state have mistakenly defined “specialty” mental health as those services designed to address “severe” mental health need, without a consistent definition of “mild, moderate, and/or severe” and ignoring the enhanced mandates to those under age 21 through the Early, Periodic, Screening Diagnosis, and Treatment (EPSDT) benefit. Additionally, language in the contracts between DHCS and the County MHPs have allowed each MHP to create additional definitions, requirements and restrictions related to medical necessity, services, documentation, and audits.

Recommendations:

1. DHCS should provide and clearly define medical necessity criteria. In the case of youth under age 21, DHCS must release medical necessity definitions which are compliant with SB 1287 (Statutes 2018) and federal statute. DHCS must then monitor MMCPs and County MHPs to ensure the standards are being applied consistently throughout the state.
2. DHCS should develop assessment tools and documentation requirements that are applied consistently throughout the state. Any assessment tool or documentation that an MMCP or MHP plans to add must be submitted to DHCS and the aforementioned Behavioral Health Accountability Commission, including a justification statement, for approval before it can be used.
3. A statewide Electronic Health Record (preferred) or Health Information Exchange needs to be developed to ensure coordination of care and increase the consistency of documentation. It is unconscionable that a state housing Silicon Valley has such an antiquated data system.
4. MMCP and MHP should be prohibited from adding auditing standards for their network providers and/or contractors.

Traditional Healers and Natural Helpers in DMC-ODS:

Strengths: CalAIM proposes to introduce Indian Health Care Providers into the DMC-ODS waiver, increasing access to competent providers.

Challenges: Limiting “traditional healers and natural helpers” to Indian Health Care Providers and only in the DMC-ODS system is unacceptably limiting. Additionally, traditional healers and natural helpers are already able to deliver mental health services as an “Other Qualified Provider” or other approved mental health provider, but are not routinely used by either the MMCP or MHP.

Recommendations:

1. Expand access to and employment of recognized traditional healers and/or natural helpers of each of California’s unique cultures (defined by the cultural group themselves) for both mental health and substance use/abuse services. Culture must be defined beyond race and ethnicity, and include gender identity, sexual orientation, generation, and geographic region.
2. Immediately issue guidance to MMCPs and MHPs that describes their ability to utilize these essential members of the behavioral health workforce now through the provider category of “other qualified provider” or other provider category.

Payment Reform:

Strengths: CalAIM proposes to transition to a payment structure that is designed to decrease administrative burdens and increase quality and value based care.

Challenges: The proposal transitions to HCPCS level I and level II codes and will establish reimbursement rate after implementation to determine actual costs. The crosswalk to current codes has not been provided to stakeholders and there is currently no plan to develop local codes for the services and supports valued by California stakeholders (including wraparound, natural healers, and culturally relevant care). There is also concern that the rates established will be based on what the MMCP and MHP are willing to pay and not the actual cost of providing quality services.

Recommendations:

1. DHCS should release a crosswalk to current codes. A workgroup of youth and adult consumers, private non-profit providers, legal advocates, and other non-governmental stakeholders should be established to identify services and supports not included in the CPT/HCPCS system, after which DHCS should develop local codes for appropriate items on the list.
2. Contracted providers and community-based organizations should be required to track all allowable expenses associated with the delivery of each service, as well as the cost of unrealized best practices to determine a more accurate reimbursement rate at the end of the study period, rather than just tracking what each MHP/MMCP is willing to pay for each service.

Peer Support Specialist Programs:

Strengths: Peers (individuals with lived experience similar to those they serve including adult consumers, family members of adult consumers, youth consumers, and parents/caregivers of youth consumers) are increasingly recognized as essential members of the behavioral health workforce. Expanding on SB 806, CalAIM plans to expand access to this classification of providers.

Challenges: Peer support workers have long been eligible to work in the public mental health system under the category “other qualified provider” in California’s system of care but many MMCPs and MHPs do not utilize them. Additionally, many MHPs have robust Youth Mentors and Parent Partners/Family Advocates in their EPSDT system. There is concern that the CalAIM proposal will reverse gains that have been made to use these peers in parts of the state. The cost and content in mandated peer training could become a barrier to those eligible for these positions. Finally, the proposal creates peer support specialists as an optional benefit for MMCPs and MHPs, which will increase cultural and regional disparity.

Recommendations:

1. The state should release an RFP (statewide or regional) seeking non-profit peer run organizations to develop and deliver training and certification of a peer workforce which confirms mastery of essential skills determined by a statewide advisory committee. The training requirements and certification process should be overseen by the Department of Consumer Affairs, as is done for other components of the healthcare workforce. “Grandmothering” (formerly known as “grandfathering”) and acceptance of experience will need to be accepted as fulfilling all or some of

the training curriculum. To delegate the training requirement to a governmental or quasi-governmental entity would compound bureaucratic barriers to fully implement this essential workforce.

2. Stipends should be made available to peers accepted into training programs to cover living expenses (such as minimum wage for each hour in training) to enable/encourage them to complete the training program.
3. DHCS will need to partner with MMCPs, MHPs, providers and contracted CBOs to identify the current number of peers providing Medi-Cal services and supports, and then set annual goals for increases to the peer workforce.
4. The Peer Support Specialist should be a mandated member of the workforce of all MMCPs and MHPs.

Out of State Former Foster Youth:

Strengths: The state is essentially the “parents” of youth in foster care. Therefore, ensuring that these youth continue to be insured by Medi-Cal, (their “parent’s” insurance) until age 26 provides parity with those families insured through commercial insurance.

Challenges: Communication of the current benefit has been poor, with many youth unaware that they can access the supports and services through the Medi-Cal system. By limiting this element to youth who “age out” of foster care at age 18, the state creates a disincentive for families to adopt teens, a sub-population of foster youth that already experience one of the lowest rates of adoption. As the state has recognized, foster youth are much more likely to experience trauma and require ongoing and expensive behavioral health supports and services.

Recommendations:

1. Engage former foster youth and the DSS Foster Care Ombudsman to develop communication strategies and materials to increase knowledge of this benefit among current and former foster youth.
2. Lower the eligibility age of when youth exit the foster care system to support potential adoption families, providing them confidence that they will be able to access behavioral health services for the youth to whom they provide a forever family.

Community-Based Adult Services:

Strengths: CalAIM is attempting to move services “upstream”, before crises occur.

Challenges: Lack of holistic care and limited medication management services. For example, lack of supportive housing is negatively impacting adult consumers’ ability to benefit from community based services.

Recommendations:

1. Ensure all community-based supports and services provided abide by SAMHSA defined recovery principles.
2. Community-based services should include providing information to consumers to enable them to become their own advocate, and/or to have a peer support staff partnered with them for support and advocacy.
3. Consumers must be able to receive all needed services and supports at their preferred location and time. For example, if the consumer is receiving both mental health and substance use services, they should be able to receive both at the same day/time, or at minimum, at the same location.

Services to Justice Involved Populations 30 day pre-release:

Strengths: This section of the CalAIM proposal addresses a critical transition period that has previously been ignored, leading to poor outcomes including fiscal and human costs.

Challenges: The proposal only addresses a narrowly selected “type” of individuals and services. In addition, Californians placed in out-of-state or private facilities are not eligible for these pre-release services and supports.

Recommendations: Expand criteria for participation in this benefit and in the services and supports to which individuals are eligible.

Cal Voices appreciates the opportunity to provide our comments. We would welcome the opportunity to discuss the perspective of mental health consumers and their family members further. I can be reached at sgallagher@calvoices.org or (916) 366-4600 to provide more details to our comments and/or to arrange focus groups with consumers and family members of all ages and cultures throughout the state.

May 6, 2021

Via Email: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, California 95899-7413

Subject: CalAIM Section 1115 & 1915(b) Waivers

Kaiser Foundation Health Plan, Inc. (the "Plan") appreciates the opportunity to provide comments to the Department of Health Care Services ("DHCS") on the Section 1115 and 1915(b) waiver applications prepared by DHCS that cover the California Advancing and Innovating Medi-Cal ("CalAIM") proposal. The Plan is supportive of the three primary goals of CalAIM, and believes that many of the various components within CalAIM align with the Plan's goal of providing the highest quality care to its members.

As DHCS is aware, the Plan contracts directly with DHCS to provide services to approximately 170,000 Medi-Cal enrollees under the Geographic Managed Care model in all or portions of Sacramento, El Dorado, Amador, Placer, and San Diego Counties. The Plan also provides services to an additional 655,000 Medi-Cal enrollees in 17 counties as a delegated health plan of 12 separate Plan Partners across its Northern and Southern California Regions. As a result, the Plan participates in three of the Medi-Cal Managed Care Models: the GMC model, the Two-Plan model, and the County Organized Health System model, and the Plan serves approximately 825,000 Medi-Cal members in 22 counties throughout the state.

The Plan supports programs and policies that ensure all individuals have access to affordable, high-quality health care, and applauds DHCS in its efforts to prioritize the impacts of health disparities, inequities, and social determinants of health on Medi-Cal beneficiaries. The Plan believes that collaboration across Medi-Cal managed care plans ("MCPs"), community organizations, and state and county agencies is crucial to increasing community engagement and to providing whole person care for Medi-Cal beneficiaries. As individuals and as organizations, our communities now more than ever during this global pandemic are being stretched to do more with their existing resources. Collectively, we have a shared responsibility to improve community health, and a critical component of this goal is improving engagement across our communities. While the Plan is thus supportive of the majority of the components of the CalAIM proposal, the following unresolved issues remain.

The Plan Needs the Flexibility to Serve as an Enhanced Care Management Provider in its Unique, Integrated Care Model

The Plan organizes and delivers care through high performing, exclusively contracted multispecialty medical groups and a tightly connected system of full-service medical centers and hospitals that are enabled by advanced medical technology and a robust Electronic Health Record system (collectively, “Kaiser Permanente”). In California, Kaiser Permanente consists of the Plan, Kaiser Foundation Hospitals (“KFH”), The Permanente Medical Group, Inc. (“TPMG”) in the Plan’s Northern California Region, and the Southern California Permanente Medical Group (“SCPMG”) in the Plan’s Southern California Region. It is the integration of all these entities that enables effective, efficient delivery of care that produces high quality outcomes, achieves high levels of patient satisfaction, and optimizes the use of provider capacity. Independent quality review organizations consistently find that coordinated, integrated, provider-driven health plans provide significantly higher quality care to enrollees than plans that rely on non-integrated provider networks. Kaiser Permanente’s integrated care delivery model is instrumental in several quality awards received by Kaiser Permanente, including the Plan’s continued receipt of top scores on the DHCS Medi-Cal Managed Care Performance Dashboard.

The Plan understands that DHCS would like Enhanced Care Management (“ECM”) providers to be community providers, who are “on the ground” and closest to members, and with limited exceptions, will not permit Medi-Cal Managed Care Plans (“MCPs”) to serve as ECM providers. With 26 KFH hospitals and 497 medical offices and outpatient facilities located statewide, the Kaiser Permanente system is a community-based delivery system. In the case of the Plan’s participation in the Health Homes Program, certain responsibilities of the Community Based Care Management Entity (“CB-CME”) are held by TPMG, SCPMG, and KFH, while others are covered by the Plan in collaboration with TPMG, SCPMG, and KFH. This is feasible due to Kaiser Permanente’s unique, integrated health care model. As part of Kaiser Permanente’s integrated care model, the Plan also partners with many community agencies to provide wholistic care to members in community settings (e.g., housing navigation services in the Health Homes Program, and through the use of an internal platform that connects members to various social services in their communities). As the Health Homes Program transitions into the ECM benefit, Kaiser Permanente would like to leverage certain existing workflows and processes among the Plan and its providers that exist today as the Health Homes Program CB-CME for the Plan’s members. As such, the Plan requests that DHCS add explicit flexibility for MCPs to serve as ECM providers in delivery systems such as Kaiser Permanente where the MCP participates in a comprehensive integrated care model with its providers.

The Plan Emphasizes the need for Flexibility for Delegated MCPs

As noted above, the Plan covers approximately 655,000 Medi-Cal members in 17 counties, through 12 separate Plan Partner arrangements, and 2 Direct Contracts across 5 counties in its Northern and Southern California Regions. As CalAIM moves forward, it is critical that the Plan have the flexibility to implement two regional models of care with KFH and its two exclusively contracted medical groups – TPMG and SCPMG – rather than 14 different variations among 26 different counties, inclusive of the Plan’s GMC counties. For successful implementation, the Plan

must have flexibility as a delegated MCP to operate models that differ from its Plan Partners, but are more appropriately suited for the Plan's members within its unique, integrated health care model – including, but not limited to, ECM, in lieu of services (“ILOS”), and Population Health Management. As noted above, Kaiser Permanente's model of care is proven to be successful with the Plan's continued leading performance in the DHCS Medi-Cal Managed Care Performance Dashboard, as well as a myriad of additional quality awards. The Plan looks forward to building upon the success of its existing model with CalAIM, and notes that many of the Plan's Medi-Cal Plan Partners have already expressed support for the Plan to have this level of flexibility.

In particular with respect to ILOS, while MCPs are not mandated to provide ILOS, the Plan understands that DHCS would like MCPs to integrate ILOS into their Population Health Management strategy, in combination with the ECM benefit. The Plan also recognizes that the needs of its delegated members differ from the needs of the members in the primary MCP, as well as the members in primary MCP's other delegated networks. The Plan specifically requests flexibility to have its ILOS offerings differ from the ILOS offerings of the primary MCP in counties where the Plan is a delegated MCP. This will allow the Plan to better address the unique needs of its assigned members. In cases where the Plan's ILOS offerings exceed that of the primary MCP, this flexibility will help build an ILOS network in counties that would otherwise not exist, promoting the goal of CalAIM of providing a “statewide platform to comprehensively address the needs of beneficiaries with the most complex health challenges.”

The Plan's concerns remain regarding the Specialty Mental Health Carveout in Sacramento and Solano Counties

Medi-Cal members with specialty mental health conditions are typically among the most vulnerable in the Medi-Cal population, who benefit significantly from the current integration of their physical and mental health care needs. In CalAIM, DHCS has emphasized a “no wrong door” approach to behavioral health reforms, which is exactly what the current carve in provides for the Plan's members in Sacramento and Solano counties. Removing the long-standing integration of specialty mental health services does the opposite for DHCS's stated waiver goal of to “advance quality outcomes, reduce health disparities, and drive delivery system transformation and innovation through value-based initiatives.” In addition, it contradicts with DHCS's intent to move toward with Full Integration Plans. We strongly urge DHCS to put the interests of our impacted members ahead of the desire for administrative simplification, and retract this element of the CalAIM proposal. We believe that providing the highest quality integrated care for our extremely vulnerable members, who will be left with gaps in services should this proposal move forward, must take priority over the administrative benefits DHCS will achieve by carving these services back out in Sacramento and Solano counties.

In the recent months of working with DHCS to prepare for this transition, it is clear to the Plan that DHCS initially believed the total impacted membership was much smaller than is the case (on a scale of hundreds vs. thousands). While DHCS may have assumed based on such initial small numbers that the counties could quickly build network adequacy to transition the impacted members, such a task by January 1, 2022 would be nearly impossible when the more accurate,

higher volume of impacted members is considered. It is also clear, based on DHCS's draft member notices, that DHCS does not believe this proposal will change any covered services for members. However, the Plan offers inpatient "step down" specialty mental health services that are not typically offered by counties, such as intensive outpatient treatment, partial hospitalization programs, crisis stabilization, and residential hospital alternative programs. The majority of impacted members will no longer be able to receive these "step down" specialty mental health services through the counties – so there is in fact a change in covered services for these members. In summary, the Plan's concerns from its December 16, 2019 comment letter to DHCS remain today, including without limitation:

- Whether Sacramento and Solano counties have adequate capacity to care for the Plan's members;
- Whether the same quality of care can be provided without the current level of integration that the Plan provides for these members for their physical and mental health care;
- Why DHCS wants these members to access another separate delivery system when CalAIM acknowledges the difficulty of transitions between multiple systems;
- The counties' ability to cover members' continuity of care requests;
- Member dissatisfaction upon being required to change providers; and,
- As it occurs in other counties where specialty mental health services are carved out, that the Plan will ultimately cover specialty mental health services to members who cannot access them in the counties, but now will no longer be compensated for covering such services.

As state above, we strongly urge DHCS to put the interests of our impacted members ahead of the desire for administrative simplification, and retract this element of the CalAIM proposal. Providing the highest quality integrated care for our extremely vulnerable members, who will be left with gaps in services and access should this proposal move forward, must take priority over the administrative benefits DHCS will achieve by carving these services back out in Sacramento and Solano counties.

The Plan would like to Continue to Work with DHCS on Dual Eligible Special Needs Plan (D-SNP) Changes

The Plan appreciates DHCS's commitment to working with the Centers for Medicare & Medicaid Services ("CMS") to ensure that delegated MCPs are viewed as the primary MCP for purposes of aligned enrollment. As noted above, the Plan is a delegate of twelve different Medi-Cal Plan Partners that are contracted directly with DHCS. In these situations, duals enrolled in the Plan's D-SNP and the Plan's delegated Medi-Cal product will have much better alignment than if enrolled in the Plan's D-SNP and the directly contracted MCP's Medi-Cal plan (see above for a description of the Plan's integrated care model – when enrolled in the Plan's D-SNP and the Plan's Medi-Cal product, members will have the same providers in SCPMG or TPMG, and access to the same KFH hospitals, all connected through a robust Electronic Health Record system). Allowing for such alignment, even when the Plan serves as a delegated MCP, will improve care coordination to improve health outcomes for duals.

In addition, the Plan recommends that DHCS remove the current enrollment restrictions on D-SNPs in the 7 Coordinated Care Initiative (“CCI”) Counties. Since Cal MediConnect will be ending, it is no longer necessary to prevent dual eligible beneficiaries in the 7 CCI counties from having the full range of Medicare plan options available to them. Dual eligible beneficiaries who prefer Kaiser Permanente coverage today may choose only the Kaiser Permanente Medicare Senior Advantage Plan, and cannot choose Kaiser Permanente’s D-SNP. To increase beneficiaries’ choices, the Plan would like to be able to offer its D-SNP to dual eligible beneficiaries who have already expressed an interest in Kaiser Permanente coverage.

The Plan Emphasizes the Comments Provided by the California Association of Health Plans

As stated above, the Plan is conceptually supportive of the majority of DHCS’s CalAIM proposal as presented in DHCS’s 1115 and 1915(b) waivers, and the outcomes that CalAIM seeks to achieve. The Plan has worked extensively with the California Association of Health Plans (“CAHP”) with respect to the comment letters CAHP has submitted to DHCS on CalAIM. As detailed in such comment letters, there are still many open issues to resolve – including but not limited to the constricted implementation timing, data sharing barriers, rates, and incentive payments. The Plan looks forward to working collaboratively with both DHCS and CAHP to resolve these concerns to ensure a smooth and successful implementation of CalAIM – from the perspective of DHCS, the Plan, and most importantly, the Plan’s 825,000 Medi-Cal members.

Sincerely,

Nathaniel Oubre, VP, Medi-Cal, CHIP and Charitable Care
Kaiser Foundation Health Plan, Inc.

Cc: Deborah Espinal, Executive Director of Health Plan Policy
Kaycee Velarde, Director, Medi-Cal Regulatory Policy
Elizabeth Elson, Senior Counsel
Kyle Murphy, Executive Director, Medi-Cal, State Programs Southern CA
Javier Sanchez, Executive Director, Medi-Cal Contract Management
Elizabeth Reno, Executive Director, Medi-Cal, Strategy and Operations Northern CA
Judy Liu, Executive Director, Medi-Cal Regulatory Reporting and Financial Strategies

5/6/2021

Kris Christie, MSN-RN, PHN
11 Southern Heights Boulevard
San Rafael, CA 94901

Comments on the Proposed CalAIM Section 1115 Demonstration Application

As Administrator with DayOut ADHC/CBAS in Merced, I am writing in support of the California Department of Aging proposal to use the renewal of the 1115 Waiver through CalAIM and modernize the Medi-Cal funded CBAS model, incorporating lessons learned during the Public Health Emergency and aligning those lessons with the goals of the Master Plan for Aging to improve access to Home and Community Based Services throughout the state. We believe that the flexibility granted through a demonstration and research model lends itself to such innovation. In an effort to support the most underserved and underrepresented populations by improving access to community-based care, we can improve health outcomes and decrease overutilization of services through a robust expansion of community-based services.

Following the Temporary Alternative Services (TAS) model empowers the CBAS Multidisciplinary Team to navigate care that meets people where they are at -- in their home and community. This also allows Enhanced Care Management as a feature of CBAS, to deliver the coordinated care model, serving our population while alleviating unnecessary stressors the hospital systems.

We have risen to new challenges during this 2020/2021 pandemic and together we have learned to stay flexible and adapt to change while remaining committed to the continued service we provide for adults with access and functional needs. We are hopeful that we can continue to expand our reach through the Proposed CalAIM Section 1115 and increased enrollment into CBAS over the 5-year period as dual eligible beneficiaries.

Thank you for your time, energy, and consideration.

Sincerely,

Kris Christie, MSN-RN, PHN



737 West Childs Avenue, Merced, CA 95341 (Corporate Office)
2926 G Street, Suite 201, Merced, CA 95340 (Administrative Office)
1.866.682.4842
www.gvhc.org

[Via Electronic Submission \(CalAIMWaiver@dhcs.ca.gov\)](mailto:CalAIMWaiver@dhcs.ca.gov)

May 5, 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:

Golden Valley Health Centers (GVHC) 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, GVHC 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.

GVHC is an FQHC that cares for Medi-Cal and uninsured patients in Stanislaus, Merced and San Joaquin. 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 58 contract pharmacies

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Director Lightbourne

5/5/2021



Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows GVHC 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, GVHC annually saves an estimated \$3,500,000 per year through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow GVHC 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, GVHC patients have better access to more services, just as Congress intended in enacting the 340B program.

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." 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. GVHC incorporates by reference the CHCAPA public comment letter into this letter. GVHC 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, GVHC 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

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Director Lightbourne

5/5/2021

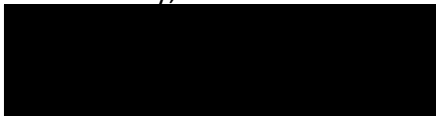


meaningful input and alternatives for DHCS' consideration. Doing so will enable GVHC and DHCS to “work in partnership to provide individuals access to affordable healthcare, including prescription drugs” as now-Secretary Becerra described.



Thank you for your time and consideration. GVHC looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries. If you have further questions or concerns please contact Yamilet Valladolid via email at yvalladolid@gvhc.org for follow up.

Sincerely,



Tony Weber, MBA
President and CEO
Golden Valley Health Centers
tweber@gvhc.org

Encl.

YOUR HEALTH IS OUR PRIORITY

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



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	Hill Country Health & Wellness Center	San Ysidro Health
Clinicas de Salud del Pueblo	Imperial Beach Community Clinic	Shasta Community Health Center
Community Health Centers of the Central Coast	La Maestra Family Clinic	South of Market Health Center
Desert AIDS Project	MCHC Health Centers	TrueCare
Family Health Centers of San Diego	Mission Area Health Associates	United Health Centers of the San Joaquin Valley
Gardner Family Health Network	Omni Family Health	Vista Community Clinic
Golden Valley Health Centers	Open Door Community Health Centers	WellSpace Health
HealthRIGHT 360	Ravenswood Family Health Network	Central California Partnership for Health (Affiliate Support Organization)
	San Francisco Community Health Center	

Hanson Bridgett LLP
500 Capitol Mall, Suite 1500, Sacramento, CA 95814 hansonbridgett.com

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Teresa DeCaro, Acting Director
April 16, 2021
Page 2

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

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 Waiver¹

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 care². 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 them⁴. 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

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 fund⁶. 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. 14⁷. 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 dispensing 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 Notice⁸. However, the state’s Legislative Analyst’s office explicitly stated that Medi-Cal Rx would directly affect FQHC funding and patient care coordination⁹. 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 Rx¹⁰. 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 dollars¹¹. 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 billion¹². 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

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/mceestimates/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 years¹⁴. 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
PARTNER
DIRECT DIAL (916) 491-3024
DIRECT FAX (916) 491-3079
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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**.

Judith Cash, Director
March 18, 2021
Page 3

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
<u>Audiological Services</u>	<u>Audiology Services</u>	<u>Audiological services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
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 ⁷⁶
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)	<u>Service is not covered under the State Plan EPSDT</u>	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.	<u>X</u>	<u>X</u>	<u>X⁹ X⁶X⁴</u>	<u>X</u>	<u>X</u>	<u>X</u>

**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)

Certified Family nurse-Nurse practitioner-Prac titioner	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
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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
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	<u>EPSDT</u>	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)	<u>EPSDT</u>	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

**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
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	<u>X</u>	<u>X</u>	<u>X</u>
Comprehensive Perinatal Services	Extended Services for Pregnant Women-Pregnancy Related and Postpartum Services	Comprehensive perinatal services means obstetrical, psychosocial, nutrition, and health education services, and related case coordination provided by or under the personal supervision of a physician during pregnancy and 60 days following delivery.	X	X	X	X	X	X

**Attachment N
Capitated Benefits Provided in Managed Care**

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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 <u>administered in-office</u> , 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 <u>EPSDT Supplemental Services</u>	EPSDT	<u>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.</u> Preliminary evaluation to help identify potential health issues.	X²⁶	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷	X⁶⁷
Erectile Sexual Dysfunction Drugs		FDA-approved drugs that are <u>may</u> be prescribed for <u>a male or female sexual dysfunction are non-benefits of the program.</u> patient experiences an inability or difficulty getting or keeping an erection as a result of a physical problem.						

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
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 ^B	X ^B	X ^B	X ^B	X ^B	X ^B
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

**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
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.	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷	X¹⁴X⁸⁷
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

**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
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

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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			

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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.	<u>X</u>	<u>X</u>	X	<u>X</u>	<u>X</u>	<u>X</u>
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 <u>contract</u> .	X	X	X	X	X	X

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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

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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

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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

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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

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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.						

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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	X⁵X^{3,965}	X⁵X^{3,596}	X⁵³	X⁵X^{3,5}	X⁵X^{3,5}	X⁵X^{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. <u>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</u> 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. <u>NMT is transportation by private or public vehicle for</u>	X	X	X	X	X	X

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

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		<u>beneficiaries people who do not have another way to get to their appointment.</u>						
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

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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	<p>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:</p> <ul style="list-style-type: none"> • 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

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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 ^{9/14} X ^{65/14}	X ^{9/14} X ^{65/14}	X ^{9/14} X ^{65/14}			
Pharmaceutical Services and Prescribed Drugs <u>(effective Jan 1 – Mar 31, 2024)</u> 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
<u>Pharmaceutical Services and Prescribed Drugs (effective Apr 1, 2021 onward)</u>	<u>Pharmaceutical Services and Prescribed Drugs</u>	<p><u>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.</u></p> <p><u>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).</u></p> <p>Covers medications other than those carved-out to Medi-Cal Rx including prescription and nonprescription and total parenteral and</p>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>

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		<u>enteral nutrition supplied by licensed physician.</u>						
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 <u>the same</u> prior authorization <u>procedures that govern physicians</u> , 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.	X⁴	X⁴	X⁴	X⁴	X⁴	X⁴
Preventive Services	Preventive Services	All preventive services articulated in the state plan.	X	X	X	X	X	X

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Prosthetic and Orthotic Appliances	Prosthetic and Orthotic 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, 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	X⁸	X	X	X
Rehabilitation Center Outpatient Services	Rehabilitative Services	A facility providing therapy and training for rehabilitation <u>on an outpatient basis</u> . 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

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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 equipment and drugs.	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ X	X⁸ 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 ⁷	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 ⁷⁶
Specialty Mental Health 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

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<u>Speech Pathology</u>	<u>Speech Pathology</u>	<u>Speech pathology services are covered when provided by persons who meet the appropriate requirements</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>	<u>X¹</u>
State Supported Services		State funded abortion services that are provided through a secondary contract.	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
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 <u>and</u> Services-	Targeted Case Management	<u>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.</u> 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						

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		<p>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.</p>						
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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 GenCal Health.~~

⁴ ~~Not covered by GenCal~~ Covered by GenCal 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.~~

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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).

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

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

~~⁹⁻⁶⁵Services 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.~~

~~¹⁰⁻⁷⁶Benefit coverage is limited to only beneficiaries under 21 years of age for services rendered pursuant to EPSDT program requirements.~~

~~¹¹⁻⁸⁻⁷Health 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.~~

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(X = covered by plan. If service is not covered, plan is contractually required to provide care coordination to members)

⁸The 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.

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

Exhibit B

Reply all | Delete Junk |

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



[Redacted Name]
[Redacted Email Address]

[Redacted]

[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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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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.

*****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.



Our Mailing Address is:

P.O. Box 2088 Rancho Cordova, CA 95741-2088, United States

[Unsubscribe](#)



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

1 HANSON BRIDGETT LLP
KATHRYN E. DOI, SBN 121979
2 ANDREW W. STROUD, SBN 126475
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3 Sacramento, California 95814
Telephone: (916) 442-3333
4 Facsimile: (916) 442-2348
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6 REGINA M. BOYLE, SBN 164181
LAW OFFICE OF REGINA M. BOYLE
7 Post Office Box 163479
5531 7th Avenue
8 Sacramento, CA 95816-9479
Telephone: (916) 930-0930
9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12

13

UNITED STATES DISTRICT COURT

14

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

15

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

18 Plaintiffs,

19 v.

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

22 Defendants.
23

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**

24

25 I, Francisco Castillon, declare as follows:

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

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

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

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

12 4. In order to comply with applicable State and Federal law relating to the
13 340B program OFH has registered each of our FQHC sites that dispenses drugs to Medi-
14 Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only 340B
15 drugs to our Medi-Cal patients.

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

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

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

27 ///

28 ///

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

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

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

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

22 12. If the Medi-Cal Rx Transition became effective on April 1, 2021,
23 approximately seventy percent of our prescriptions would be filled through Medi-Cal's
24 340B-specific fee-for-service reimbursement schedule. This will require changes to our
25 current operations, which may include discontinuing home delivery of drugs to those
26 unable to come to the clinic for health reasons or due to a lack of transportation.
27 Additionally, we would need to discontinue stocking of more expensive medications.

28 ///

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

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

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

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

1 provided primary care services to 131,449 unduplicated patients, and had 588,936
2 patient visits (encounters). The distribution of OFH patients as a percentage of poverty
3 guidelines is 62,160 patients (47.29%) at 100 percent and below the federal poverty
4 level; 10,102 patients (7.69%) at 101 to 150 percent of the federal poverty level; 4,009
5 patients (3.05%) at 151 to 200 percent of the federal poverty level; 2,433 patients
6 (1.85%) at over 200 percent of the federal poverty level; and 52,745 patients (40.13%)
7 whose percent of the federal poverty level is unknown.

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

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

14 19. As reported on our UDS report, with respect to OFH visits involving patients
15 with two or more diseases/diagnoses, the most common diseases/diagnoses involved
16 were: Diabetes Mellitus = 37,494 visits, Overweight and Obesity = 48,295, Hypertension
17 = 52,168, and Heart Disease = 4,747. In addition, the most common visits provided for
18 mental health conditions and substance disorders were: anxiety disorder/PTSD = 37,001,
19 depression and mood disorders = 39,324, and other mental disorders (excluding drug or
20 alcohol dependence) = 22,011.

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

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

7 21. OFH's current 340B prescription drug program includes five (5) onsite and
 8 eighty (80) contract pharmacy sites. From January 1, 2020 through September 30, 2020,
 9 OFH's in-house pharmacies filled 228,791 prescriptions, 26,861 of which were
 10 prescriptions filled for uninsured patients. OFH's 80 contract pharmacies filled nearly
 11 10,000 prescriptions, of which over 10 percent were dispensed for uninsured patients.

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

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

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

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

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

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

8 25. OFH estimates 340B savings generated from our pharmacies through the
9 340B Drug Pricing Program account for about 20 percent of our direct patient care
10 staffing expenses.

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

26 ///

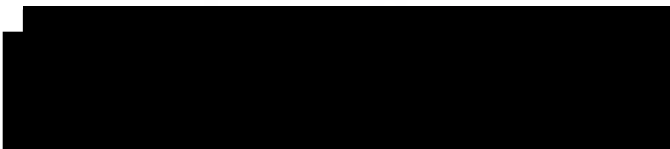
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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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



Francisco Castillon

Exhibit C
to letter dated 4/16/2021

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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

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UNITED STATES DISTRICT COURT

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EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

15

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

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Plaintiffs,

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v.

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

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Defendants.

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24

25 I, C. Dean Germano, declare as follows:

26

1. I am the Chief Executive Officer ("CEO") of Shasta Community Health

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Center ("SCHC") and have been in this position since 1992. I am a past Board President

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of the California Primary Care Association ("CPCA") and am currently Board Emeritus

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

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

14 2. As CEO of SCHC, I am responsible for overseeing care to 40,000
15 unduplicated patients, providing over 130,000 visits a year in a multi-specialty type
16 practice that includes mental health and dental. Over 92% of SCHC's patients live below
17 200% of the federal poverty line. I also have oversight of our 340B Program. For many
18 years, the savings that SCHC has retained through the discounted drug purchase prices
19 available through the 340B program has been used to benefit our patients through such
20 things as the passing of the 340B price to our uninsured and underinsured patients,
21 allowing us to charge many sliding fee patients no more than \$10 for prescriptions at our
22 contract pharmacies, and providing services such as transportation assistance, covering
23 a significant portion of lab costs for sliding fee patients, and covering patient education
24 services and gap funding for departments that are not profitable, such as telemedicine.
25 In 2019, SCHC's 340B Medi-Cal savings totaled \$1.79 million. The Medi-Cal transition to
26 managed care would result in a loss of these savings and would force SCHC to make
27 cuts to these programs that will have a negative impact on patient care and service to our
28 community.

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

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

12 5. In connection with establishing the SPP, in the fall of 2019, the Department
13 and CPCA asked community health centers to report their projected loss of 340B savings
14 to the State. According to CPCA, 109 community health centers submitted data to the
15 State and 91 submitted data to CPCA and the State. The total amount of lost savings
16 reported by the community health centers that responded to the data request was
17 \$105 million. CPCA staff and the CPCA board also appointed a “Solutions Team” to
18 work with the Department regarding implementation of the SPP. I was one of the people
19 appointed to the Solutions Team.

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

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

28 ///

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

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

6 9. Ultimately, the SPP was adopted in the Budget Trailer Bill, and codified as
7 California Welfare & Institutions Code § 14105.467, which became effective on June 29,
8 2020. This legislation requires the Department to "establish, implement, and maintain a
9 supplemental payment pool for nonhospital 340B community clinics, subject to an
10 appropriation by the Legislature." Qualifying FQHCs are to receive fee-for-service-based
11 supplemental payments from a fixed-amount payment pool to compensate them for their
12 loss of 340B program revenue.

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

19 11. Section 14105.467 also requires the Department to establish a stakeholder
20 process that "shall be utilized to develop and implement the methodology for distribution
21 of supplemental pool payments to qualifying nonhospital 340B community clinics."
22 Section 14105.467 further requires the Department to conduct at least three meetings
23 with stakeholders and to finalize the methodology for distribution no later than October 1,
24 2020.

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

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

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

3 (c) The SPP would be simple to administer.

4 (d) The SPP will be renewed annually.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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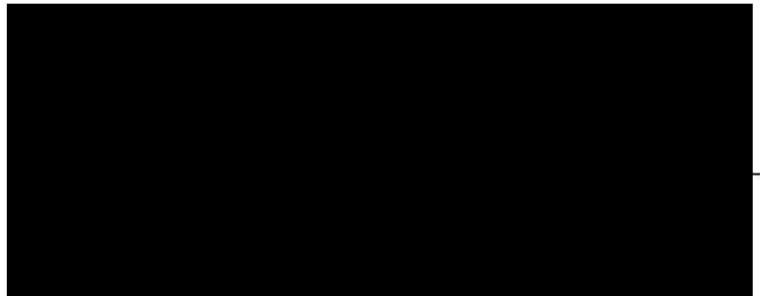
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1 down the chain relating to the provision of services, including the benefits available to
2 the Medi-Cal beneficiaries who will receive those services.

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

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



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Exhibit D
to letter dated 4/16/2021

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10 Attorneys for Plaintiffs
COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

15
16 COMMUNITY HEALTH CENTER
ALLIANCE FOR PATIENT ACCESS, et
17 al.,

18 Plaintiffs,

19 v.

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

22 Defendants.
23

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**

24 I, Ricardo Roman, declare as follows:

25 1. I am the Chief Financial Officer ("CFO") at Family Health Centers of San
26 Diego ("FHCS") and have held this role since September 2010. As CFO, I report
27 directly to the Chief Executive Officer ("CEO") and am responsible for leading and
28

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

8 2. FHCSO is a Federally Qualified Health Center ("FQHC") that receives
9 federal grant funding under Section 330 of the Public Health Service Act. FHCSO meets
10 all current statutory requirements under Section 330 of the Public Health Service Act.
11 FHCSO has served the medically underserved communities of San Diego County since
12 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health
13 Center, the flagship clinic of FHCSO. FHCSO has since transformed into the tenth
14 largest health center in the country (47 service delivery sites), providing care to over
15 149,000 patients each year, of whom 90 percent are low income (under 200% of Federal
16 Poverty Level) and 31 percent are uninsured. FHCSO serves all patients regardless of
17 their ability to pay.

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

20 4. In order to comply with applicable State and Federal law relating to the
21 340B program, FHCSO has registered each of our FQHC sites that dispenses drugs to
22 Medi-Cal beneficiaries in the Medicaid Exclusion File, indicating that we dispense only
23 340B drugs to our Medi-Cal fee-for-service patients.

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

1 paid at “actual acquisition cost” plus a \$10.05 or \$13.20 dispensing fee.

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

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

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

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

22

23 Clinical Service	Number of Patients	Percent of Patients	Number of Visits	Percent of Visits
24 Medical (Primary Care)	126,178	84.54%	457,021	50.73%
25 Dental	24,344	16.31%	70,816	7.86%
26 Mental Health	18,819	12.61%	110,624	12.28%
27 Substance Abuse	1,504	1.01%	18,046	2.00%
28 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 FHCS D 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, FHCS D’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 FHCS D 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%

1	Race		
2	Asian	9,506	6.37%
3	Native Hawaiian/Other Pacific Islander	1,090	.73%
4	Black/African American	13,331	8.93%
5	American Indian/Alaska Native	839	.56%
6	White	91,968	61.62%
7	More than 1 Race	6,249	4.19%
8	Race Unreported/Refused	26,261	17.60%
9	Ethnicity		
10	Hispanic/Latino	81,076	54.33%
11	Non-Hispanic	56,032	37.54%
12	Ethnicity Unreported/Refused	12,136	8.13%
13	Medical Conditions		
14	Hypertension	23,482	15.73%
15	Diabetes	13,015	8.72%
16	Asthma	7,025	4.71%
17	Symptomatic/Asymptomatic HIV	1,361	.91%
18	Prenatal Care Patients		
19	Number of Patients	3,650	100.00%
20	Number of Patients who Delivered	2,017	55.26%
21	Chronic Disease Management		
22	Use of Appropriate Meds for Asthma	1,127	93.70%
23	Statin Therapy for Prevention & Treatment of Cardiovascular Disease	13,663	78.70%
24	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	2,245	89.67%
25	Controlling High Blood Pressure	21,886	69.74%
26	Diabetes: Controlling Hemoglobin A1c	12,656	64.08%
27	% 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.” FHCS D’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, FHCS D’s 340B onsite pharmacy and contract pharmacy

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

- 6 • Affordable Patient Medication & Pharmacy Programs
- 7 • HIV and Hep C Patient Screening and Care Management
- 8 • Expanded Patient Vision Services
- 9 • Increased Access to Mobile Medical & Mental Health Services
- 10 • Expanded Older Adult Patient Services
- 11 • Critical Workforce Development Initiatives
- 12 • Expanded Clinical Patient Services
- 13 • Patient Weight Management Program
- 14 • Expanded Patient Health Education
- 15 • Urgent Care Services
- 16 • Patient Clinical Care Coordination/Patient Case Management
- 17 • Expanded Patient Specialty Services
- 18 • Patient Quality Improvement Staff and Programs
- 19 • Clinical Computer Upgrades
- 20 • Clinical Infrastructure Upgrades
- 21 • Patient Substance Abuse and MAT Programs
- 22 • Clinical Lab and Point of Care Testing Upgrades
- 23 • Expanded Podiatry Services
- 24 • Patient Security Control
- 25 • PHI Security and Server Upgrades

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

28

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

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

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

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

14 17. FHCSO is also at the heart of the battle against the COVID-19 pandemic in
15 San Diego County. As the largest community clinic organization serving the area,
16 FHCSO's clinics are located in already disadvantaged communities and those hardest hit
17 by the pandemic. As evidenced by the positivity rates seen at FHCSO, health center
18 patients carry more COVID-19 burden than the general population. Since the pandemic
19 onset, FHCSO has performed 35,213 COVID-19 PCR tests with a 16.9% overall test
20 positivity rate. Despite that high positivity over many months, each week in November
21 and December 2020, our test positivity continued to climb to a current rate of 28.5%,
22 more than double California's current test positivity rate of 12.2%. In short, FHCSO and
23 FQHCs across the state are at ground zero of the COVID-19 pandemic. Eliminating the
24 savings realized through the current 340B structure would be devastating to our ability to
25 continue to care for a population with such high test positivity rates. As we near 2021, the
26 drain on FHCSO resources has made it increasingly difficult to maintain quality
27 healthcare for the communities we serve. With high levels of virus in the community, our
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1 providers and support staff are also testing positive at higher rates than the County
2 average. The resulting personnel shortage and dual struggle of increased demand for
3 testing while trying first to vaccinate our staff and then the high-risk populations we care
4 for are placing an unprecedented burden on our health care delivery system.

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

12 19. FHCS D has other concerns about the CSOSR process, as well. For
13 example, as part of the CSOSR process, a health center with multiple sites is required to
14 submit a home office cost report in addition to a cost report for each site that is seeking a
15 change to its rate based on a change in the scope of its services. 340B drug costs
16 associated with a health center's contract pharmacy arrangements are not included in the
17 reimbursable costs of the health center because the contract pharmacy (such as a
18 Walgreen's or CVS or corner drug store) incurs all of the costs associated with managing
19 and dispensing the drugs, with the exception of the payment for the replenishment of the
20 drugs, which is paid for by the health center. In connection with an FHCS D CSOSR that
21 is currently under consideration by DHCS, DHCS is proposing to treat FHCS D's 340B
22 drug costs as a non-reimbursable cost center and to allocate an amount of FHCS D's total
23 overhead costs to the non-reimbursable cost center based on the proportion of overall
24 costs represented by the "costs" of the 340B drugs. This proposed adjustment to the
25 home office cost report will result in lower rates for the sites that are undergoing the
26 CSOSR because a disproportionate amount of home office costs will be allocated to the
27 340B drug costs and away from sites that actually use and benefit from the costs

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

5

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

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

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Ricardo Roman

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Exhibit E
to letter dated 4/16/2021

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17 Attorneys for Plaintiffs
 18 COMMUNITY HEALTH CENTER ALLIANCE
 19 FOR PATIENT ACCESS, ET AL.

20 **UNITED STATES DISTRICT COURT**
 21 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**

22 COMMUNITY HEALTH CENTER
 23 ALLIANCE FOR PATIENT ACCESS, et
 24 al.,

25 Plaintiffs,

26 v.

27 WILLIAM LIGHTBOURNE, Director of the
 28 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

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

5 2. DAP was founded in 1984 by a group of community volunteers in the face
 6 of the AIDS crisis. Since that time, DAP has been named one of the "Top 20 HIV/AIDS
 7 Charities" and has expanded its mission to other disenfranchised members of the
 8 Coachella Valley community. Today, DAP is a FQHC that serves over 7,000 active
 9 clients, almost a third of which are living with, affected by, or at-risk for HIV/AIDS. The
 10 majority of DAP's clients are low-income, with more than 75 percent of the immediate
 11 population living under 200 percent of the Federal Poverty Level. DAP receives federal
 12 grant funding under Section 330 of the Public Health Service Act. DAP meets all current
 13 statutory requirements under Section 330 of the Public Health Service Act. DAP also is a
 14 340B-eligible Ryan White Part A (RWI) grantee provider organization.

15 3. According to the most recent DAP Uniform Data System ("UDS") report
 16 submitted to the federal Health Resources and Services Administration ("HRSA") for
 17 2019, DAP conducted clinic visits with the following distribution of services for the 7,487
 18 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%

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

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

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

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

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

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

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

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

13 Executed this 16th day of December 2020, in Palm Springs, California.

14
15 A black rectangular redaction box covering the signature of David Brinkman.

16
17 David Brinkman

Exhibit F
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Kelvin Vu, declare as follows:

25 1. I am currently a family physician at Open Door Community Health Centers
26 ("Open Door"), where I have worked for the last ten years. I also currently serve as Chief
27 Medical Officer at Open Door. I received my medical training from Western University
28 and completed my Family Medicine Residency at the University of California, Davis

DECLARATION OF DR. KELVIN VU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

1 Medical Center, where I also served as Chief Resident in my final year. As a family
2 physician, I regularly interact with patients, prescribe medications, and ensure my
3 patients are receiving their medications and following the treatment regimens. As the
4 Chief Medical Officer, I also receive reports from the other physicians about the provision
5 of services to their patients, including concerns about challenges and suggestions for
6 improving services. The majority of Open Door's patients are Medi-Cal beneficiaries who
7 are members of a Medi-Cal managed care plan ("MCP"). I have personal knowledge of
8 the facts set forth herein, and if called to do so, could and would testify competently
9 thereto. I make this declaration in support of Plaintiffs' Reply to Defendants' Opposition
10 to the Motion for a Preliminary Injunction.

11 2. Open Door is a Federally Qualified Health Center that receives federal
12 grant funds under Section 330 of the Public Health Services Act. Open Door is
13 committed to providing excellent health care and health education to medically
14 underserved patients in the Humboldt and Del Norte Counties, two rural counties in the
15 far northwest region of Northern California along the coast. Open Door currently
16 operates twelve community health centers across both counties, serving more than
17 55,000 patients each year while employing nearly 700 members of the community.

18 3. Humboldt and Del Norte Counties are predominately rural, and tend to rank
19 near the bottom for health outcomes among California counties. Like many rural areas,
20 our patients struggle with widespread problems of poverty, opioid use disorder, lack of
21 health education, lack of reliable housing and transportation, and numerous other socio-
22 economic barriers to health care that directly affect their well-being in the short and the
23 long term. As a physician who has worked in this community for ten years, I am well-
24 aware that these socio-economic problems often cause my patients to forego necessary
25 medical treatments in order to focus on other urgent aspects of their lives, such as going
26 to work to support their families, or using their limited incomes to buy food or pay rent
27 instead of paying for their prescribed medications.

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1 4. Open Door is committed to meeting our patients where they need us to be.
2 To that end, we operate under a patient-centered medical home model (“Medical Home”)
3 that allows us to coordinate an individual patient’s care across specialties so that we treat
4 the whole person, rather than individual symptoms. As their Medical Home, Open Door
5 proudly serves as a one-stop-shop for all of our patients’ medical needs, as well as their
6 unique needs for accessing transportation assistance, housing, and food. The Medical
7 Home also helps patients follow their medical treatment plans because they do not need
8 to go to multiple facilities – all of their providers are in one place, which greatly improves
9 the patients’ overall health outcomes.

10 5. The Medical Home includes coordination with pharmacy services and the
11 MCP member services team. The ability for me as a prescribing physician to work
12 directly with the MCP and case managers greatly improves my patients’ ability to access
13 necessary treatments. For example, if I prescribe a Lidocaine patch – a non-opioid
14 chronic pain treatment – I will have access to real-time information regarding what the
15 cost will be to the patient, when and if the patient is able to pick up the patch, or if the
16 patch is not covered by the patient’s plan. If the Lidocaine patch is not available for some
17 reason, I am able to find out immediately and make same-day adjustments to the
18 treatment plan so that my patient’s needs are met. This is just one concrete example of
19 how the pharmacy benefit’s inclusion in managed care facilitates medical services for
20 both doctors and patients, leading to better care and outcomes for the most vulnerable,
21 medically underserved people in California.

22 6. The inclusion of the pharmacy benefit in managed care also enables me to
23 tailor my treatment plan to the patient’s needs. With the pharmacy and medical benefits
24 linked, the current managed care model allows me to see and track if my patients are
25 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
26 returning for medical follow-ups on time. This information is critical to creating a
27 treatment plan for my patients, tracking their progress and condition, and scheduling
28 necessary follow-up appointments.

1 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
2 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
3 This will directly undermine Open Door's Medical Home model and my ability to treat my
4 patients effectively. For example, disconnecting pharmacy services from medical
5 services will require our patients to take multiple trips to receive their care and their
6 medication. For most of my patients, this is not simply one more errand in their day – it is
7 an insurmountable barrier because they do not have access to reliable transportation to
8 make multiple trips, or they cannot take additional time from work during the day, or they
9 need to be home to take care of children or other family members.

10 8. Additionally, Medi-Cal Rx will fundamentally alter the way I and other Medi-
11 Cal providers at FQHCs will be able to treat our patients. For example, I will no longer
12 have access to real-time information as to the availability of medications or my patients'
13 adherence to the treatment plan. Using the example of the Lidocaine patch discussed
14 above, under the Medi-Cal Rx fee-for-service model, I would prescribe the patch and my
15 patient would have to make a separate trip to a pharmacy to get it. However, if that
16 pharmacy does not have it in stock or the pharmacist needs prior authorization, I will no
17 longer be notified as part of managed care and will not necessarily be advised that my
18 patient was unable to pick up their prescription. Because of the type of patients I work
19 with and the challenges they face in making multiple trips to different healthcare
20 providers, there is a high likelihood that my patient would forego the treatment altogether.
21 I would not discover the problem until months later in a follow-up visit with my patient, at
22 which point their condition and pain has worsened because they could not access the
23 treatment I prescribed.

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1 9. It is also my understanding that Medi-Cal Rx will also change Open Door's
2 and other FQHCs' reimbursement for drugs purchased under the federal 340B drug
3 discount program. I am gravely concerned that the proposed fee-for-service
4 reimbursement, actual acquisition costs of the drug plus a nominal dispensing fee, would
5 not cover the cost of providing necessary pharmacy services to my patients.

6 10. In addition, the savings and reimbursement Open Door receives from the
7 340B program go directly to providing additional, much-needed services for our patients that
8 are not otherwise reimbursed by Medi-Cal. One key example is Open Door's Medication
9 Assistance ("MAT") Program. MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid use disorder to overcome and manage their addiction. The drug is very
12 expensive, so without 340B pricing, our patients would not be able to receive it at all.
13 Additionally, MAT includes support groups that help patients maintain sobriety, which
14 requires efforts from case managers and member services staff. However, these
15 counseling services are not reimbursable by the Medi-Cal program, and are instead
16 directly funded by 340B revenue and savings. Without services like our MAT Program,
17 Open Door's patients will be denied access to a highly effective treatment option that can
18 help them get away from opiates and improve their overall lifestyle.

19 11. Based on my experience as a family physician at an FQHC, I believe that
20 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
21 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
22 as how those patients access their Medi-Cal benefits. I am greatly concerned that
23 removing the pharmacy benefit from managed care will directly prevent Open Door's
24 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
25 their unique and varied needs. Additionally, the loss of 340B revenue will force Open
26 Door to cut off critical resources for patients who are struggling with opioid use disorder
27 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
11 FOR PATIENT ACCESS, ET AL.

12
13 **UNITED STATES DISTRICT COURT**
14 **EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION**
15

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

18 Plaintiffs,

19 v.

20 WILLIAM LIGHTBOURNE, Director of the
California Department of Health Care
21 Services; CALIFORNIA DEPARTMENT
OF HEALTH CARE SERVICES,
22

23 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

24 I, Dr. Paramvir Sidhu, declare as follows:

25 1. I am currently a family physician at Family Health Care Network ("FHCN"),
26 where I have worked for the last ten years. I also currently serve as Chief Clinical Officer
27 at Family Health Care Network. I received my medical training in India and completed
28 my residency in family medicine at the Riverside Community Medical Center, Riverside,

1 California. As a family physician, I regularly interact with patients, prescribe medications,
2 and ensure my patients are receiving their medications and following the treatment
3 regimens. As the Chief Clinical Officer, I also receive reports from the other physicians
4 about the provision of services to their patients, including concerns about challenges and
5 suggestions for improving services. The majority of FHCN patients are Medi-Cal
6 beneficiaries who are members of a Medi-Cal managed care plan ("MCP"). Although
7 FHCN is not a named plaintiff in this action, it is an affiliate of the Community Health
8 Center Alliance for Patient Access. I have personal knowledge of the facts set forth
9 herein, and if called to do so, could and would testify competently thereto. I make this
10 declaration in support of Plaintiffs' Reply to Defendants' Opposition to the Motion for a
11 Preliminary Injunction.

12 2. FHCN is a Federally Qualified Health Center ("FQHC") that receives federal
13 grant funds under Section 330 of the Public Health Services Act. FHCN is committed to
14 providing excellent health care and health education to medically underserved patients in
15 the Tulare, Kings and Fresno Counties, three rural counties in the San Joaquin Valley of
16 Central California. FHCN currently operates forty-one (41) community health centers
17 across these counties, serving more than 221,000 patients each year while employing
18 nearly 1,500 members of the community.

19 3. The patients we serve from Tulare, Kings and Fresno counties are
20 predominately from rural communities, and tend to rank near the bottom for health
21 outcomes among California counties. Our patients struggle with widespread problems of
22 poverty, lack of health education, lack of reliable housing and transportation, and
23 numerous other socio-economic barriers to health care that directly affect their well-being
24 in the short and the long term. A large majority of our patients are Seasonal and Migrant
25 farmworkers who suffer from severe health care disparities. As a physician who has
26 worked in this community for ten years, I am well aware that these socio-economic
27 problems often cause my patients to forego necessary medical care in order to focus on
28 other urgent aspects of their lives. These patients have to choose between utilizing their

-2-

DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

1 limited resources to either buy food or pay rent to support their families, or pay for their
2 prescribed medications.

3 4. FHCN is committed to meeting our patient's needs and provide access to
4 quality medical care to everyone. We are Joint Commission Accredited clinics and we
5 operate under a patient-centric medical home model ("Medical Home") that allows us to
6 coordinate an individual patient's care across specialties so that we treat the whole
7 person, rather than individual symptoms. As their Medical Home, FHCN proudly serves
8 as a one-stop-shop for all of our patients' medical needs, as well as their unique needs
9 for accessing transportation assistance, housing, and food and connect the patients with
10 resources in the communities. The Medical Home also helps patients follow their medical
11 treatment plans because they do not need to go to multiple facilities – all of their
12 providers are in one place, which greatly improves the patients' overall health outcomes.

13 5. A part of the Medical Home also includes pharmaceutical services for our
14 patients. Having pharmacies in our health centers and medications under the 340B
15 program allows me as a prescribing physician to work directly with the pharmacists and
16 greatly improve my patients' ability to access necessary treatments. For example, if I
17 prescribe Insulin– a lifesaving treatment for diabetes – I will have access to real-time
18 information as to when and if the patient is able to pick up the medication at a very
19 affordable price. If the Insulin is not available for some reason or not covered by the
20 patient's plan, the pharmacist is able to call and inform me and provide alternatives to the
21 medication. This allows me to make same-day adjustments to the treatment plan and
22 patient leaves the visit with medications. Relatedly, our in-house pharmacists have
23 access to a patient's Electronic Health Record, allowing them to track prescription
24 dosages and types, which enhances patient safety. For example, our pharmacist can
25 see and verify the weight of a pediatric patient who is prescribed antibiotics for an
26 infection, verify the dosage calculation, and consult with me prior to the patient leaving
27 the health center. Another example would be the pharmacist reviewing the medical
28 record and noting additional medications or supplements listed in the patient's medication

-3-

DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS'
OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION

1 list that could have contraindications when taken with the prescribed medication. Again,
2 this can be discussed with me before the patient leaves the health center. These are just
3 a few concrete examples of how the pharmacy benefit's inclusion in managed care
4 facilitates medical services for both doctors and patients, leading to better care and
5 outcomes for the most vulnerable, medically underserved people in California.

6 6. The inclusion of the pharmacy benefit in managed care also enables me to
7 tailor my treatment plan to the patient's needs. First, with the pharmacy and medical
8 benefits linked, the current managed care model allows me to see if my patients are
9 getting their prescriptions, taking them on schedule, re-filling them as prescribed, and
10 returning for medical follow-ups on time. This information is critical to creating a
11 treatment plan for my patients, tracking their progress and condition, and scheduling
12 necessary follow-up appointments. Second, the 340B savings allow us to operate a
13 robust in-house pharmacy program, including a Director of Pharmacy who sits on our
14 Medical Director Team. This coordination allows us to create a formulary for our
15 pharmacy specific to the clinical needs of our patient population and at the lowest
16 acquisition price possible, benefiting our patients both clinically and financially. Without
17 the 340B program, this cross-collaboration and comprehensive care management will not
18 be possible, as the dramatic cuts that would need to be made to our in-house pharmacies
19 would no longer allow us to have a Director of Pharmacy, and pharmacists would no
20 longer be able to dedicate time to comprehensive care management.

21 7. It is my understanding that, effective April 1, 2021, the Medi-Cal Rx initiative
22 will transfer the pharmacy benefit out of managed care and into a fee-for-service model.
23 This will directly undermine FHCN's Medical Home model and my ability to treat my
24 patients effectively. For example, disconnecting pharmacy services from medical
25 services will require our patients to take multiple trips to receive their care and their
26 medication. For most of my patients, this is not simply one more errand in their day – it is
27 an insurmountable barrier because they don't have access to reliable transportation to
28 make multiple trips, or they cannot take additional time from work during the day, or they

1 need to be home to take care of children or other family members.

2 8. It is also my understanding that Medi-Cal Rx will also change FHCN's and
3 other FQHCs' reimbursement for drugs purchased under the federal 340B drug discount
4 program. I am gravely concerned that the proposed fee-for-service reimbursement,
5 actual acquisition costs of the drug plus a nominal dispensing fee, would not cover the
6 cost of providing necessary pharmacy services to my patients. It will also impact our
7 ability to provide other benefits that are significant to our patients. For instance, we
8 currently have an extensive patient transportation program that provides door-to-door
9 service from a patient's home to the health center, which we would need to be scaled
10 back or eliminated if we no longer received revenue from the 340B program.
11 Additionally, we will have to increase the nominal fee offered to uninsured patients on our
12 pharmacy sliding fee scale, which will increase the costs for patients who cannot afford
13 higher out-of-pocket expenses for medical care. Such a change could result in uninsured
14 patients forgoing prescriptions, leading to worse health outcomes.

15 9. Medi-Cal Rx will also fundamentally alter the way I and other Medi-Cal
16 providers at FQHCs will be able to treat our patients. For example, FHCN has a Diabetic
17 clinic where the goal is to provide coordinated diabetic care to patients. This includes the
18 patient getting education about diabetes from health educators, necessary screenings
19 and immunizations, and behavioral-health counseling. These services are in addition to
20 medical care and treatment the physicians provide during the same (single) visit for the
21 patient. Using the example of the Insulin discussed above, under the Medi-Cal Rx fee-
22 for-service model, I would have to prescribe the Insulin and my patient would have to
23 make a separate trip to a pharmacy to get it. However, if that pharmacy does not have it
24 in stock, the cost is too high, or the pharmacist needs prior authorization, I will not be
25 notified immediately that my patient was unable to pick up their prescription. Because of
26 the type of patients I work with and the challenges they face in making multiple trips to
27 different healthcare providers, there is a high likelihood that my patient would forego the
28 treatment altogether. I would not discover the problem until months later in a follow-up

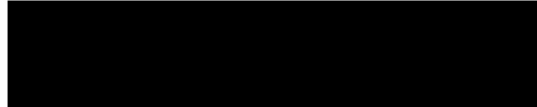
1 visit with my patient, at which point their condition has worsened and severe
2 complications developed because they could not access the treatment I prescribed, or
3 the supportive Diabetic clinic services. The result for that patient is deteriorated clinical
4 outcomes and, most likely, costly trips to the emergency room paid for by the Medi-Cal
5 program for a Medi-Cal beneficiary.

6 10. In addition, the savings and reimbursement FHCN receives from the 340B
7 program go directly to providing additional, much-needed services for our patients that are
8 not otherwise reimbursed by Medi-Cal. One key example is FHCN's Medication
9 Assistance Program ("MAT"). MAT provides access to the medication buprenorphine,
10 also known as Suboxone, which is scientifically proven to help patients struggling with
11 opioid addiction to overcome and manage their addiction. The drug is very expensive, so
12 without 340B pricing, our patients would not be able to receive it at all. Additionally, the
13 MAT clinic includes counseling that help patients maintain sobriety, which requires efforts
14 from Behavioral Health and member services staff. However, some of these ancillary
15 services provided in the MAT clinic as well as the above mentioned Diabetic clinic are not
16 reimbursable by the Medi-Cal program, and are instead directly funded by 340B revenue
17 and savings. Without programs like MAT, FHCN's patients will be denied access to a
18 highly effective treatment option that can help them get away from opiates and improve
19 their overall lifestyle.

20 11. Based on my experience as a family physician at an FQHC, I believe that
21 Medi-Cal Rx will create additional barriers to healthcare services that my patients are
22 already struggling to obtain. It will change the way I treat my Medi-Cal patients, as well
23 as how those patients access their Medi-Cal benefits. I am greatly concerned that
24 removing the pharmacy benefit from managed care will directly interfere with FHCN's
25 ability to serve as the one-stop-shop Medical Home that our patients depend on to treat
26 their unique and varied needs. Additionally, the loss of 340B revenue will force FHCN to
27 cut off critical resources for patients who are struggling with opioid addiction and other
28 chronic conditions like Diabetes.

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

3 Executed on this 5 day of February, 2021, in VISALIA, California.
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8 DR. PARAMVIR SIDHU
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Exhibit H
to letter dated 4/16/2021

1 2HANSON BRIDGETT LLP
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 2 ANDREW W. STROUD, SBN 126475
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 3 Sacramento, California 95814
 Telephone: (916) 442-3333
 4 Facsimile: (916) 442-2348
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 5 astroud@hansonbridgett.com

6 REGINA M. BOYLE, SBN 164181
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 7 Post Office Box 163479
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 8 Sacramento, CA 95816-9479
 Telephone: (916) 930-0930
 9 Email: rboyle@cliniclaw.com

10 Attorneys for Plaintiffs
 COMMUNITY HEALTH CENTER ALLIANCE
 11 FOR PATIENT ACCESS, ET AL.

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UNITED STATES DISTRICT COURT

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EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Case No. 2:20-CV-02171-JAM-KJN4

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Plaintiffs,

DECLARATION OF FRAN BUTLER-COHEN IN OPPOSITION TO MOTION TO DISMISS PLAINTIFFS' COMPLAINT

19

v.

Judge: Hon. John A. Mendez

Date: February 23, 2021

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

Time: 1:30 p.m.

Crtrm.: 6

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Defendants.

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I, Fran Butler-Cohen, declare:

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1. I am the Chief Executive Officer ("CEO") at Family Health Centers San

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Diego ("FHCS") and have held this role since 1986. I have reviewed the data and

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associated outcomes relevant to the impact of Medi-Cal Rx on FHCS in connection with

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the preparation of this declaration. I have personal knowledge of the facts set forth

1 herein, and if called to do so, could and would testify competently thereto. I make this
2 declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

3 2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives
4 federal grant funding under Section 330 of the Public Health Services Act. FHCSD has
5 served the medically underserved communities of San Diego County since 1970, with the
6 transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's
7 flagship clinic. FHCSD has since transformed into the tenth largest health center in the
8 country, providing care to over 149,000 patients each year, of whom 90 percent are low
9 income and 31 percent are uninsured. FHCSD serves all patients regardless of their
10 ability to pay.

11 3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020,
12 FHCSD has provided free COVID-19 testing to as many patients as the staff can
13 manage. During this time, demand for FHCSD services has skyrocketed. To try to meet
14 our patients' testing needs, FHCSD has purchased additional lab equipment and
15 increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid
16 testing and notification systems to quickly identify patients with COVID-19 and reduce
17 community spread. Additionally, we have set up a separate obstetrics clinic for mothers
18 who have tested positive for COVID-19. These steps have proven necessary, since,
19 among the patients we serve, the COVID positivity rate in the second week of January
20 2021 was 35 percent, more than double the average statewide rate for the same time
21 period.

22 4. In an effort to take care of patients and to avoid sending them to hospitals –
23 which currently cannot handle an additional influx of patients – FHCSD has also ramped
24 up its ability to care for the sickest, non-emergent patients. Instead, we have started
25 Monoclonal Antibody administration for the sickest, non-emergent patients at one of our
26 clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as
27 soon as possible.

28 ///

1 5. Despite the heroic efforts of our health care workers – who have shouldered
2 the burden of coming to work every day risking their own health and the health of their
3 families – FHCS D staff is stretched beyond its limits and is struggling to continue. We
4 currently have seventy (70) members of our team out of work due to COVID, which hurts
5 FHCS D’s ability to meet patients’ needs and county demands. We have started an
6 emergency child care program to keep our workers on the job when they have no other
7 childcare options. We have also started an Employee Food Pantry Program so that
8 employees who have lost income can feed their families.

9 6. Now, with the development of a COVID-19 vaccine, San Diego County is
10 asking FHCS D to submit information regarding how many vaccinations we could
11 administer to the general public, which requires me and the FHCS D staff to study
12 guidance from the Centers for Disease Control and the Department of Defense to
13 implement massive public vaccination events, in addition to juggling the current
14 emergency needs of our patients and community.

15 7. Simultaneously, FHCS D is still required to commit time to fielding
16 government audits and meet with the State and Managed Care Organizations on metric
17 performance. In addition, FHCS D is currently in the beginning stages of a random federal
18 340B audit that has already taken several hundred hours of staff time in preparation and
19 document submission. At the same time, the Health Resources and Services
20 Administration is requesting capital funding grantees submit previously unrequired data
21 and qualitative information to help them design future grant programs. Moreover,
22 FHCS D has had to make significant modifications to contract pharmacy arrangements to
23 ensure our patients receive affordable medications due to the attack on the 340B
24 program by pharmaceutical manufacturers. All of this comes against the backdrop of the
25 State of California awarding a contract valued at approximately \$80 million annually to a
26 for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by
27 Centene, a publicly traded NYSE corporation worth \$76 billion for \$2.2 billion dollars to
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1 facilitate the state in their plan that will remove hundreds of millions of dollars from the
2 state's health care safety-net.

3 8. It is unconscionable that during this time of perpetual crisis, when our staff
4 and other healthcare workers have sacrificed so much to serve the communities that
5 need them most, FHCS and other FQHCs are required to prepare and plan for Medi-
6 Cal Rx, which will result in drastic funding reductions due to changes in reimbursement.
7 Additionally, the loss of 340B funding that helps stretch our resources to expand
8 healthcare access will further reduce staff and desperately needed health services.

9 9. Although the "effective" date of Medi-Cal Rx has been moved to April 1,
10 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring
11 health centers to adjust our conduct in a number of ways. Examples of some of the
12 activities FHCS has had to undertake in anticipation of the "go live" date for Medi-Cal
13 Rx include:

- 14 • A complete budget review and assessment of programs currently
15 funded through 340B savings, including the potential for lay-offs,
16 elimination of support programs, and reduction in hours and types of
17 services provided to our patients.
- 18 • Meetings with vendors that currently support in-house pharmacy
19 operations to ensure systems remain compliant following full
20 implementation.
- 21 • Subscribe to and dedicate staff time to monitor, review and bring
22 forward issues noted in regular updates from the Medi-Cal Rx
23 Subscription Service
- 24 • Secure Provider Portal access and enroll approximately 250
25 prescribing providers into the provider portal, necessitating hundreds
26 of hours of administrative staff time.

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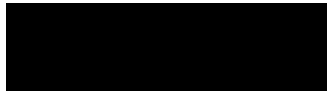
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1 patients who have suffered the most throughout the COVID-19 emergency will also bear
2 the burden of the Medi-Cal Rx initiative's consequences.

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

5 Executed this 20th day of January, 2021, at San Diego, California.

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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](#)
2. [Updates to the List of Covered Enteral Nutrition Products](#)
3. [Medi-Cal Provider Training Schedule](#)
4. [Prescriber Phone Campaign](#)
5. [Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey](#)
6. [Pharmacy Provider Self-Attestation Period Begins April 2021](#)
7. [Portal Registration](#)

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 SabaSM 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.

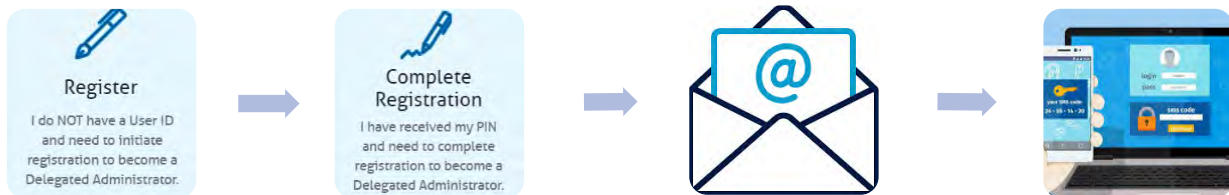
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- 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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