TABLE OF CONTENTS

CALIFORNIA MEDICAL ASSOCIATION

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

RE: Comments on the California Advancing and Innovating Medi-Cal (CalAIM) Demonstration and Waiver Proposal

Dear Director Lightbourne:

On behalf of more than 50,000 physician members and medical students of the California Medical Association (CMA), we would like to thank you for considering stakeholder input on the Department of Health Care Services' (DHCS) California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 demonstration application and Section 1915(b) waiver application to CMS. Through a comprehensive program of legislative, legal, regulatory, economic, and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physicians are committed to working to improve the Medi-Cal program and to ensure that patients have access to care. As we continue to participate in the various CalAIM stakeholder groups and as the proposal evolves or changes, we will provide additional suggestions, feedback, and comments as appropriate. CMA has been included on some of the key workgroups and continues to seek opportunities to help develop this proposal in a way that supports physicians and their patients.

IDENTIFYING AND MANAGING MEMBER RISK

Population Health Management Program

CMA supports the requirement that all Medi-Cal managed care plans (MCPs) maintain a population health management program that improves the ability of physicians and other health care providers to identify social factors and needs that impact health. We believe that a more comprehensive strategy that accounts for screenings, health assessments, case management, data collection and monitoring and risk stratification is a fundamental and much-needed improvement to the overall managed care plan responsibility. However, the plans should not develop these population health management programs in isolation. We would recommend that the plans be required to include practicing physicians from the plans' geographic service areas in the development and operationalization of their program. This local input will ensure that plans receive feedback directly from practicing physicians on the most effective ways to improve care coordination, communication, and data sharing.

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Initial Risk Assessment

One of the challenges in managing high-risk populations is the inability to share appropriate levels of data with providers in a meaningful and timely way. The Department is correct in seeking to separate risk assessments from clinical screenings. However, it is important that the results of the member-contact screening also be shared with assigned primary care physicians or specialists and not just between the plan and the DHCS. Physicians and patients would greatly benefit from additional information about a patient's social needs, including their access to food, clothing, household goods and transportation. If a health plan is obtaining this information through its assessment, CMA would recommend that a mechanism be developed to appropriately and legally share this patient information with the physicians that are caring for the patients directly. This information should also be available electronically, integrated with the patient's existing health records, and updated in a timely fashion.

The data should also be collected in such a way that it can be easily transmitted in a usable format and incorporated into the risk stratification process. We recommend that initial risk assessment be standardized to the extent that DHCS is able to compare data across plans and develop methods to evaluate the success of their population health management programs. Additionally, to the extent that member-contact screening requirements are passed down to physicians, DHCS should make sure there is adequate reimbursement for such screenings. Screening tools should be separate from screenings used for clinical screenings, cost-effective, and not negatively impact medical care or create additional burden for physicians. DHCS should also implement enhanced education on effective screening practices.

Risk Stratification

The CalAIM proposal requires Medi-Cal managed care plans to risk stratify the population to determine the level of intervention that members require based on all available data sources, as well as the results of the member-contact screening. CMA urges the department to ensure that it implements efforts to identify and address bias in the use of these risk stratification algorithms and to avoid introducing or exacerbating health care disparities in connection with the use of these tools, particularly since they will be used for vulnerable populations. While recognizing there is some proprietary intellectual property in the development of risk stratification algorithms, we would also encourage greater transparency about how these tools are being deployed as well as the underlying data being used to generate any outputs. Any algorithms used by plans should be validated nationally and required to use as complete a set of data as possible.

The reliance of risk stratification algorithms on inputted data can lead to certain associated risks. These algorithms require access to large quantities of high-quality data during training and validation. Without accurate and meaningful data, algorithms may not be correct or may not be applicable to different populations. The source of the data used during training will impact the algorithm significantly, and models must be tested on a variety of data sets for validation purposes in order to create an algorithm that works accurately across patient

populations. Otherwise, an algorithm may be trained and validated, only to produce inaccurate results when used with a population that varies based on race, gender, or socioeconomic background, medical history, hospital setting, or geographic location.[1]

Furthermore, the biases of training data can risk exacerbating existing health disparities. If models only reflect the limited populations on which they are trained, they will be less accurate for minority groups, and majority groups will have better access to accurate algorithms and thus superior health care.[2] In addition to training and validating across broad populations, MCPs should work towards increased transparency in order to provide opportunities to disclose and address system bias. Understanding data provenance, including key attributes of the training data population, is necessary to evaluating the accuracy of the risk stratification algorithms and the risks of applying the system to a different population.[3]

Provider Referrals

CMA supports the establishment of a process for providers to refer patients for case management, including a toll-free phone line for both primary care and specialists to seek technical and referral assistance when a patient requires additional evaluation and treatment. Physicians would greatly benefit from guidance on how to best assist a patient needing additional services that are beyond the physician's capacity to address, so CMA would request that plans provide physicians with specific information on how they can access this service on behalf of their patients. The information should be shared prominently rather than simply posting on a website and including it in provider materials where it may not be readily available or known about. Additionally, DHCS and MCPs should facilitate processes to guarantee a warm handoff between physicians and social service providers so that patients are able to easily access additional services that will support their health.

CMA also supports the provision of a 24-hour/7-day a week toll-free nurse advice line for members seeking assistance for physical, oral and behavioral health services. While this is a current service requirement for plans licensed under the Knox-Keene Act (28 CCR 1300.67.2.2(c)(8)), CMA is aware that some plans simply delegate this requirement to contracting physicians, with no reimbursement for providing the service. CMA would urge DHCS to not permit plan delegation of this function to a contracting physician practice unless there is a mutually agreed upon contract and reimbursement rate between the plan and its contracting physician practice for this specific service.

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[1] See Jennifer Bresnick, *Unleashing the Value of Health Data in the Era of Artificial Intelligence*. HEALTH IT ANALYTICS, *available at* https://healthitanalytics.com/features/unleashing-the-value-of-health-data-in-the-era-of-artificial-intelligence.

[2] American Medical Association Policy H-480.940; *Report 41 of the Board of Trustees (A-18) Augmented Intelligence (AI) in Health Care*, American Medical Association (2018), *available at* https://www.ama-assn.org/system/files/2019-12/a18-bot-reports.pdf.

[3] *Report 21 of the Board of Trustees (A-19): Augmented Intelligence (AI) in Health Care*, American Medical Association (2019), *available at* https://www.ama-assn.org/system/files/2019-04/a19-bot21.pdf..

Health Information Technology to Support Integrated Care and Care Coordination

CMA supports the proposal to require MCPs to implement health information technology (HIT) to support population health principles, integrated care and care coordination across the delivery system. We believe the development and funding of this HIT infrastructure is key to the success of the CalAIM proposal and would request that DHCS provide more specific information in future stakeholder meetings and written documents as to how it will be build and fund interoperable HIT and health information exchange infrastructure. We would also request more details as to the data exchange protocols MCPs will be required to develop in order to ensure care coordination with their physicians as well as between physicians and other health care providers including behavioral health specialists.

In order to personalize health care and improve health outcomes, the healthcare industry must share and effectively use health data. While we have the technical and operational ability to do this today, there is a lack of willingness of all the participants in the system to enable effective data exchange and use. For instance, currently electronic health record (EHR) vendors lack the market imperative to ensure interoperability, partly because providers bear most of the costs of integrating these devices and because there is an absence of an aligned demand to drive change in the technology ecosystem. Some larger health care providers achieve some level of medical device integration, particularly to support data to EHR integration. However, in the perceived absence of a prominent value proposition, many devices are not integrated with other technologies at all.

A report published by the West Health Institute in 2013 estimated that wide-spread medical device interoperability could eliminate at least $36 billion of waste in inpatient settings alone (West Health Institute, 2013). It was estimated that functional interoperability leads to increased efficiency, lower costs, and better quality of care through four primary drivers: reducing adverse events because of safety interlocks ($1.9 billion); reducing redundant testing ($1.5 billion); reducing clinician time spent manually entering information ($12 billion); and shortening length of stay through more timely transmission of critical information such as lab results ($18 billion).Technologically and financially, physician practices, hospitals, and clinics in California range from large and sophisticated systems to small, strained offices and facilities. Under any statewide policy requiring stakeholders to meaningfully share health information, it is reasonable for certain providers with limited infrastructure and means—such as independent physicians, rural hospitals, and safety-net clinics—to expect public subsidies and incentives to help defray the costs of participation. Moreover, other states' efforts to advance health information sharing through both strong requirements *and* funding have seen success.[4] We would recommend that DHCS consider incentive payments to physicians for adoption of new technology, and that DHCS offer electronic equipment, as

[4] The state of Michigan helps fund its statewide health information-sharing platform, and as a result, providers receive daily ADT and emergency room notifications for more than 7 million patients (out of 10 million residents). See Michigan Health Information Technology Commission Update, May 2018; https://www.michigan.gov/documents/mdhhs/May_2018_HIT_Commission_Presentation_Final_Version_631723_7.pdf

well as technical support, to ensure that every provider can participate in meaningful data exchange and a patient's health record is truly comprehensive.

Additionally, we ask that DHCS take this opportunity to create the position of state "coordinator for connected care," or its equivalent. This coordinator position would oversee all HIT efforts, including general HIT coordination among payers and providers, health IT upgrades for county mental health billing, consistency in telehealth offerings across programs, MCP and provider participation in HIE, and the promotion of interoperability among health IT systems, especially EHRs. In past experiences, such as the creation of the position of deputy secretary of health information technology within CHHS, the state was able to play a critical role in facilitating the policy, statutory, and regulatory changes needed to advance electronic health record adoption and health information exchange.

While DHCS currently has the Information Management Division, there is no individual who is tasked with such coordination efforts, especially to provide guidance to payers and providers on how to navigate the myriad billing, health records and other IT systems that are in place among and often within organizations. While we thank DHCS for expanding the breadth of telehealth-enabled services now reimbursed by the Medi-Cal program, we note that these impediments to better care coordination are likely to continue and compound for physicians serving the Medi-Cal population and DHCS as well, particularly since most Medi-Cal beneficiaries receive their services in multi-payer environments where payers may use different technology platforms with providers to provide services, and where physicians are utilizing different electronic health records vendors that make integration difficult.

Enhanced Care Management Benefit

CMA strongly supports the addition of this new benefit to the Medi-Cal program. As documented in several studies, including a recent Commonwealth Fund report,[5] five percent (5%) of the population accounts for fifty percent of the health care costs. As noted in the report, identification of the high-risk population is not enough. There must be an overall effort to change the way care is delivered through innovative methods including alternative payment models, systemic change and supporting providers in changing their own organizations. CalAIM will not be successful if this approach is not supported with the right financing and programmatic flexibility.

CMA supports efforts to promote well-coordinated and adequately funded case managers for people with complex medical and social needs. Many social and economic conditions often lead to health disparities, or differences in health outcomes, and vary by socioeconomic status, race/ethnicity, geographic location, educational attainment, sexual orientation, gender, and occupation. Strong evidence has accumulated over the last decade that links

[5] Kushal Kadakia et. Al, COMMONWEALTH FUND, ADAPTING PROMISING INNOVATIONS TO MEET THE NEEDS OF HIGH-NEED, HIGH-COST POPULATIONS (April 4, 2019), *available at* https://www.commonwealthfund.org/blog/2019/adapting-promising-innovations-meet-needs-high-need-high-cost-populations.

unmet social needs with poor health status.[6,7] A recent study found that when organizations had greater flexibility over spending, health care leaders made investments in a range of services to address housing, food, legal, and other social needs, as well as capacity-building interventions to strengthen health care and community-based organizations' ability to respond to these needs.[8]

We understand from the CalAIM proposal and from previous stakeholder meetings that the ECM benefit is designed to be provider-based and in-person, and that MCPs will contract out for these services. Additionally, we would ask DHCS to clarify in its written policies, that unlike the existing case management and complex case management benefits provided by the MCPs, ECM will be done at the provider level. We would encourage the utilization of existing provider relationships and networks, and for MCPs to continue to build on the success of existing programs like the Whole Person Care pilots. Additionally, we strongly support contracted models where MCPs will provide direct funding for physician practices to hire additional case managers who can provide this benefit to patients.

While supporting the addition of this important benefit that holds a lot of promise for tackling the most high-cost and high-risk populations, physicians report to CMA that oftentimes when managed care plans are given additional requirements for enhanced care management that require high-touch, on the ground and face-to-face contact, either programmatic or data-related, that these requirements tend to be delegated downstream to treating physicians, often without discussion or additional financing to support the new requirements. Providers, both physical and behavioral health, will be key to successfully driving these changes with individual patients. However, in order to successfully implement this new benefit, plans cannot simply add additional unfunded contract requirements to provider contracts and expect this to be absorbed into practice flows. CMA would urge the Department to require plans to include any additional requirements and associated reimbursement for enhanced care management responsibilities in physician contracts.

Quality Metrics

We also understand from previous stakeholder meetings that funding for these benefits, and for incentive-based contracts with physicians, will be based on reporting on quality metrics. We strongly encourage limiting the number of data points on which physicians need to report so that physicians can spend their time providing medical care instead of completing administrative tasks. We encourage DHCS to consider the following guiding principles for selecting incentive measures:

- The quality performance standards tied to value-based payment models must be physician specialty-validated clinical measures.

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[6] C. Mansfield and L. F. Novick, "Poverty and Health: Focus on North Carolina," North Carolina Medical Journal, Sept.-Oct. 2012 73(5):366–73.
[7] S. H. Woolf and P. Braveman, "Where Health Disparities Begin: The Role of Social and Economic Determinants—And Why Current Policies May Make Matters Worse," Health Affairs, Oct. 2011 30(10):1852–59.
[8] Hugh Alderwick, Carlyn M. Hood-Ronick, and Laura M. Gottlieb. Medicaid Investments To Address Social Needs In Oregon And California. *Health Affairs* 2019 38:5, 774-781.

- Quality reporting measures should be consistent and aligned with other programs and payers. Developing mechanisms for sharing standardized quality measure data among different programs will reduce time and resources spent reporting duplicative or redundant measures.
- The development and revision of these measures should be an ongoing process that reflects new clinical evidence and quality data.
- When new quality measures are adopted, other measure should be reviewed and evaluated before being retained.

Minimizing additional administrative burdens on physicians should be a priority. Currently, physicians are required to report multiple quality measures in different ways to different entities. This imposes significant burdens on physician practices and impedes comprehensive improvement in overall quality of care. A recent study[9] indicates physicians and their staff can spend upwards of 15 hours per week dealing with various quality measures with different payors. The physician time alone spent dealing with quality programs is estimated to be enough time to care for approximately nine additional patients and the staff time spent is incredibly costly to practices.

We encourage DHCS to emphasize quality measures that can be assessed based on available data, and to use existing encounter data rather than requiring physicians to complete additional reporting. Ensuring these measures can be automatically extracted from encounter data would reduce the need for physicians and their staff to manually extract and manipulate data measures according to the individual specifications of each entity requiring quality data reporting.

CMA strongly supports using existing sources of data when evaluating physician participation in this program and that any assessment of the proposed measures be done through existing encounter data. CMA also strongly opposes any measures that require increased manual review of medical records by physicians, their staff, or external auditors.

Data Sharing for Care Coordination

Ensuring data sharing among physicians, behavioral health providers, and social service agencies will be necessary to ensure the success of the enhanced care management benefit. Physicians face a confusing maze of legal and regulatory requirements around state and federal privacy laws. The federal Health Insurance Portability and Accountability Act (HIPAA) regulates how physicians maintain records, the security and confidentiality of medical records, patient access to their records, how physicians use and disclose records, and what to do when there is a breach of security to medical information. In addition to HIPAA, California law also governs how medical records are kept pursuant to the Confidentiality of Medical Information Act (CMIA). Certain kinds of medical records, such as mental health records and

[9] Lawrence P. Casalino, et al., *US Physician Practices Spend More Than $15.4 Billion Annually to Report Quality Measures,* HEALTH AFFAIRS (March 2016), *available at* https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1258.

substance abuse records are also subject to additional laws depending on the practice setting, who and how the information was gathered. Physicians also need to be mindful of federal and California law that governs how electronic consumer data is collected, stored, used, and disclosed.

CMA would request clear guidance from DHCS to both plans and physicians on how to share data and structure data-sharing agreements in compliance with state and federal requirements. CMA supports efforts to research historic data and promote data-sharing among social service, physical health and behavioral health providers, and correctional facilities, consistent with state and federal privacy laws, in order to provide continuous and coordinated care for people with social needs that may impact their health. Finally, given the myriad of medical records laws and regulations, and lack of clarity about compliance, CMA supports further education for physicians on their legal obligations regarding these laws.

Shared Risk, Shared Savings and Incentive Payments

The key to successfully implementing a majority of the CalAIM proposal rests on the financing and alignment of incentives. As the Department develops the mechanisms for the financial incentive payments, CMA requests that it, along with other physician organizations, be given an opportunity to offer input at key points in the rate and incentive payment process. The reason for this is two-fold:

- The CalAIM initiative will place a number of additional requirements on contracting managed care plans, their delegated entities and ultimately, the treating physician. CMA would like to ensure that these requirements are not only appropriately delegated, but appropriately reimbursed (as noted above).
- According to the proposal, the incentive funds are intended to build capacity for both enhanced care management and in-lieu of services. We believe that there will be greater pressure on the plans to support and build the in-lieu infrastructure (i.e., build additional facilities, bed capacity) and this could occur to the detriment of supporting the enhanced care management benefit. The two must be equally supported and CMA would like to ensure any such incentive structure recognizes and supports both appropriately.

Lastly, the CMA requests that the Department consider dedicating a portion of the incentive payments to some of the underlying fundamentals associated with the managed care delivery system. There are currently a very large number of plans subject to Corrective Action Plans (CAP) with 20 MCPs placed under a CAP in July 2019 for noncompliance with the Annual Network Certification requirements.[10] MCPs continue to rely heavily on alternative access standards, with approximately 6,500 requests being approved in most recent network certification process, down from around 10,000 the previous year.[11] To date, the state has

[10] Department of Health Care Services, July 2019 Annual Network Certification Corrective Action Plan Report, https://www.dhcs.ca.gov/formsandpubs/Documents/2019-July-Corrective-Action-Plan-Findings.pdf
[11] Department of Health Care Services, 2019 Approved Alternative Access Standards Report (Jan. 30, 2019), https://www.dhcs.ca.gov/formsandpubs/Documents/AB_205_AAS_Report_2019.pdf.

never offered plans an incentive payment for achieving or exceeding network adequacy standards. Given the necessity of keeping an adequate network and meeting time-and-distance standards for all Medi-Cal beneficiaries, the CMA would suggest that a portion of the new incentive dollars be provided to plans that not only meet, but exceed their minimum requirements in these critical access measures.

MOVING MEDI-CAL TO A MORE CONSISTENT AND SEAMLESS SYSTEM BY REDUCING COMPLEXITY AND INCREASING FLEXIBILITY

Transition to Statewide Long-Term Services and Supports, Long-Term Care and Dual Eligible Special Needs Plans

CMA has serious concerns about DHCS's proposal to move some of California's most vulnerable patients into mandatory Medi-Cal managed care. CMA opposes any effort to mandate that dual eligibles be enrolled in managed care. If the state decides to move forward with this mandate by 2023 as proposed, then we recommend ensuring that all efforts are made to ensure continuity of care for these patients and to learn from the lessons of the Coordinated Care Initiative (CCI) to improve patient and physician outreach and education. DHCS must also ensure there is no disruption in care for beneficiaries during this transition, which did occur during CCI implementation. Additionally, DHCS and the MCPs must provide full and clear disclosure to beneficiaries of options and implications of managed care enrollment.

DHCS should ensure robust stakeholder engagement in this endeavor and develop enrollment notices and educational materials for beneficiaries that are accurate, easy to understand, and ADA accessible. Outreach, enrollment, and coordination of care must be culturally, linguistically competent and fair for California's diverse seniors, especially those who have Limited English Proficiency. Patients and physicians must be properly educated about this plan and its implications for coverage and access to care. DHCS should provide training and materials to physicians on billing, continuity of care, and plan enrollment, which should be available well in advance of the transition in 2023. Physicians should have the resources to make an educated decision about changing their participation status in MCPs or Dual Eligible Special Needs Plans (DSNPs) and to share information about the program with their patients.

As MCPs begin to operate DSNPs, they should work to maintain the same provider networks that exist in Cal MediConnect. DHCS should make sure that all Medicare Advantage Network Adequacy requirements are enforced and encourage DSNP plans to contract fairly with physicians and to reimburse physicians at the Medicare Fee Schedule or higher. CMA strongly opposes any passive or default enrollment into DSNP for patients. Additionally, patients who do to choose to enroll should be permitted to disenroll after 30 days. Beneficiaries should have clear notice rights that they are not required to enroll in a DSNP and clear instructions about how to opt out.

Annual Medi-Cal Managed Care Plan Open Enrollment

Given the number of changes that CalAIM proposes to make in terms of greater standardization of managed care benefits (including the addition of enhanced care management and in-lieu of services) and the emphasis that the Department is making on care coordination for all populations in Medi-Cal, the CMA is supportive of the concept of annual open enrollment. This concept, if implemented and enforced appropriately, will allow plans and their network providers to invest the necessary time and resources in patient care coordination. It is difficult, and almost impossible, to coordinate complex patient care if the patient is changing their plan multiple times in a year, especially if the changes are because of administrative burden or access issues. CMA's support of this particular CalAIM concept is based on the consumer-friendly exemption process as currently proposed, especially as it allows a patient to keep their primary care physician or specialist if a physician contract has been terminated with an existing Medi-Cal managed care plan as long as the physician is contracting with a different network/plan in the same region.

Regional Managed Care Capitation Rates

Since the passage of Proposition 56 in 2016, the Department of Health Care Services and CMA have worked closely to design and implement the supplemental payments for physicians. This collaboration has been both productive and instructive in how these supplemental payments can be targeted to incentivize certain services (i.e., preventive screenings) as well as provide necessary funding to support existing Medi-Cal providers and the work they do in stabilizing our safety net. The CMA supports the important work done by the Department when it comes to rate-setting and overseeing the supplemental payments directed through the managed care plans. As the state moves to regional rate setting, the CMA understands that this will dramatically reduce the number of rates that must be developed by the department and approved by the federal government. While we are pleased that the State has increased the availability of supplemental Medi-Cal payments for certain services, this should not be viewed as a reason for plans to reduce base Medi-Cal rates. As the Department begins to implement these regional rates, CMA would urge caution as the potential downward pressure on capitated rates that some plans may experience because of this shift to regional rates may result in downward pressure in physician contracted rates. Physicians already struggle to participate in the Medi-Cal program due to low reimbursements, and further reductions in already low rates could have serious negative consequences for network adequacy and access to care.

Improving Beneficiary Contact and Demographic Information

The CMA is strongly supportive of efforts to improve beneficiary contact and demographic information, especially as it pertains to the increasing emphasis on care coordination and face-to-face interactions for the highest cost/highest complexity patients in Medi-Cal. CMA supports efforts to improve the Medi-Cal enrollment process to require as few client contacts and follow-ups as possible, and to expedite and simplify inter-county transfers. Additionally, CMA supports allowing eligible uninsured patients to enroll in Medi-Cal and other publicly funded health care programs at the time that they receive care. Historically, the beneficiary

information has been inaccurate and is a significant factor in preventing a provider from contacting a patient for follow-up care or referral information.

CMA supports the addition of Welfare and Institutions Code Section 14184.600(c) to direct DHCS to convene a workgroup to develop and implement one or more initiatives designed to improve the collection and use of beneficiary demographic and contact information in administering the Medi-Cal program and other applicable public assistance programs.

Extending the CalAIM Implementation Timeline

CalAIM is an ambitious, multi-year initiative by DHCS to improve the quality of life and health outcomes of our population by implementing broad delivery system, program, and payment reform across the Medi-Cal program. DHCS released a revised CalAIM proposal on January 8, 2021 with a proposed implementation timeline that envisions that the bulk of the implementation will be completed by December 2023, with additional deadlines for NCQA accreditation occurring in 2026. CMA is generally concerned about the timing, both the short timeframe for the rollout of these proposals, but also how the timing of the implementation of CalAIM matches up with other large proposals such as Medi-Cal Rx. It is likely that implementation of the various program components will be interdependent and need to take place simultaneously. Providers will need time to be trained on how the new programs will operate, make necessary changes to their practices, and to educate their patients. As demonstrated by the current issues and delays with the implementation of the Medi-Cal Rx rollout, it is critical to set flexible deadlines to avoid disruptions to provider practices and patient care.

CONCLUSION

Thank you in advance for your consideration of our comments on DHCS's CalAIM Section 1115 demonstration application and Section 1915(b) waiver application to CMS. California's physicians look forward to working with you to develop strategies and recommendation that improve quality care for Medi-Cal beneficiaries. We hope this letter will serve as guidance as this proposal is developed and implemented. If you have additional questions, please contact Jessica Rubenstein, Associate Director of Health Policy, at jrubenstein@cmadocs.org.

Sincerely,

[redacted]

Peter N. Bretan, Jr., M.D.
President
California Medical Association

Comments on the Proposed CalAIM Section 1115 Demonstration Application

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

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

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

Add Research Component for CBAS: There has already been published research on the benefits of an ADHC-based Community Based Health Home model designed as a pilot project unique to California.[1] Further research has explored the impact of the COVID emergency on participants and families who lost full access to congregate services during the PHE. [2] We would like to see a

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

[2] Vora, P., Missaelides, L., Trinh-Shevrin, C., & Sadarangani, T. (2020). Impact of Adult Day Service Center Closures in the Time of COVID-19. *Innovation in Aging*, *4*(Suppl 1), 949. https://doi.org/10.1093/geroni/igaa057.3472

Tina Sadarangani, Jie Zhong, Paayal Vora & Lydia Missaelides (2021) "Advocating Every Single Day" so as Not to be Forgotten: Factors Supporting Resiliency in Adult Day Service Centers Amidst COVID-19-Related Closures, *Journal of Gerontological Social Work,* 64(3), 291-302, DOI: 10.1080/01634372.2021.1879339

1) research component built into CalAIM specific to CBAS, building on existing literature and the national movement toward common outcome measures.

2) **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.

3) **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.

4) **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.

5) **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.

Tina Sadarangani, Jie Zhong, Paayal Vora & Lydia Missaelides (2021) "Advocating Every Single Day" so as Not to be Forgotten: Factors Supporting Resiliency in Adult Day Service Centers Amidst COVID-19-Related Closures, *Journal of Gerontological Social Work,* 64(3), 291-302, DOI: 10.1080/01634372.2021.1879339

Sincerely yours,

Jennifer Hurlow-Paonessa, LCSW
Board President

May 6, 2021

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

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

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

Dear Director Lightbourne,

Redwood Coast Medical Services (RCMS) appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

RCMS 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 vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

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

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

RCMS 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, RCMS 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 us.

Sincerely,

[redacted]

Ara Chakrabarti
Chief Executive Officer
RCMS COMMUNITY HEALTHCARE
Redwood Coast Medical Services, Inc.

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Gualala, CA 95445-1100
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Tel: (707) 884 - 4050

May 6, 2021

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

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Mr. Lightbourne,

On behalf of Children's Institute (CII) we applaud the improvements in the California Advancing and Innovating Medi-Cal (CalAIM) process and believe there is great opportunity to redefine behavioral health as essential for healthy development.

Children's Institute is one of the largest and oldest human service agencies serving Los Angeles County working to transform the lives of children exposed to adversity and poverty. Central to our work is a dual-generation wraparound strategy, providing trauma-informed, evidence-based services including early education, behavioral health and family strengthening programs for 30,000 children and family members annually. Children who disproportionately suffer from toxic levels of exposure to trauma have been hit the hardest by COVID-19, and the inequities have only compounded for communities of color. Furthermore, mental health needs such as anxiety and depression have increased during this pandemic, with suicidal ideation and attempts occurring at younger ages.

As a specialty mental health provider, we know that increased access through presumptive eligibility for transition aged youth in foster care, children experiencing homelessness, and children exposed to toxic stress is critical to positive learning, wellbeing and success in life. We believe all children deserve equal and equitable access to receive behavioral health service, regardless of adversity screening "scores" and it is critical to remove barriers to quality care. The initial CalAIM proposal offered meaningful changes for specialty mental health; however, the 1915(b) waiver compromises these advancements in the following contradictory requirements and we advocate for the following:

1) **Remove the medical necessity requirement for a high trauma score as a mandate for services**. Any positive screen and more importantly request for support ensures our system is authentically centering the needs of children and families for immediate support.

2) **Maintain consistency of care where children are screened and provided with mental health services, not sent elsewhere.** The goal of a child being served in the system in which they originally present their need is eroded by the level of care proposal and accompanying screening tools.

3) **Clarify related impacts for payment reform.** There are unanswered questions and concerns around the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

Thank you for the opportunity to submit comments. Please feel free to contact me at tkim@childrensinstitute.org with any questions.

Sincerely,

[redacted]

Terry Kim
Director of Government Relations & Advocacy

UNIVERSITY OF CALIFORNIA, SAN DIEGO

BERKELEY · DAVIS · IRVINE · LOS ANGELES · MERCED · RIVERSIDE · SAN DIEGO · SAN FRANCISCO

SANTA BARBARA · SANTA CRUZ

DEPARTMENT OF PSYCHIATRY

May 7, 2021

To Director Will Lightbourne and the broader DHCS,

I write to you as a clinical psychologist with expertise in treating children and transitional age youth with mental health problems, and a Health Sciences Assistant Clinical Professor at University of California San Diego in the Department of Psychiatry.

While the initial CalAIM proposal offered ambitious, tangible, and critically needed changes for specialty mental health care for children and their families, language in the 1915(b) Waiver appears to overturn key aspects of these advancements. My colleagues and I assert that these erosions of the original CalAIM proposal will lead to perpetuation of a broken system of services for vulnerable families in our state. The science of healthy early childhood development and the services that promote it clearly demonstrate that behavioral health is an essential support for healthy development, not a response to pathology. To address these concerns and promote lasting family wellness, we urge timely revision of the proposal in the following manners:

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 request for support from a beneficiary, regardless of screening score, 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 cannot be stopped or interrupted until or if there is a transition in care.
3. Provide the public with answers to questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

Thank you for reading this letter and considering these revisions. With concerted effort, the CalAIM proposal will make significant strides to meet the mental health needs of California's children and families.

In partnership,

Kristen Duarte, Ph.D.
HS Assistant Clinical Professor
University of California San Diego
Department of Psychiatry
kjezior@health.ucsd.edu

Via email

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

RE: CalAIM Section 1115 & 1915(b) Waiver

Dear Secretary Ghaly:

Thank you for your commitment to children and families enrolled in Medi-Cal. We know that considerable effort has been made to improve the health and wellbeing of our state's most vulnerable citizens. We are encouraged by the Administration's commitment to innovation to improve their lives.

Our organizations are deeply committed to the improvement of Medi-Cal to ensure that families and children not only have access to critical services and programs, but make sure that they fully utilize available and appropriate resources. For the last few years our organizations have been advocating for a modernized version of Healthy Start - AB 1117 (Wicks) - an innovative system which would integrate supports for families and students in new ways to lead to improved academic and health outcomes. It is through our advocacy that we have learned some lessons on how to make improvements to Medi-Cal to maximize its effectiveness for families and children.

We are concerned that CalAIM Section 1115 & 1915 (b) waiver does not go far enough and does not fully take advantage of all the opportunities available in the Medicaid program, especially with children and families in mind.
The proposal must be revised to:

- Resist pathologizing adversity—as evidenced by proposed tools to "screen in for a high risk score" for ongoing services. We must honor the wisdom and intelligence of low income communities to determine their own definition of medical necessity. Any positive screen, and more importantly, any request for support from a beneficiary should qualify a child for services and support.

- Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan--or if such a tool is to be used it must only be used during the course of treatment and treatment can not be stopped or interrupted until or if there is a transition in care.

- Fully honor the commitment to no wrong door by removing the future creation of a level of care tool and plan--or if such a tool is to be used it must only be used during the course of treatment and treatment can not be stopped or interrupted until or if there is a transition in care.

- Clarify unanswered questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

Thank you for your careful attention to our comments on CalAIM. We welcome any opportunity to participate in addressing the issues that we are addressing here. Thank you for your efforts to respond to comments presented by advocates and stakeholders. We look forward to the opportunity to collaborate with you to design the best possible Medi-Cal program for California's children and families

Sincerely,

Shimica Gaskins
Executive Director
Children's Defense Fund - California

President & CEO
United Ways of California

175 N. Redwood Dr., Ste. 130
San Rafael, CA 94903
415-472-7974 | www.mcdsweb.org

May 6, 2021

RE: Dental managed care authority and dental fee-for-service.

To Whom it May Concern:

There is a disconnect between the Medi-Cal and Denti-Cal in providing preventive dental care to children and this is something that the Marin County Dental Society, the Oral Health Committee (of which I am a member) and other community organizations are interested in remedying.

The following letter was penned by Children Now that details the issues:

> The Medi-Cal Dental Program 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 in order to form any plans to scale this model other parts of the state.

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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.

Thank you for your kind consideration,

Carissa

Carissa Green | Executive Director
Marin County Dental Society
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Ravenswood
Family Health Network
South County Community Health Center, Inc.
dba Ravenswood Family Health Network

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:

Ravenswood Family Health Network (RFHN) 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, RFHN 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.

RFHN

RFHN is an FQHC that cares for Medi-Cal and uninsured patients in the Cities of East Palo Alto, Belle Haven in Menlo Park and North Fair Oaks in San Mateo County, as well as Palo Alto, Mountain View and Sunnyvale in the County of Santa Clara. 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 one in-house pharmacy and twenty-two contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows RFHN 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, RFHN annually saves an estimated $1.2 million through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow RFHN 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

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of the current managed care system, RFHN 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. RFHN incorporates by reference the CHCAPA public comment letter into this letter. RFHN 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, RFHN 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 RFHN 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. RFHN looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

[redacted]

Luisa Buada, RN BSN MPH
Chief Executive Officer

Encl.

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

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

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Comments on the CalAIM Proposal

Breaking the Cycle of Intimate Partner Violence through Medi-Cal Policy

May 6, 2021

Acknowledgements: This brief was informed by research conducted by Mathematica staff Amanda Lechner, Alexandra Donnelly, Britta Seifert, Emily Gardner, and Toni Abrams Weintraub, and insights provided by Lisa James at Futures Without Violence and Lena O'Rourke. Funding provided by Blue Shield of California Foundation.

blueshieldcafoundation.org

Preventing IPV through Medi-Cal Policy: Comments on the CalAIM Proposal

Overview

The California Advancing and Innovating Medi-Cal (CalAIM) proposal presents an opportunity to improve the health and well-being of beneficiaries by addressing a major social determinant of health: intimate partner violence (IPV). IPV is a widespread, multigenerational threat that profoundly affects health. Medi-Cal can use the CalAIM proposal to enact policies that prevent IPV and provide health care and social support services for survivors. This brief describes the health impacts and prevalence of IPV among Medi-Cal beneficiaries and details specific policy recommendations that would prevent IPV, identify those at risk, and provide health care and social support services for survivors.

Impact of IPV on Medi-Cal beneficiaries

IPV is pervasive in California. Among California residents, 35 percent of women and 31 percent of men report experiencing IPV or stalking by an intimate partner in their lifetimes.[1] While IPV occurs across racial, ethnic, and socioeconomic groups[2, 3] low-income populations, which Medi-Cal serves, experience greater barriers to leaving violent relationships and may be more vulnerable to poor health outcomes related to IPV.[4, 5]

Experiencing IPV is linked to profound, long-term impacts on the survivor's physical, reproductive, and behavioral health, and overall well-being. More than one in four women injured by an intimate partner require medical care for their injuries.[6] In addition to acute injuries, women and men disclosing IPV are more likely to experience asthma, chronic pain, irritable bowel syndrome, headaches, poor sleep, and activity limitations. Women are more likely to experience sexually transmitted infections, unintended pregnancy, pregnancy complications, and genitourinary problems.[7] Behavioral health conditions that are significantly more common among survivors of IPV than the general population include depression, anxiety, post-traumatic stress disorder, suicidal ideation, and alcohol and drug use.[8] In California specifically, studies suggest adult survivors of IPV were three times more likely to report experiencing serious psychological distress over the previous year than adults who were not exposed, and 33 percent of survivors reported needing help for a mental, emotional, or alcohol or other drug-related problem.[9]

Beyond physical and behavioral health conditions, survivors are more likely to experience a range of social needs. For example, experiencing domestic violence (DV) is a significant contributor to homelessness for women, with about 50 percent of all homeless women reporting DV as the immediate cause of homelessness.[10, 11] Survivors of IPV are at also at high risk for experiencing food insecurity, unemployment, and lack of transportation.[12, 13] In addition, compared to non-survivors, survivors tend to have less social support, such as friends and family members who can provide childcare, financial assistance, or safe places to stay.[14]

IPV is not just an issue that affects adults; many children witness domestic violence, an experience that affects their health and well-being. For example, about one in five children in the United States witness the assault of a parent before age 18.[15] Witnessing DV is associated with adverse behavioral health outcomes in children, including symptoms of post-traumatic stress disorder and difficulty with regulating emotions.[16] Also, strong evidence links experiencing or witnessing violence in childhood to increased

likelihood of perpetrating or experiencing IPV later in life, thereby creating a multigenerational cycle that perpetuates the negative sequalae.[17, 18]

Interrupting the cycle of IPV requires effective and meaningful interventions that provide targeted health care and social support services for survivors and their families. These services should intervene at critical periods in the life course and address root causes such as poverty, housing instability, health inequities, and gender perceptions and bias.[19, 20, 21] Successful interventions require building partnerships across health care and social service providers to address the diverse challenges facing people affected by IPV, including physical and behavioral health needs, unstable housing, and unemployment.[22]

Because Medi-Cal insures one-third of California residents and serves low-income populations that are more vulnerable to the impacts of IPV, it is critical that Medi-Cal recognize the effects of IPV and implement evidence-based strategies to support survivors. Over the past several years, Medi-Cal and its partners have increasingly focused on improving quality of care and outcomes for vulnerable populations, including those with high behavioral health needs and those who experience social risk factors and health disparities.[23] Survivors of IPV should also be a focus of these efforts. By preventing IPV, and providing more effective health care and social support services to survivors, Medi-Cal has an opportunity to improve health outcomes and the lives of individuals and to interrupt the intergenerational cycle of IPV.

Opportunities to address IPV through the CalAIM proposal

CalAIM is a delivery system, program, and payment reform initiative that aims to improve quality of life for all Californians, while implementing targeted approaches to improve outcomes among people enrolled in Medi-Cal with complex needs, such as those experiencing homelessness, those with behavioral health conditions, and those with frequent emergency department visits or hospital stays. Because a large focus of the proposal is improving care for beneficiaries with complex needs, there are opportunities to specifically addresses prevention of IPV and the needs of survivors. For example, the proposal has several features:

- It calls for managed care plans to develop person-centered population health management programs to promote beneficiaries' wellness and identify and respond to the needs of high-risk populations—which would include those experiencing and at risk of IPV.
- It authorizes managed care plans to provide in lieu of services, or nonmedical services as alternatives to standard Medicaid benefits. In lieu of services include housing transition and navigation services, housing deposits, and housing tenancy and sustaining services, and should include other essential services such as economic support, employment support, and family support—which are critical services for survivors seeking to escape a violent home.
- It revises behavioral health medical necessity criteria to provide specialty mental health services to beneficiaries before a diagnosis is made—which would help improve timely access to mental health care for survivors.

Below we discuss policy recommendations related to each of these elements of the proposal. Exhibit 1 is a cross-walk and summary of the waiver provisions and the related policy recommendations.

Exhibit 1. Summary of opportunities to address IPV through the CalAIM proposal

Waiver provision	Recommendations for DHCS
Population health management program CalAIM would require managed care plans to develop a whole system, person-centered population health management program to promote beneficiaries' wellness and identify and respond to the needs of high-risk populations. DHCS will develop a standardized, 10 to 15 question Individual Risk Assessment (IRA) Survey Tool. Medi-Cal managed care plans would use the IRA to assign members to risk tiers. Managed care plans' population health management programs would be required to conduct risk assessments, stratify beneficiaries by risk level, and implement strategies such as case management to address identified health-related social needs.	1. **Specifically include individuals who experience or are at risk for IPV as a high-risk population whose needs should be identified and addressed** • Promote universal education about IPV in health care settings. • Consult with IPV advocacy organizations and service providers to develop guidance for managed care plans and providers about best practices to safely and effectively screen for IPV. • Encourage managed care plans to provide guidance to health care providers on how to safely and effectively screen for IPV in accordance with established best practices. • Partner with IPV advocacy organizations and service providers to develop guidance as to how managed care plans can promote relationships between health care providers and community-based IPV service providers. • Include specific questions about IPV when developing the IRA Survey Tool, which plans will use to stratify beneficiaries into risk tiers.
In lieu of services The CalAIM proposal would authorize managed care plans to provide in lieu of services, or nonmedical services as alternatives to more costly standard Medicaid benefits. Examples of in lieu of services specified in the CalAIM proposal include housing transition and navigation services, housing deposits, and housing tenancy and sustaining services.	**2. Consider the nonmedical needs of IPV survivors when developing guidance for provision of in lieu of services and/or value added services** • Encourage and provide guidance to managed care plans on how to apply a trauma-informed approach to promote housing stability among beneficiaries experiencing or surviving IPV. • Ensure that IPV service providers are able to participate with managed care organizations by supporting the unique privacy and confidentiality needs of survivors. • Partner with IPV service providers and advocacy organizations to develop guidance for innovative strategies managed care plans can use to safely cover IPV services. • Encourage and provide guidance to managed care plans on how to cover additional non-medical IPV services for survivors. • Encourage managed care plans to cover services for IPV survivors provided by a wide range of community-based, non-medical support providers who have been trained in and use trauma-informed practices, including community health workers (CHWs) and *promotores.*

Waiver provision	Recommendations for DHCS
Revisions to behavioral health medical necessity criteria DHCS proposes to update and clarify medical necessity criteria for specialty mental health services for adults and children, including allowing reimbursement of treatment before diagnosis. DHCS also proposes to clarify Early Periodic Screening, Diagnostic, and Treatment services (EPSDT) protections for beneficiaries younger than 21 by developing criteria for children to access specialty mental health services based on experience of trauma and risk of developing future mental health conditions, such as involvement in child welfare or experience of homelessness.	**3. Facilitate access to specialty mental health services specifically for adults and children who experience or are at risk for IPV** • Explicitly include experiencing or witnessing IPV as a risk factor that qualifies children to access services through EPSDT.

IPV survivors need a wide array of survivor-centered services

Strategies to address IPV must promote survivor-centered approaches that prioritize survivors' rights and preferences, provide whole-person care, and facilitate access to a range of clinical and non-clinical services to meet survivors' health and social needs. Survivor-centered approaches must include health care and social service providers who are knowledgeable about IPV and trained in providing trauma-informed care. Above all, survivor-centered approaches must promote the dignity and autonomy of survivors by respecting their choices[24] and providing a comprehensive array of services and supports to promote independence and wellbeing, including physical and behavioral health care as well as economic support, employment support, child care and family support. Exhibit 2 presents a list of IPV services—that is, essential services to support survivors of IPV as part of a survivor-centered, whole-person care approach.

Exhibit 2. Essential services to support survivors of IPV[25]

Screening and referral: Universal screening in healthcare settings for IPV, reproductive coercion, and behavioral risk factors such as substance use and depression, and referral to services.

Trauma-informed behavioral health care: Trauma-informed care to address depression, anxiety, PTSD, substance use, and other behavioral health conditions. Evidence-based approaches include Cognitive Behavioral Therapy and Cognitive Trauma Therapy for Battered Women.

Comprehensive health care: Access to medical care to treat and manage survivors' physical health conditions, which may include physical injuries from IPV, sexually transmitted infections, and chronic conditions. Access to reproductive healthcare.

Tailored services for survivors: Access to survivor-centered services such as hotlines, crisis intervention and counseling, and shelters. Navigation services to help survivors access community resources and maintain employment, such as temporary childcare, transportation assistance, and nutrition support.

Housing support: Emergency shelters and transitional housing to support survivors leaving unsafe relationships. Housing navigation services and flexible funds that can be used for security deposits, rent, transportation, and other needs so as to support long-term housing stability.

Economic support, including childcare and nutrition support: Services to promote financial security among survivors, such as income supplements and cash transfers, employment assistance, nutrition assistance including the Supplemental Nutrition Assistance Program (SNAP), childcare subsidies, and tax credits.

Legal advocacy services and access to civil legal protections: Legal support to help survivors navigate the criminal and civil legal systems, and promote safety through protective orders, supervised visitation programs, and removal of lethal weapons from perpetrators.

Evidence-based family support interventions: Interventions that provide support and education for families, such as early childhood home visiting programs and prenatal support interventions.

Recommendation 1: Specifically include individuals who experience or are at risk for IPV as a high-risk population whose needs should be identified and addressed in the **population health management program**

The CalAIM proposal would require managed care plans to develop a whole system, person-centered population health management program to promote beneficiaries' wellness and identify and respond to the needs of high-risk populations. Through the population health management program, managed care plans would conduct risk assessments, stratify beneficiaries by risk level, and implement strategies such as case management to address identified social needs.

Because IPV survivors comprise a high-risk population with a range of health care and social support needs (see Exhibit 2), DHCS should incorporate the needs of survivors into the design of the population health management program requirements.

Specifically, we recommend that DHCS:

- **Promote universal education about IPV in health care settings.**

  DHCS can encourage managed care plans to promote universal education about IPV in health care settings, using a model such as Futures Without Violence's CUES (Confidentiality, Universal Education and Empowerment, Support) intervention. CUES is an evidence-based intervention that teaches health care providers how to provide universal education about violence and healthy relationships, and how to create a patient-centered care plan and warm handoff to IPV services. Providing screening and education to all patients presents opportunities for survivors to receive education and resources, even if they do not choose to disclose their risk, and creates prevention opportunities to interrupt the cycle of violence. Studies of this intervention in primary care settings have shown that (1) women receiving the intervention were 60 percent more likely to end a relationship because it felt unhealthy or unsafe and (2) patients' knowledge of resources and harm reduction strategies increased.[26]

- **Consult with IPV advocacy organizations and service providers to develop guidance for managed care plans and providers about best practices to safely and effectively screen for IPV.**

  DHCS should engage with IPV advocacy organizations and service providers to develop guidance for providers and managed care plans regarding the best practices for screening for IPV and addressing identified safety needs. An example of an IPV advocacy organization that DHCS should engage is the California Partnership to End Domestic Violence (CPEDV). DHCS should also engage local IPV service providers, such as WEAVE in Sacramento, which provides crisis intervention services for IPV survivors along with referrals to community resources for other social support services. The CPEDV website also includes a list of IPV service providers in California that DHCS can engage.

  In consultation with IPV advocacy organizations and service providers, DHCS can adapt existing screening guidelines. As one example, the Maryland Department of Health developed a guide for health care providers with recommendations for how to screen for IPV and connect patients to appropriate community resources. Recommended practices include screening patients in private without anyone else present, avoiding stigmatizing words such as abuse or battered, and using culturally relevant language. Screening can occur during routine, preventive, and urgent visits. When providers suspect abuse, screenings should include safety assessments—to determine if patients are in immediate danger—and safety planning.[27]

  In consultation with IPV experts, DHCS can use or adapt an existing screening guide for providers, such as the guidance developed by Maryland. Exhibits 3 and 4 also include examples of IPV screening tools that DHCS can use to formulate IPV screening questions.

Exhibit 3. Examples of IPV screening tools

To determine appropriate questions for IPV screening, DHCS can use several tools the U.S. Preventive Services Task Force has determined accurately detect IPV, including Humiliation, Afraid, Rape, Kick (HARK); Hurt, Insult, Threaten, Scream (HITS); Extended–Hurt, Insult, Threaten, Scream (E-HITS); Partner Violence Screen (PVS); and Woman Abuse Screening Tool (WAST).[28]

Exhibit 4. Example of IPV screening questions from North Carolina's Standardized SDOH Screening Questions[29]

Do you feel physically and emotionally safe where you currently live? Yes or no

Within the past 12 months, have you been hit, slapped, kicked or otherwise physically hurt by someone? Yes or no

Within the past 12 months, have you been humiliated or emotionally abused in otherwise by your partner or ex-partner? Yes or no

- **Encourage managed care plans to provide guidance to health care providers on how to safely and effectively screen for IPV in accordance with established best practices.**

  After developing guidance for screening for IPV in consultation with experts, DHCS should encourage managed care plans to disseminate and promote screening guidance to health care providers. Educating providers is critical because there is evidence that many providers lack the knowledge and training to effectively screen for and follow-up on IPV disclosures or may be uncomfortable doing so.[30] In addition, there are important safety concerns for survivors related to disclosures of abuse that providers need to understand. For example, it is important to screen patients while they are alone; if the perpetrator is present, a patient will be less likely to disclose abuse, and the perpetrator may not allow the patient to return for care.

  Managed care plans should provide trainings emphasizing that screening and universal education are critical, and that disclosure itself is not the end goal. For example, while screening increases disclosures, screening also encourages survivors to seek help outside of the health care system—even in cases where survivors do not disclose to health care providers immediately. Trainings should also emphasize that it generally takes multiple screenings for survivors to disclose to trusted providers and that appropriate responses to disclosures require addressing survivors' varied health and social support needs and coordinating responses across health care and IPV service providers.[31]

- **Partner with IPV advocacy organizations and service providers to develop guidance as to how managed care plans can promote relationships between health care providers and community-based IPV service providers.**

  In addition to appropriately identifying survivors of IPV through screening, we recommend that DHCS encourage providers refer to, and managed care plans to coordinate health care and social support services with, community-based organizations that provide IPV services. To meet federal Medicaid managed care requirements regarding care coordination and continuity of care, managed care plans must coordinate services that beneficiaries receive from community and social support providers. In addition, the CalAIM proposal includes requirements for managed care plans to provide member services, referrals, transportation, health education, system navigation, and warm handoffs to community-based providers or other delivery systems. The proposal would also require managed care plans to mitigate Adverse Childhood Experiences (ACEs) and social determinants of health by using community resources and providing individual social care. IPV service providers serve these roles for survivors by offering trauma-informed services and supports—such as assistance with safety planning and connections to other community resources.[32]

  DHCS should engage with IPV advocacy organizations and service providers, such as CPEDV and WEAVE, to develop specific guidance as to how managed care plans can best build relationships

with community-based organizations. As DHCS engage with advocacy organizations and service providers, it can also consider examples of partnership building from within California and in other states. Exhibit 5 includes an example of building relationships between California providers and community-based organizations through the Domestic Violence and Health Care Partnerships project. The Oregon Health Care Coordinated Care Organizations, discussed in Exhibit 6, represent another example of building connections between Medicaid managed care and community-based organizations.

As a part of this relationship-building, DHCS should identify ways for managed care plans to compensate IPV service providers and should engage IPV service providers in identifying appropriate payment methods that protect the safety and privacy of survivors. In consultation with IPV service providers, DHCS can promote use of payment methods that North Carolina's Medicaid program will employ in the Healthy Opportunity Pilots. Specifically, under the pilots, IPV community-based organizations would receive a per-member-per-month payment for IPV case management and violence intervention services, whereas dyadic therapy for survivors and their children and linkages to legal supports would be reimbursed per occurrence (see Exhibit 8 for more detail). As another option, DHCS could encourage Medi-Cal managed care plans to pursue similar arrangements as those that they have previously used with Community Health Workers (CHWs), such as directly employing IPV service providers or contracting with community partners that employ IPV service providers.

Exhibit 5. Example of building connections between providers and community-based organizations: The Domestic Violence and Health Care Partnerships

A model for building provider capacity and relationships with community organizations is the Domestic Violence and Health Care Partnerships, a collaboration of the Blue Shield of California Foundation and Futures Without Violence. This project partnered health care safety net providers with DV service providers and included training for health care providers regarding how to screen for DV, discuss these topics with patients, and provide referrals to the partnered DV organizations. The program showed an increase in the number of providers who screened for and discussed DV with their patients. Health care providers and DV service providers also reported greater confidence in referring clients to one another.[33] The evaluation of this project found establishing communication protocols and referral processes between health care providers and DV organizations to be critical for building collaboration and integration across settings. Specific communication protocols included formal agreements regarding the referral processes and written protocols for health care providers regarding assessment and response to DV.

Exhibit 6. Example of building connections between managed care and community-based organizations: Oregon Health Care Coordinated Care Organizations[34]

One model for linking Medicaid managed care with community organizations is the Oregon Health Care Coordinated Care Organizations (CCOs). CCOs are regional entities that are responsible for the whole well-being of Oregon Medicaid managed care beneficiaries. CCOs coordinate mental and physical health care and focus on preventive care. Oregon law mandates they work with traditional health workers, which includes Community Health Workers (CHWs), peer support specialists, and doulas. As part of their mission to address upstream health issues, CCOs may offer "flexible services funding," which pays for nontraditional medical services, such as advocacy services, and "community benefit initiatives," which are investments at the community level in care management or provider capacity. For example, one CCO granted community investment funds to a local women's resource center to enable the center to expand its advocacy and build its health care partnerships. CCOs also have local advisory councils to which they are accountable, which IPV organizations can join.

- **Include specific questions about IPV when developing the IRA Survey Tool, which plans will use to stratify beneficiaries into risk tiers.**

  While developing the guidance for conducting population risk assessments, DHCS can encourage managed care plans to promote screening to identify beneficiaries experiencing or living in a household with IPV.[1] In addition, given the substantial health risks associated with experiencing and witnessing IPV, when constructing algorithms for risk stratification or segmentation, DHCS should encourage managed care plans to consider IPV as a factor for placing beneficiaries into a higher risk tier.

  When DHCS develops the IRA Survey Tool that plans will use to validate risk tier placement, the survey should include specific questions about experiencing IPV. Some of the suggested categories for the IRA to cover, including emergency department use, access to basic needs, housing assessment, and availability of social supports, align with the needs of survivors of IPV, but the tool should also include an explicit question about experiencing or witnessing violence—such as from one of the screening tools listed in Exhibit 3. DHCS should provide plans with similar guidance to that which is given to providers regarding best practices for conducting screenings for IPV to ensure that plans' care managers conduct risk assessments, screenings and referrals without causing harm to survivors or putting them in danger.

Recommendation 2: Consider the nonmedical needs of IPV survivors when developing guidance for provision of **in lieu of services** and/or value added services.

The CalAIM proposal includes a list of 14 non-medical in lieu of services as alternatives to standard Medicaid benefits that managed care plans can choose to provide. Examples of in lieu of services specified in the CalAIM proposal include housing transition and navigation services, housing deposits, and housing tenancy and sustaining services. DHCS should include additional services and encourage managed care plans to provide these as in lieu of or value added services that address the needs of IPV survivors, especially transportation support, job placement services, childcare subsidies, financial

[1] The CalAIM proposal would require population health management programs to include preventative health visits for all adults in accordance with U.S. Preventive Services Task Force Grade "A" and "B," which include a recommendation for screening women of reproductive age for IPV.

services, home visiting and parenting programs, and navigation and peer support services provided by community health workers (CHWs) and *promotores*.

Given IPV survivors' particular need for housing supports and increased risk for health and behavioral health conditions, DHCS can develop specific guidance related to addressing IPV survivors' housing and social support needs through a trauma-informed lens and to covering these support services as in lieu of and/or value added services. The eligibility criteria for housing services specified in the CalAIM proposal include being "homeless," "chronically homeless" or "at risk of homelessness," as defined in Section 91.5 of Title 24 of the Code of Federal Regulations *and* receiving enhanced care management, having one or more serious chronic condition(s) and/or serious mental illness (SMI) and/or being at risk of institutionalization or requiring residential services as a result of a substance use disorder (SUD). These criteria represent risks that are elevated among IPV survivors. For example, in California, women who have experienced DV are four times as likely to report housing insecurity than those who have not.[35] In 2020, HUD Continuums of Care in California reported 1,960 victims of DV were in emergency shelter, 819 were in transitional housing, and 7,996 were unsheltered.[36]

To address the needs of survivors, DHCS should:

- **Encourage and provide guidance to managed care plans on how to apply a trauma-informed approach to promote housing stability among beneficiaries experiencing or surviving IPV.**

  DHCS should provide managed care plans with guidance on how to provide and tailored housing services to support survivors who are at risk of or experiencing homelessness. Guidance from DHCS should include important components of housing assistance for IPV survivors, such as providing trauma-informed and survivor-driven services with flexible financial assistance to enable survivors to meet their housing needs. Exhibit 7 highlights the DV Housing First pilot programs in California and Washington State as examples of survivor-driven housing assistance programs which managed care plans can connect survivors to or replicate.

Exhibit 7. Examples of addressing housing instability for DV survivors: The DV Housing First Pilots

The DV Housing First Pilots implemented in Washington State and California are evidence-based models that increase access to permanent and affordable housing as a foundational step for empowering survivors to leave violent environments and rebuild their lives. The Washington State program, funded by the Bill & Melinda Gates Foundation, included 13 agencies serving more than 500 survivors across the state.[37] The California pilot, funded by the California Office of Emergency Services, was implemented in 33 nonprofit agencies across the state by 2017 to support survivors in need of housing and supportive services. Participants received funds that they could use for rental assistance, move-in costs, transportation, and debt assistance. An evaluation of 925 survivors who received flexible funds found that the majority of participants (58 percent) used their funds to prevent homelessness.[38] Currently, California has over 65 sites that have received grants for DV Housing First, and California's DV Housing First Program served over 10,000 new individuals in FY 2019-2020.[39] The evaluations of the California and Washington models emphasized the importance of flexible funding to meet each survivor's unique needs.

- **Ensure that IPV service providers are able to participate with managed care organizations by supporting the unique privacy and confidentiality needs of survivors.**

Given the safety issues regarding disclosure of IPV, there is a need for special consideration regarding payment of IPV services, related documentation of services, and reporting requirements. Managed care plans should support survivors' use of and trust in the health care system by training providers on several key protections including: robust and informed patient consent about sharing of health care data; patient control over how their data is shared and with whom; transparency over who has access to their data and when data is shared; and enforceable penalties for violations of privacy. In addition, health plans must consider how information is shared on explanation of benefit forms so that information about the receipt of sensitive services or providers is not included and potentially accessible to perpetrators.

- **Partner with IPV service providers and advocacy organizations to develop guidance for innovative strategies managed care plans can use to safely cover IPV services.**

  IPV service providers offer critical services to survivors, including trained IPV advocates who assist with safety planning and who provide connections to community supports such as housing and employment services. Studies have shown IPV service providers help improve survivors' quality of life and reduce instances of abuse.[40] DHCS can seek recommendations from IPV service providers for innovative strategies Medi-Cal can employ to pay for DV services without compromising beneficiaries' safety. Payment models, such as monthly flat fees that cover services for an assumed number of survivors, rather than payment tied to billing based on services rendered to individual beneficiaries, could help protect the privacy and ensure the safety of survivors. The North Carolina Healthy Opportunities Pilots, described in Exhibit 8, are one state Medicaid agency's approach to creating a mechanism that integrates and pays for nonmedical social support services, including IPV services provided by community-based organizations. DHCS should engage with IPV service providers in California to develop a similar approach or identify other innovative strategies for Medi-Cal to fund the services of IPV services.

Exhibit 8. Covering interpersonal violence advocacy services under the North Carolina Healthy Opportunities Pilots[41, 42]

North Carolina is pursuing direct reimbursement for interpersonal violence advocacy services under its Health Opportunities Pilots. These pilots are part of the state's Medicaid Section 1115 demonstration and its transition to Medicaid managed care. Within these pilots, a local lead entity will facilitate relationships between local human services organizations, including organizations providing services that address interpersonal violence. The state managed care plans will pay the local lead entities, which in turn will pay local human services organizations for covered services. Payment rates will depend on a fee schedule generated by the state and approved by the Centers for Medicare & Medicaid Services (CMS). Two services, Interpersonal Violence Case Management Services for survivors and Violence Intervention Services for perpetrators, will be paid for on a per-member-per-month basis, whereas parenting support programs, evidence-based home visiting services, and dyadic therapy will be reimbursed on a fee-for-service basis.

Note: This pilot program was put on hold due to the COVID-19 public health emergency; the North Carolina Department of Health and Human Services has resumed reviewing proposals for the pilots as of January 2021 but has yet to post information regarding selected contract awards or a new start date of the pilots on its website.

- **Encourage and provide guidance to managed care plans on how to cover additional non-medical IPV services for survivors.**

Because survivors are at higher risk for experiencing unmet social support needs including DHCS should encourage managed care plans to cover additional in lieu of and/or value-added services to help survivors access the service they need. For example, IPV is not limited to physical abuse; perpetrators may engage in financial abuse (such as withholding money or sabotaging employment) or use their relationship or custody of children to harm the survivors and limit their ability to access both medical and social support services. Survivors should receive assistance navigating job placement services, transportation services, and financial services that can allow them to attain financial independence. Legal services are also essential for survivors who may need personal protection orders, help with dissolving marriages or domestic partnerships, or assistance in securing custody of children. In addition, survivors with children need access to childcare and parenting support, such as secure places to send their children while they pursue employments, housing, or attempt to meet other social needs. Parenting programs can also help to end the cycle of violence by teaching positive parent practices and increasing prosocial behaviors in children.[43] DHCS should encourage managed care plans to cover these critical services as in lieu of service or value-added services.

DHCS should consult with IPV service providers to develop guidance regarding appropriate payment methods for in lieu of and value-added services. For example, as described above, DHCS and experts may consider following the model of the North Carolina's Healthy Opportunities Pilots—which include per-member-per-month payment and per occurrence payments depending on the specific service types (see Exhibit 8 for more detail).

- **Encourage managed care plans to cover services for IPV survivors provided by a wide range of community-based, non-medical social support providers who have been trained in and use trauma-informed practices, including community health workers (CHWs) and *promotores*.**

  Many Medi-Cal managed care plans, particularly those participating in the Health Homes Program and the Whole Person Care Pilot, employ or contract with CHWs and *promotores* to provide outreach, navigation, and peer support services to beneficiaries with complex needs.[44] CHWs and *promotores* are typically trusted community members and/or individuals with a particularly strong understanding of the communities they serve; thus, CHWs and *promotores* can be uniquely positioned to build trust with survivors, identify health and social needs, and help survivors navigate services.[45, 46] Evidence suggests CHWs and *promotores* increase patients' engagement with the health care system and improve a variety of health outcomes, including chronic disease management and cervical cancer screening. Of note, there is evidence that CHWs and *promotores* are effective in improving outcomes among populations that face cultural, linguistic, and geographic barriers to care.[47] There is also some evidence that CHWs can successfully engage IPV survivors in services and help improve survivors' feelings of safety.[48] As one example of a Medi-Cal managed care plan using CHWs, the Inland Empire Health Plan has deployed more than 100 CHWs to provide care management for beneficiaries with chronic physical and behavioral health conditions. Inland Empire Health Plan provides intensive training for CHWs, covering topics such as trauma-informed care, motivational interviewing, and linkage to community resources.[49]

Recommendation 3: Facilitate access to **specialty mental health services** specifically for adults and children who experience or are at risk for IPV

Given the substantial psychological trauma and risks associated with IPV, many survivors have considerable need for mental health services. The proposed changes to medical necessity criteria in the CalAIM proposal—specifically allowing reimbursement for services before receipt of diagnosis and expanding access to specialty mental health services for children, adolescents, and young adults based on experience of trauma and risk of developing future mental health conditions—can remove barriers to care for beneficiaries experiencing or witnessing IPV. For example, many survivors have not engaged with a behavioral health provider or received a behavioral health diagnosis; barriers may include perceived stigma, lack of affordable or linguistically appropriate services, or coercive behavior from a perpetrator who prohibits access to services. Allowing reimbursement for treatment before diagnosis can help survivors who are in immediate need of care and potentially prevent development or progression of chronic mental health conditions. Expanding access to mental health services for adults and for children at risk of IPV can help families heal and play a role in breaking the intergenerational cycle of violence.[50]

DHCS should:

- **Explicitly include experiencing or witnessing IPV as a risk factor that qualifies children to access services through EPSDT.**

  Enabling children who need specialty mental health services to receive them on the basis of IPV exposure is an important mechanism for intervening at critical junctures in their development and disrupting the intergenerational cycle of IPV. The proposed clarification to the EPSDT protections criteria will allow children to access specialty mental health services based on experience of trauma, such as IPV, and can help ensure children receive care that can prevent future mental health conditions. Screening children specifically for exposure to IPV is critical given the increased risk of emotional and behavioral problems as well as emotional, physical, and sexual abuse among children who experience or witness IPV.[51]

  When clarifying the EPSDT criteria, DHCS should explicitly include exposure to IPV as a risk factor that qualifies children as scoring in the high-risk range on the DHCS-approved trauma screening tool and, therefore, eligible to access specialty mental health services. The Pediatric Adverse Childhood Experiences (ACEs) and Related Life Events Screener (PEARLS), the screening tool for ACEs that Medi-Cal providers currently use as part of the ACEs Aware Initiative, includes a screening question related to children's exposure to violence.[52] DHCS should promote managed care plans' use of the PEARLS screening tool as an approved trauma screening tool.

Conclusion

The CalAIM proposal presents an opportunity for Medi-Cal to help beneficiaries who currently experience IPV. While IPV occurs across income levels, low income survivors and their families are less likely to have access to the resources they need to leave violent environments and improve their lives. By encouraging appropriate screening for IPV, building community connections to IPV service providers, and connecting survivors to important resources—including housing support, CHWs, and *promotores*—DHCS can enable survivors to get the support they need to improve health and wellbeing for themselves and their children. To ensure clinical and non-clinical services are survivor driven, DHCS should engage with IPV service providers— and with advocacy organizations and survivors—to develop guidance for health care provider's regarding screening and referral to services, and managed care plans' coverage of in lieu of and value-add services. CalAIM also presents an opportunity to help break the intergenerational

cycle of violence by promoting universal education about healthy relationships and safety resources, helping to reduce children's exposure to violence within the home, and helping to ensure that children and adults who have experienced IPV can access the services they need to heal. The recommendations in this brief will help address the needs of some of the most vulnerable Californians and support attainment of CalAIM's goals: to manage beneficiaries' risk, improve health care quality and outcomes, and reduce health disparities.

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FAMILY HEALTH CENTERS OF SAN DIEGO

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Beach Area Family Health Center
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Grossmont Spring Valley Family Health Center
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Ibarra Family Health Center
Lemon Grove Family Health Center
Logan Heights Family Health Center
Mobile Medical Units
National City Family Health Center
North Park Family Health Center
Oak Park Family Health Center
Rice Family Health Center
Sherman Heights Family Health Center

May 04, 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:

Family Health Centers of San Diego 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, Family Health Centers of San Diego 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.

Family Health Centers of San Diego is an FQHC that cares for Medi-Cal and uninsured patients in San Diego. 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

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows Family Health Centers of San Diego 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, Family Health Centers of San Diego experiences annual 340B savings through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow Family Health Centers of San Diego 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, Family Health Centers of San Diego 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. Family Health Centers of San Diego incorporates by reference the CHCAPA public comment letter into this letter. Family Health Centers of San Diego 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, Family Health Centers of San Diego 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 Family Health Centers of San Diego 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. Family Health Centers of San Diego looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

[redacted]

Encl.

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

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

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

May 03, 2021

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

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

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

Dear Director Lightbourne:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[4] 42 U.S.C. § 1396n(b).

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

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

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

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

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

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

Sincerely,

Anthony White
President

Encl.

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April 16, 2021

VIA OVERNIGHT DELIVERY

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

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

Dear Director DeCaro:

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

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

Avenal Community Health Center

Clinicas de Salud del Pueblo

Community Health Centers of the Central Coast

Desert AIDS Project

Family Health Centers of San Diego

Gardner Family Health Network

Golden Valley Health Centers

HealthRIGHT 360

Hill Country Health & Wellness Center

Imperial Beach Community Clinic

La Maestra Family Clinic

MCHC Health Centers

Mission Area Health Associates

Omni Family Health

Open Door Community Health Centers

Ravenswood Family Health Network

San Francisco Community Health Center

San Ysidro Health

Shasta Community Health Center

South of Market Health Center

TrueCare

United Health Centers of the San Joaquin Valley

Vista Community Clinic

WellSpace Health

Central California Partnership for Health (Affiliate Support Organization)

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

Thank you,

Kathryn E. Doi
Partner

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

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

April 16, 2021

VIA FEDERAL EXPRESS

Teresa DeCaro, Acting Director
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Centers for Medicare & Medicaid Services
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Baltimore, MD 21244-1850

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

Dear Director DeCaro:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. Conclusion

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

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

Thank you for your time and consideration.

Sincerely,

Anthony White
President, CHCAPA

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

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

Exhibit A
to letter dated 4/16/2021

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March 18, 2021

VIA FEDERAL EXPRESS

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

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

Dear Ms. Cash:

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

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

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

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

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

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

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

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

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

Your attention to this matter is greatly appreciated.

Very truly yours,

Kathryn E. Doi
Partner

KED:KQD
Encls.

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

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

Exhibit A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Long Term Care (LTC)		Care in a facility for longer than the month of admission plus one month. Medically necessary care in a facility covered under managed care health plan contracts	~~X~~[5] ~~X~~[3,9~~65~~]	~~X~~[5] ~~X~~[3,5~~96~~]	X[53]	~~X~~[5] ~~X~~[3,5]	~~X~~[5] ~~X~~[3,5]	~~X~~[5] ~~X~~[3,5]
Medical Supplies ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. ~~Does not include incontinence creams and washes~~	X	X	X	X	X	X
Medical Supplies (effective April 1, 2021 onward)	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. Does not include medical supplies carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including medical supplies described in the Medi-Cal Rx All Plan Letter (APL 20-020). [1] ~~Medically necessary supplies when prescribed by a licensed practitioner.~~	X	X	X	X	X	X
Medical & Non-Medical (NMT) Transportation Services	Transportation-Medical & Non-Medical ~~(NMT)~~Transportation (NMT) Services	Covers ambulance, litter van and wheelchair van medical transportation services are covered when the beneficiary's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically contraindicated, and transportation is required for the purpose of obtaining needed medical care. NMT is transportation by private or public vehicle for	X	X	X	X	X	X

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Exhibit B

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

[redacted]

Attachment N Updates ...
119 KB

Attachment N Updates ...
104 KB

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[redacted]

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

Good Morning,

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

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

Changes to Attachment N include:

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

Reply all | Delete Junk |

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

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

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

Exhibit C

Reply all | Delete Junk |

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

Reply all | Delete Junk |

[redacted]

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

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

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

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

Reply all | Delete Junk |

<Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good Morning,

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

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

Changes to Attachment N include:

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

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

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

Exhibit D

Christopher M. House

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

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

U.S. District Court

Eastern District of California - Live System

Notice of Electronic Filing

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

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

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

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

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

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

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

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

Regina Mary Boyle rboyle@cliniclaw.com

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

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

Exhibit E

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

Dear Stakeholders,

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

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

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

DHCS anticipates providing further information in May.

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

Thank you,
DHCS

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

MCRxSS Announcement

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

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

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

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

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Important Update on Medi-Cal Rx

February 17, 2021

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

Exhibit B
to letter dated 4/16/2021

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

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, Francisco Castillon, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

/ / /

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Francisco Castillon

Exhibit C
to letter dated 4/16/2021

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

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, C. Dean Germano, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) The SPP would be simple to administer.

(d) The SPP will be renewed annually.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

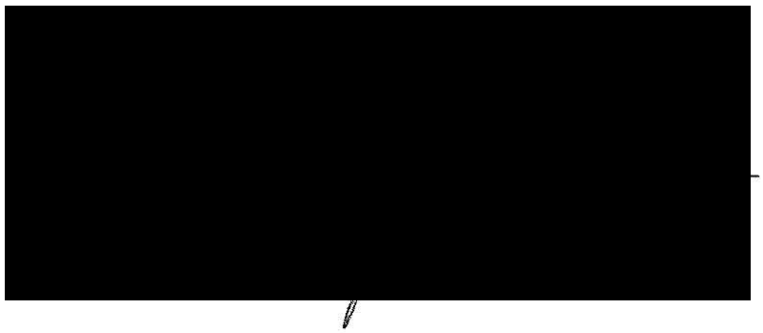

Exhibit D
to letter dated 4/16/2021

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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, Ricardo Roman, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[redacted]

Ricardo Roman

Exhibit E
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, David Brinkman, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[redacted]

David Brinkman

Exhibit F
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

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

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

I, Dr. Kelvin Vu, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

Executed on this 2 day of February, 2021, in Arcata, California.

DR. KELVIN VU

Exhibit G
to letter dated 4/16/2021

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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al., Plaintiffs, v. WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES, Defendants.	Case No. 2:20-CV-02171-JAM-KJN4 **DECLARATION OF DR. PARAMVIR SIDHU IN SUPPORT OF PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO THE MOTION FOR A PRELIMINARY INJUNCTION** Judge: Hon. John A. Mendez Date: March 9, 2021 Time: 1:30 p.m. Crtrm.: 6

I, Dr. Paramvir Sidhu, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Executed on this 5 day of February, 2021, in Visalia, California.

[redacted]

DR. PARAMVIR SIDHU

Exhibit H
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF FRAN BUTLER-COHEN IN OPPOSITION TO MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Judge: Hon. John A. Mendez
Date: February 23, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Fran Butler-Cohen, declare:

1. I am the Chief Executive Officer ("CEO") at Family Health Centers San Diego ("FHCSD") and have held this role since 1986. I have reviewed the data and associated outcomes relevant to the impact of Medi-Cal Rx on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth

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

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

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

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

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

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

7. Simultaneously, FHCSD is still required to commit time to fielding government audits and meet with the State and Managed Care Organizations on metric performance. In addition, FHCSD is currently in the beginning stages of a random federal 340B audit that has already taken several hundred hours of staff time in preparation and document submission. At the same time, the Health Resources and Services Administration is requesting capital funding grantees submit previously unrequired data and qualitative information to help them design future grant programs, Moreover, FHCSD has had to make significant modifications to contract pharmacy arrangements to ensure our patients receive affordable medications due to the attack on the 340B program by pharmaceutical manufacturers. All of this comes against the backdrop of the State of California awarding a contract valued at approximately $80 million annually to a for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by Centene, a publicly traded NYSE corporation worth $76 billion for $2.2 billion dollars to

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facilitate the state in their plan that will remove hundreds of millions of dollars from the state's health care safety-net.

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

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

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

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- Review all medication and pharmacy related policies and protocols across the organization to align with new systems and ensure compliance.
- Educate providers about the transition from the MCO formulary to using drugs on the FFS formulary.
- Educate providers on the new Prior Authorization (PA) systems as drugs prescribed that are therapeutic substitutions for more commonly prescribed drugs not found on the CDL, including any step therapy or pre-requisite therapies.
- Educate clinic directors, billing staff and other administrative personnel as to the new systems, how to use them and how to trouble shoot difficulties for patients and providers.
- Review how FHCSD payor mix will change given the pharmacy transition and evaluate whether it's beneficial for FHCSD and our patients to maintain current contract pharmacy relationships or cancel them.

10. The state and local governments still expect FHCSD to maintain the same quality of care and to serve more patients in more ways while implementing Medi-Cal Rx, which will squeeze FHCSD's resources at precisely the wrong time. Without the 100 percent reimbursement rate guaranteed by federal Medicaid law and the 340B savings FHCSD relies on, we simply will not be able to provide the same level of care for the patients we have worked tirelessly to serve. I fear that the healthcare workers and

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

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

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

[redacted]

FRAN BUTLER-COHEN

Exhibit I
to letter dated 4/16/2021

Medi-Cal Rx Monthly Bulletin

April 1, 2021

The monthly bulletin consists of alerts, bulletins and notices posted to the Medi-Cal Rx Web Portal within the previous month.

Contents

1. Changes to the Contract Drugs List Effective April 1, 2021

The below changes have been made to the Contract Drugs List effective April 1, 2021.

For more information, see the Contract Drugs List on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Asenapine	FDA-approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Cabotegravir/Rilpivirine	Added to CDL with a restriction.	April 1, 2021
Exenatide	Extended release injectable suspension vial obsolete. Removed from CDL.	April 1, 2021
Leuprolide Acetate	Injection and powder for injection removed from CDL. Labeler restriction updated to 00074 only.	April 1, 2021

Drug Name	Description	Effective Date
Lurasidone Hydrochloride	FDA approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Morphine Sulfate/Naltrexone	Drug obsolete. Removed from CDL.	April 1, 2021
Nevirapine	Labeler restriction (00597) added to liquid only.	April 1, 2021
Propranolol	Additional liquid strength (1.28 mg/ml) added to CDL with a restriction.	April 1, 2021
Relugolix	Added to CDL with a restriction.	April 1, 2021
Sodium Zirconium Cyclosilicate	Added to CDL with labeler code restriction.	April 1, 2021

2. Updates to the List of Covered Enteral Nutrition Products

Effective for dates of service on or after March 1, 2021, the List of Covered Enteral Nutrition Products has been updated on the Medi-Cal Rx Web Portal. Effective for dates of service on or after April 1, 2021, products deleted from the List of Covered Enteral Nutrition Products will no longer be reimbursable, even with an approved prior authorization. The Maximum Acquisition Cost (MAC) for these products is no longer guaranteed.

3. Medi-Cal Provider Training Schedule

The transition of all administrative services related to Medi-Cal pharmacy benefits billed on pharmacy claims from the existing intermediaries, Medi-Cal Fee-for-Service (FFS) or Managed Care Plan (MCP) providers, will transition to the new Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (MMA).

This article serves as a guide to outline the trainings planned for March 2021 until the Medi-Cal Rx implementation that will assist pharmacy providers, prescribers, and their staff as they transition to Medi-Cal Rx.

User Administration Console Training

All Medi-Cal Rx pharmacy providers, prescribers, and their staff will need to complete registration in order to access the secure areas of the Medi-Cal Rx Web Portal. Access to the secured Medi-Cal Rx Provider Portal starts with registration via the User Administration Console (UAC) application.

Training Information:

To assist pharmacy providers, prescribers, and their staff with UAC registration, there are job aids and computer-based trainings (CBTs) available to walk users through the registration process. Those materials are as follows:

- UAC Quick Start Guide
- UAC Tutorial #1: Start Registration Process
- UAC Tutorial #1 Supplement: Alternate Address Instructions
- UAC Tutorial #2: Complete Registration
- UAC Tutorial #4: Granting Access for Yourself and Staff

If you run into any issues or have any questions about the UAC registration process, feel free to attend an office hours session with one of our Pharmacy Representatives (PSRs) who can assist with the process.

To register for a UAC office hours session, please email the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of Office Hours session

As of April 1, 2021 UAC Office Hours Sessions will be offered on an as-needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Saba LMS Training

Saba is the one-stop shop for Education and Outreach information for Medi-Cal Rx pharmacy providers and prescribers. Topics to be covered during the Saba training sessions include how to view the Education and Outreach events calendar, how to register to attend an event or take an online course, and how to complete evaluations of training effectiveness.

Training Information:

Training for Saba includes a job aid with step-by-step instructions:

Medi-Cal Rx Saba℠ Provider Job Aid

In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via Hewlett Packard Enterprise (HPE) MyRoom™. To register to attend a live webinar, please email Medi-Cal Rx Education and Outreach at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of training session

Before enrolling in a Saba training session, providers will need to confirm in their email if they have completed the following tasks:

- Registered successfully for UAC
- Received a PIN letter and completed UAC registration
- Registered as the Delegated Administrator or have been created as a user by the Delegated Administrator
- Have added or been granted access to the Saba application

As of April 1, 2021, Saba Training Sessions will be offered on an as needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Medi-Cal Rx Transition and Resources and Web Portal Training

This training is intended to give pharmacy providers and prescribers an overview of the Medi-Cal Rx Transition and the resources that are available on the Medi-Cal Rx Web Portal. Topics that will be covered in this training include the following:

- Medi-Cal Rx background and high-level changes affecting pharmacy providers and prescribers
- Point-of-Sale (POS) Technical and Operational Readiness
- Web Claims Submission and overview of the Finance Portal

Training Information:

Training will be available via job aids and live webinars coming April 2021.

Training sessions for Medi Cal Rx Transition and Resources and Web Portal will be offered via a series of videos and job aids with step-by-step instructions. In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via HPE MyRoom™. To register to attend a live webinar, please refer to the Saba Training Calendar for specific dates and times.

Pharmacy providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to the Saba application.

Medi-Cal Rx Transition and Resources and Web Portal Training Sessions (April 2021)	
Dates	**Times**
April 2021	Please refer to the Saba Training Calendar for specific dates and times.

Prior Authorization Training

A Prior Authorization (PA), previously known as a Treatment Authorization Request (TAR), requires providers to obtain approval before rendering certain services such as prescriptions.

This training will be intended for pharmacy providers and prescribers that plan to use the new Medi-Cal Rx Secured Portal to submit PAs.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available, live webinar training will be available via Saba. Providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and PA applications.

Web Claims Submission Training

This training will give providers an overview of the new Medi-Cal Rx Web Claims Submission system. Providers currently using a POS system to process prescription claims can still continue to submit web claims via this channel.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available live webinar trainings will be available via Saba. Pharmacy providers and prescribers and their staff that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and Medi-Cal Rx Web Claims Submission applications.

4. Prescriber Phone Campaign

Pharmacy Service Representatives (PSRs) will begin reaching out by phone to introduce the new Medi-Cal Rx Web Portal and available resources and functionality. This outreach to prescribers will accomplish the following:

- Provide guidance on how to start registration for the Secured Provider Portal.
- Inform prescribers of currently available training and resources for Medi-Cal Rx.

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure Web Portal registration in order to access Education and Outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba, and providers will have the ability to enroll in web-based, instructor-led, or computer-based training.

To access Saba, providers need to utilize the User Administration Console (UAC) application. Click the **Medi-Cal Rx Training** hyperlink on the Education & Outreach page of the Medi-Cal Rx Web Portal or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration.

To register for an Office Hours session, please email MediCalRxEducationOutreach@magellanhealth.com and include the following information:

1. Name of Individual
2. Provider Name
3. National Provider Identifier (NPI)
4. Phone Number
5. Email Address
6. Preferred Date and Time of Office Hours Session

5. Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey

How do you and your peers currently conduct business for Medi-Cal pharmacy services? We'd love to hear from you! The results of the Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey will be used to tailor training offerings for Medi-Cal Rx to ensure you are prepared for the upcoming transition. The information you provide is confidential and will be used only for future training.

6. Pharmacy Provider Self-Attestation Period Begins April 2021

Although currently delayed, Medi-Cal pharmacy benefits will eventually be transitioned to and thereafter administered through the Fee-for-Service (FFS) delivery system for all Medi-Cal beneficiaries (generally referred to as "Medi-Cal Rx"). The Department of Health Care Services (DHCS) has partnered with Magellan Medicaid Administration, Inc. (MMA) to provide a wide variety of administrative services and support for Medi-Cal Rx.

MMA has contracted with Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to administer the annual pharmacy provider self-attestation survey for professional dispensing fee reimbursement. The objective of the next self-attestation survey is to assign professional dispensing fee rates for Medi-Cal-enrolled pharmacies beginning July 1, 2021 and ending June 30, 2022.

DHCS, through Mercer, will be initiating the provider self-attestation process in April 2021 for the 2020 calendar year reporting period for those pharmacy providers seeking the higher of two professional dispensing fee rates determined by annual prescription volume. Key changes to the self-attestation process include the following:

- The provider self-attestation period for the calendar year 2020 reporting period will run from April 1 through April 30, 2021 (in previous years, the survey period was January 15 through the end of February).
- Mercer, on behalf of MMA and DHCS, will administer the provider self-attestation survey with options for online submission or an email submission of a Microsoft® Excel®-formatted template.
- In addition to the standard online submission, pharmacies will have an additional survey submission option that will allow a bulk submission for multiple locations. The new template will allow a corporate office for chain-affiliated stores under common ownership to submit multiple stores in one self-attestation survey file.

As in previous years, newly approved FFS pharmacy providers that are notified of their Medi-Cal enrollment approval after the attestation period closes will automatically receive the higher dispensing fee. However, those same providers will have to attest for subsequent reporting periods in order to continue to be eligible for the higher dispensing fee in subsequent fiscal years.

Pharmacy providers may refer to the updated Pharmacy Provider Self-Attestation FAQs for more information.

DHCS reminds the Medi-Cal pharmacy FFS provider community to closely monitor upcoming Medi-Cal pharmacy bulletins for additional information regarding future updates by signing up via the Medi-Cal Rx Subscription Service.

For updates on Medi-Cal Rx, please visit the Medi-Cal Rx Web Portal and the DHCS Medi-Cal Rx Transition website. In addition, DHCS encourages stakeholders to review the Medi-Cal Rx Frequently Asked Questions (FAQ) document, which continues to be updated as the project advances.

7. Portal Registration

What is Medi-Cal Rx and When Does it Happen?

Medi-Cal Rx is the name the Department of Health Care Services (DHCS) has given to the collective pharmacy benefits and services that will be administered through the Fee-for-Service (FFS) delivery system by its contracted vendor, Magellan Medicaid Administration, Inc. (MMA). Medi-Cal Rx will include all pharmacy services billed as a pharmacy claim, including but not limited to outpatient drugs (prescription and over the counter), Physician-Administered Drugs, enteral nutrition products, and medical supplies.

DHCS is delaying the planned Go-Live date of April 1, 2021, for Medi-Cal Rx. For more information, please see the Important Update on Medi-Cal Rx alert dated February 17, 2021.

What Should I Do Now?

Start by visiting the new Medi-Cal Rx Web Portal to review general information about the transition and to access registration and training for the Web Portal. This website serves as a platform to educate and communicate on Medi-Cal Rx resources, tools, and information. To stay informed, sign up for the Medi-Cal Rx Subscription Service (MCRxSS). Similarly, closely monitor Medi-Cal Rx news and bulletins for additional information regarding any future updates.

Next, register for the secure Medi-Cal Rx Provider Portal. Providers will need to complete registration for the User Administration Console (UAC) application. UAC is a registration tool that controls and manages a user's access to the secure section of the Medi-Cal Rx Web Portal and associated applications.

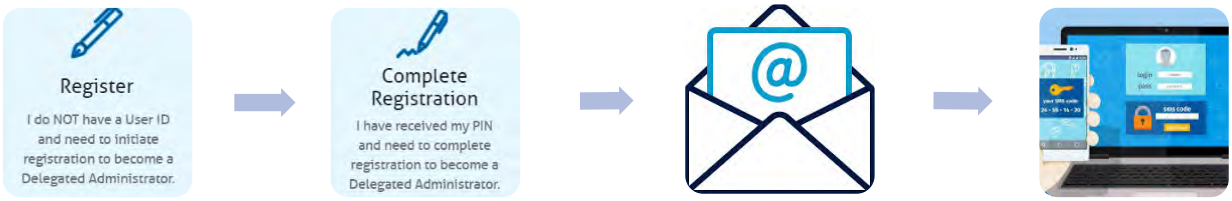
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- Prior Authorization System
- Secure Chat and Messaging Features
- Beneficiary Eligibility Lookup
- Web and Batch Claims Submission
- Education & Outreach Calendar and Training Registration

Refer to the UAC Quick Start Guide (PDF) and the information below for assistance with registering for UAC.

UAC Registration

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure web portal registration in order to access education and outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba and providers will have the ability to enroll in web-based, instructor-led, or computer-based training. To access Saba, providers need to utilize the UAC application. Click the hyperlink under **Medi-Cal Rx Training** on the Education & Outreach page of the Medi-Cal Rx Web Portal, or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration. To register for an Office Hours session, please email MediCalRxEducationOutreach@MagellanHealth.com and include the following information in your email: name of individual, provider name, National Provider Identifier (NPI), phone number, email address, and preferred date and time of Office Hours session.



To register, visit https://uac.magellanrx.com.

- Click **Register**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering as many IDs as necessary
- Click **Submit**

You will receive a letter with a PIN number.

- Return to the UAC website
- Click **Complete Registration**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering and validating all necessary IDs
- Click **Submit**

You will receive an email with an activation link (check spam or junk folder).

- Click activation link
- Confirmation screen appears indicating *You Have Been Successfully Added*
- Click on link in confirmation screen directing you to UAC application
- Here you can assign access and create accounts

Assign access/privileges and organizations.

- The first time you log into UAC, set up multifactor authentication
- Continue with sections 2.0, 3.0, and 4.0 in the Medi-Cal Rx UAC Quick Start Guide located at https://medi-calrx.dhcs.ca.gov/home/education

Christopher M. House

From: UPS <pkginfo@ups.com>
Sent: Monday, April 19, 2021 7:22 AM
To: Christopher M. House
Subject: [EXTERNAL] UPS Delivery Notification, Tracking Number 1ZA47F260198305886

Hello, your package has been delivered.

Delivery Date: Monday, 04/19/2021
Delivery Time: 10:20 AM
Left At: DOCK
Signed by: ANDRE

HANSON BRIDGETT LLP

Tracking Number:	1ZA47F260198305886
Ship To:	CENTER FOR MEDICAID & CHIP SERVICES 7500 SECURITY BOULEVARD, MAIL STOP S2-25-26 BALTIMORE, MD 212441850 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	2.0 LBS
Reference Number:	37366.3
Reference Number:	FHCSD / CHCAPA
Reference Number:	KATHRYN DOI

Download the UPS mobile app

CALAIM comments for dental programs
The CalAim proposal for dental managed care at the county level is an exciting opportunity to increase access and utilization for dental services. Extending P4P for preventive dental services for preventive services would also augment the low reimbursement rates for dental services on the FFS model.
Comments on the specific dental proposals are provided below:

1. The Current CALAIM proposal limits SDF to children 0-6 years and patients with special needs residing in skilled nursing facilities. SDF can be beneficial for patients of all ages and special needs patients living at home and being cared for by their families equally. Limiting SDF to skilled nursing facility residents also is an issue that increases the disparity among the special needs populations.
2. Special needs patient residing in skilled nursing care facilities will also be allowed to have more frequent dental recalls under the proposal. More frequent recalls for patients with special needs residing with their families in critical to providing preventive dental services and preventing disease and also unnecessary emergency room visits. Limiting special needs patients that reside at home and are cared for by their families to a recall solely based on age (which for most adults is once per year) is not equitable. Frequent recalls should be based on age and the medical diagnosis that challenges preforming oral hygiene at home rather than by the location of residence.

In addition, I want to point out that tele-health in dentistry is a promising practice. To that end, Access is to dental services is important to keep patients out of the emergency room. Access to services is also important to maintain oral health and improve overall health outcomes. This is especially important for patients with special needs. With the pandemic, we have utilized and piloted use of tele-dentistry beyond what was being proposed pre-pandemic. Tele-dentistry is one important modality that will help improve access and lower costs to the systems if access to the dental provider would prevent a visit to the ED for non-traumatic dental conditions. Tele-dentistry also presents opportunities to level the playing field when it comes to achieving racial and ethnic equity for access to dental services.

Yogita Butani Thakur DDS, MS
Chief Dental Officer
Ravenswood Family Health Center
1807 Bay Road
East Palo Alto, CA 94303
Ph: 650-289-7710
Fax: 650-853-1018
Appointments: 650-289-7700

Mendocino Coast Clinics, Inc. • 205 South Street, Fort Bragg, CA 95437 • 707.964.1251 ~ www.mccinc.org

May 6, 2021

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

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

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

Dear Director Lightbourne,

Mendocino Coast Clinics Inc. appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

Mendocino Coast 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. Our patients have received notification of the transition and then a letter announcing the delay, once again they were noticed about the change and again about the delay. This is confusing and frightening when they rely on medications and fear having no way to acquire them. Especially right now when economic fragility is such a reality in their lives, having concerns about paying out of pocket for medication is unacceptable. Recognizing the rapidly evolving pandemic response, as well as the current challenges and unknown resolution to conflict concerns with the project's contractor vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

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

The CalAIM proposal will ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, treatment services are not available until a patient completes an assessment, which often can be counterproductive to patient engagement, especially for patients in crisis or in substance withdrawal. For that reason, we applaud the Administration proposal regarding allowing treatment during the assessment period and the "no wrong door" proposal that will ensure provider's ability to render necessary medical services to patients. However, questions remain as to how providers can comply with, and bill for, those services if they are not contracted with a county specialty mental health (SMH) and substance use disorder (SUD) health plan. Health centers often are the entry into the SMH/SUD system, yet few health centers are contracted providers with their county SMH/SUD health plans. This arrangement often leaves health centers in a financially disadvantaged position where they must provide needed services under federal law but cannot bill for those services. Mendocino Coast Clinics has no contractual relationship with the SMH/SUD health plan in the county. This means making referral outside our health center which makes it more complicated for our patients to access these services. Equity, integration, and access should be the goal of CalAIM therefore this issue must be seriously considered. 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 Mendocino Coast 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).***

Mendocino Coast 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, Mendocino Coast 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 Lucresha Renteria, 707-961-3433, lrenteria@mccinc.org .

Sincerely,

[redacted]

Lucresha Renteria
Executive Director
Pronoun- she/her/hers
Mendocino Coast Clinics

Re: CalAIM Section 1115 & 1915(b) Waivers

May 6, 2021

Dear Director Lightbourne:

We applaud the DHCS efforts to advance goals of improving mental health services for Medi-Cal beneficiaries under 21 years old, and we support moving the CalAIM initiative forward, including through the important step of seeking federal approval of the 1115 and 1915(b) waivers. However, we write to express our concerns, specifically with the language in Appendix 2 of the 1915(b) waiver related to criteria of medical necessity to access specialty mental health services for beneficiaries under 21 years old.

Specifically, in regards to "Criteria 1," we feel it is potentially harmful to many vulnerable children to require (for those outside the child welfare system or those not experiencing homelessness) a “high-risk” score on a trauma screening tool to access services. While we applaud the promotion of trauma screening tools such as the PEARLS ACEs screener as a method to help identify more children at risk for toxic stress, such a tool should not be the sole indicator for whether a child might need access to specialty mental health care. There are many children that may need specialty mental health services that don't have a diagnosis as specified in Criteria 2 and yet do not also have a high risk score on a trauma screening tool. While a high risk score can be one criteria for medical necessity, it should not restrict those without high risk scores from being able to access services based on their own determination of need or that of a responsible adult.

As a school model serving primarily Medi-Cal beneficiaries in East Palo Alto, we have supported referring many students — in coordination with their families and pediatricians — for specialty mental health services over the last five years. We have identified these students not with a trauma screening tool, but rather by request of either the family, who were seeking more support, or from school staff who were working daily with the child. We are thankful for DHCS’s support for open door pathways, which enable referrals to specialty mental health from partners in a school setting, but we want to ensure the criteria for medical necessity for children under age 21 remains expansive and inclusive at a level that allows providers to serve all children in need.

As such, we respectfully request that you reconsider the language regarding medical necessity prior to submitting the 1115 and 1915(b) waivers for federal approval.

Sincerely,

[redacted]

Courtney Garcia
CEO, The Primary School
East Palo Alto, CA

[redacted]

Ryan Padrez, MD, FAAP
VP of Health and Medical Director, The Primary School
East Palo Alto, CA

DEPARTMENT OF MENTAL HEALTH
hope. recovery. wellbeing.

JONATHAN E. SHERIN, M.D., Ph.D.
Director

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

Dear Mr. Lightbourne:

CalAIM SECTION 1115 & 1915(B) WAIVERS

We thank the Department of Health Care Services (DHCS) for this opportunity to provide Public Comments on the Section 1915(b) Waiver (also titled the CalAIM Section 1915(b) Waiver) and the Section 1115 Demonstration (also titled the CalAIM Demonstration), which as a collective seek to advance several elements of the DHCS CalAIM Proposal that has an ultimate goal of improving the health outcomes of Medi-Cal beneficiaries and other low-income individuals living in California.

DHCS, referred to as the Department in the rest of these Public Comments, within the CalAIM 1915(b) Waiver has identified its vision and approach for an Integrated Delivery System of Care, which includes the shifting of authorities associated with Medi-Cal Managed Care (MCMC), Dental Managed Care (Dental MC), several elements of Drug Medi-Cal Organized Delivery System (DMC-ODS), and the Whole Person Care (WPC) Pilot from the current Section 1115 Demonstration into the 1915(b) Waiver where the current authority for Specialty Mental Health Services (SMHS) Program is and will remain. The goals of the Department to utilize whole person care approaches and address Social Determinants of Health (SDOH) to 1) identify and manage member risk, 2) streamline the Medi-Cal System to facilitate reduction of complexity and increase flexibility, and 3) improve quality outcomes, decrease health disparities, and transform the delivery system via payment reform and value-based initiatives are worthy ones to embark upon. We embrace the opportunity to partner and collaborate with you in these endeavors. Our comments, encapsulated in the pages below , highlight items worthy of consideration and resolution to facilitate attainment of the abovementioned desired goals and outcomes.

Enhanced Care Management (ECM)

We are thankful for the vision of the Department to recommend to the Center for Medicare and Medicaid Services (CMS) that a new benefit, Enhanced Care Management (ECM), is needed to meet the current needs experienced by the Medicaid (i.e., Medi-Cal in California) population today. The Core Components of ECM described in the Department's CalAIM Proposal are services and approaches that the County Mental Health Plans (MHPs) have expertise and capacity to provide. Our history is that while we have the expertise to provide these identified ECM Core Components, many of the associated services were not reimbursed under the current Medi-Cal benefit and reimbursement rules. As a result, County MHPs have accessed other non-Medi-Cal funding streams to reimburse for clinically necessary services provided to the Medi-Cal beneficiary. We request that the Department ensures that County MHP Providers that contract to be ECM Providers with the Medi-Cal Managed Care Plans (MCPs) in their respective counties receive Medi-Cal reimbursement for the ECM Core Component Services, provided to the Medi-Cal beneficiary, which heretofore have not been reimbursable by Medi-Cal. County MHP ECM Providers should not be expected to continue to access non-Medi-Cal funding streams for ECM Core Component Services that are now included in the Medi-Cal benefit.

Furthermore, we request that the eligibility criteria for the ECM benefit is not overly restrictive and prescriptive. We appreciate the Department identifying seven (7) ECM Target Populations with the proviso that additional ECM Target Populations can be defined by the MCPs for consideration by the Department for inclusion in the ECM Target Populations. One of the current ECM Target Populations is identified as "SMI, SED, and SUD Individuals at Risk for Institutionalization." One of the examples provided to describe a potential candidate for this Target Population is an individual "...with repeated incidents of emergency department use, psychiatric emergency services, psychiatric inpatient hospitalizations, including stays at psychiatric health facilities, or short-term skilled nursing facility stays who could be served in community-based settings with supports" (CalAIM Proposal, January 2021, pg. 162).

We posit that Risk of Institutionalization should not be connected to a set number of events (e.g., psychiatric inpatient hospitalizations, psychiatric emergency services) that have taken place since there are Medi-Cal beneficiaries who have serious mental illness and also experience homelessness who could meet criteria for hospitalization but due to isolation of being homeless, they suffer in silence. Also, some Medi-Cal beneficiaries who have serious mental illness may isolate and withdraw in their dwellings when experiencing psychiatric crises, and due to this silent suffering they do not receive facility-based services. In both of these examples, the individuals could benefit from ECM however could potentially not be identified as eligible for ECM due to the lack of encounter data associated with facility-based services.

As the MCPs will be responsible for administering the ECM benefit, one of the tasks assigned to them by the Department is to utilize Population Health Management processes to determine which Medi-Cal Beneficiaries are eligible for ECM. Claims data will be used as one of the elements to inform the determination of eligibility for ECM. It will be imperative that the MCPs enter into relationships with County Mental Health Plans (and other Organizations) to gain access to additional data sets (e.g., Housing-related data sets) that are situated outside of the Medi-Cal claims system due to the services delivered not being eligible for Medi-Cal reimbursement. This information will be essential for MCPs to gain a robust understanding of the clinical and non-clinical services received by the Medi-Cal beneficiary that inform the risk stratification and risk segmentation, which will be used to facilitate determination of ECM eligibility.

In Lieu of Services (ILOS)

The suite of pre-approved In Lieu of Services (ILOS) identified by the Department is welcome to see as they can serve to address various SDOH that disproportionately impact the Medi-Cal population and thus negatively impact the health outcomes of the population. County MHPs currently provide several of the pre-approved ILOS, including Housing Transition Navigation Services, Housing Deposit, and Housing Tenancy and Sustaining Services.

As with ECM, County MHP Providers have expertise and the capacity to provide the above three (3) mentioned ILOS. Our reality is that many of the activities provided in these three (3) ILOS are currently not reimbursable by Medi-Cal, but the County MHPs access non-Medi-Cal funding streams to provide these necessary and at times lifesaving services. We request that the Department ensures that the County MHP Providers that contract with the MCPs in their respective counties to be ILOS Providers receive reimbursement from the MCPs for ILOS offered by the MCPs and provided by our County MHP ILOS providers. County MHP ILOS Providers should not be expected to continue to access non-Medi-Cal funding streams for ILOS made available to the Medi-Cal beneficiary by the MCPs and thus funded by the MCPs.

Documentation Reform and Audit Process

The Department's stated commitment to the standardization of federal requirements where permissible by statute/regulation and reduction of administrative complexity is welcome. We propose that one path to accomplishing this is via the attainment of true and transformative Documentation Reform that will remove historic documentation burden. The approach to the development of a Treatment Plan is an example of the type of Documentation Reform needed. The Treatment Plan (client and clinician co-created goal(s) for treatment) is most meaningful when continuously updated with the latest

information received at each encounter. Stand-alone treatment plans are not well-suited for this purpose. Too often these plans are not updated because they do not fall within the natural flow of treatment. As an alternative we suggest that treatment planning be included in the initial assessment and ongoing progress notes that are more dynamic "point-in-time" documents.

We appreciate the Department's approach of engaging in collaborative dialogue with Stakeholders to advance the imagining and subsequent implementation of Documentation Reform and look forward to participating in this ongoing work. A tightly coupled item to Documentation Reform is the revamping of the Department's Audit Process. As new transformative Documentation Reform takes place, an updated Audit Process must be enacted that syncs with the new Documentation standards. An approach that can be utilized to facilitate this is to transition from a Quality Assurance/Recoupment-focused Chart Review process to a Quality of Care/Quality Improvement-focused Chart Review process, and utilization of existing Managed Care Industry Standards to address Fraud, Waste, and Abuse.

Treatment during Assessment Period

We welcome the language and clinical approach that identifies medically necessary treatment services can be provided during the Assessment Period. However, it is noted that Mental Health Rehabilitation Services (e.g., Skills building like Anger Management, Communication, Stress Management, etc.), Targeted Case Management, and Intensive Care Coordination are not included as types of treatment services that can be provided during the Assessment Period. Mental Health Rehabilitation Services, Targeted Case Management, and Intensive Care Coordination are critical to the successful recovery journeys of the Medi-Cal beneficiaries served in the MHP Delivery System. To withhold services during the Assessment Period is "...counterproductive to client engagement, especially for patients in crisis..." as stated clearly by the Department in the CalAIM 1915(b) Waiver. We believe that in addition to the Treatment Services already identified by the Department, Mental Health Rehabilitation Services, Targeted Case Management and Intensive Care Coordination provided during the Assessment Period can support and advance client engagement and begin the amelioration of some of the mental health symptoms and/or mental health related behaviors being experienced by the Medi-Cal beneficiary.

No Wrong Door

It is appreciated that the Department seeks to facilitate access to care via the No Wrong Door approach that affords the Medi-Cal beneficiary access to Mental Health Services in either the non-Specialty Mental Health Services (non-SMHS) Delivery System or the Specialty Mental Health Services (SMHS) Delivery System. However, further clarification

is needed by the Department that addresses nuances that emerge when a Medi-Cal beneficiary initially accesses services in one Mental Health Delivery System, but it is determined they can receive services appropriately in a different Mental Health Delivery System and the beneficiary is willing to do so. An example of a needed clarification is related to diagnosis. Adult Medi-Cal beneficiaries with certain diagnoses (e.g., Schizophrenia, Bipolar, etc.) do not automatically need to receive services indefinitely in the SMHS Delivery System. If the Adult Medi-Cal beneficiary is and has been utilizing various strategies that result in their ability to function well in multiple Life Areas (e.g., Familial Relationships, Social Relationships, Employment/Education, Physical Health, etc.), they can appropriately receive needed ongoing mental health services in the non-SMHS Delivery System.

Co-Occurring Disorders

This shift in policy is a good one as it demonstrates one of the commitments of CalAIM that emphasizes providing care to the whole person. Operationally defining how treatment of co-occurring disorders can be evidenced in the MHP SMHS Delivery System is needed to shape the clinical culture change that is needed with this policy change. Examples of the types of operational definitions and/or clarifications that are needed include: 1) Provision of SMHS in the MHP SMHS Delivery System to a Medi-Cal beneficiary with a Primary SUD diagnosis and a Secondary Mental Health diagnosis; and 2) Identification of types of services that are not included in the construct "treatment of co-occurring disorders" in a MHP SMHS Delivery System that is not Drug Medi-Cal certified.

Special Programs for Foster Children and Caregivers

We appreciate the Department's plan to provide clarification on the authority for County Mobile Response and Stabilization Teams for the provision of Specialty Mental Health Services (SMHS). We ask that the Department goes further in its clarification on the authority of these Teams to provide SMHS when the identified response is non-mental health related. We also ask the Department to include in its clarification on the authority for SMHS to be delivered as part of the Family First Prevention Services Act (FFPSA) requirements, information that addresses situations where the identified response is not amenable to an EBP Intervention. This type of clarification is needed on the flexibility of FFPSA.

Behavioral Health Payment Reform

The Department has presented in its Behavioral Health Payment Reform elements that seek transformative change to advance improved quality outcomes and reduction of health disparities for the Medi-Cal beneficiaries served in the Behavioral Health Delivery

Systems of Care. Some of the change elements are seismic in nature and we request the following consideration from the Department.

Rate Setting Methodology: The current Short-Doyle/Medi-Cal reimbursement process allows eligible costs of utilization review/quality assurance (UR/QA) and administration to be reimbursed without a cap. However, the proposed rate setting methodology adds UR/QA and administration components to the rate at unspecified percentages on top of the service component. This, potentially, can limit the reimbursement of eligible costs if percentages are set too low. We recommend sufficient percentage levels are used to ensure appropriate reimbursement.

County Readiness to implement requisite infrastructure changes: We appreciate the Department's consideration to ensure county readiness, and would like to emphasize the importance of realistic and sufficient timelines for the significant preparation counties need to undergo, including updates to the eHR/claiming system, contracting processes, accounting setup, etc.

New Reporting/Compliance Standards: The Department's effort to reduce administrative burden by eliminating the lengthy and laborious cost reconciliation process is appreciated. It is expected that the proposed changes to reduce the administrative burden will require new and/or amended standards for counties to demonstrate adherence. We request the Department provides clarity on other reporting, reconciliation, and/or auditing requirements that may be streamlined, eliminated, or added due to the payment reform proposal.

SMI/SED Demonstration

The Department's expressed commitment to request Section 1115 demonstration authority to address the long-standing Medicaid Institutions for Mental Disease (IMD) exclusion, and thus facilitate the provision of short-term residential treatment services in IMD settings for Adult Medi-Cal beneficiaries (ages 21 – 64) is welcome and much needed news. The IMD exclusion, built into the foundation of the Medicaid program in 1965, has resulted in states being prohibited from receiving Medicaid payments for adults receiving treatment in an IMD. This rule exists, in part, to encourage the delivery of behavioral health care outside of large institutions, but it has inadvertently resulted in contributing to a serious shortage of mental health care treatment beds. This has been a problem in Los Angeles County.

Los Angeles County is committed to providing individuals with the most appropriate care in the most appropriate setting, and the IMD exclusion limits the County's ability to develop needed inpatient and residential care for those with serious mental illness. Far too often, individuals who need IMD care instead experience repeat hospitalizations,

homelessness, and episodes of incarceration. Repealing the IMD exclusion is not only necessary to address the mental health care needs of individuals requiring and deserving adequate residential services to heal, it is also an important step in resolving both the critical parity gap between physical and mental health care that continues to plague this field from a fiscal perspective, as well as the societal stigma that interferes with access to treatment at the expense of those most impacted by brain illness.

Los Angeles County Department of Mental Health is prepared to provide the required elements in the requested Section 1115 demonstration authority, including ensuring quality of institutional care; improving care coordination and transition to community-based care; increasing access to crisis stabilization services; and identifying SEDs and engaging in treatment early through increased integration. As we work locally to build up this continuum of outpatient and community-based care along with crisis stabilization services, we welcome opportunities to partner with DHCS to facilitate the successful submission of the request to CMS for Section 1115 demonstration authority.

Thank you for the opportunity to provide our comments to inform the final versions of CalAIM Section 1115 demonstration and Secion 1915(b) waiver that will be submitted to the Centers for Medicare and Medicaid Services (CMS). We look forward to the ongoing collaborative work with the Department as we collectively seek to meet the needs of the individuals we serve.

Sincerely,

[redacted]

Director

JES:tld

May 6, 2021

Submitted via electronic transmission

Jacey Cooper
Chief Deputy Director, Health Care Programs & State Medicaid Director
California Department of Health Care Services
1501 Capitol Avenue
Sacramento, CA 95899

RE: Stakeholder Feedback on California Advancing and Innovating Medi-Cal (CalAIM) Proposal

Dear Ms. Cooper:

CBHA is a statewide association of mental health and substance use disorder (behavioral health) non-profit community agencies, and our providers serve thousands of children, youth, families, adults and older adults throughout the state. We believe that Californians deserve a comprehensive, community-based behavioral health system that is adequately funded. We support the integration of behavioral health, physical health, housing, education and vocational rehabilitation services for children, youth, adults and older adults.

Considering the reach of our diverse membership, we are grateful for the state's forward thinking in designing the California Advancing and Innovating Medi-Cal (CalAIM) waiver. We appreciate how the state has incorporated the voice of behavioral health community-based provider organizations into the stakeholder discussions to date. Below, we provide comments on aspects of the CalAIM proposal.

Full Integration Pilots

First, we want to express appreciation for the extension of the full integration pilots until 2027. We believe full integration of behavioral health with physical health is prudent and consistent with national trends and best practice models in designing healthcare models that are client centered. However, we acknowledge that this effort requires a team lift to ensure that the pilots are designed and implemented in the most efficient and effective manner, and we look forward to continued discussion about the design of the full integration pilots.

Drug MediCal Organized Delivery System (DMC-ODS)

We also support the Department's proposals for the DMC-ODS. Specifically, we are aligned with the lifting of restrictions on residential care, inclusion of the ASAM

criteria for screening and brief intervention, guidelines around clinical consultation and contingency management.

Payment Reform

We are optimistic about CalAIM payment reform and the potential positive policy changes. We know that under this new proposal, the State will have more funding available for new services with higher rates and be able to reduce current state expenditures to the extent they are currently claiming below their Upper Payment Limit and potentially participate in performance incentive payments. By eliminating the need for reconciliation, a final cost report with interim payments should result in significant administrative savings for both providers and the State.

CBHA remains cautious about the payment system having less budget control and more budget risk. While not an ideal system, the current structure including staffing, reimbursement and cost control, are determined by providers and contractors. Under the proposed new Inter-governmental transfer (IGT) structure, tax revenue is transferred to the State and then billed back with the federal match one service at a time. This leaves our service delivery system vulnerable to payment lags, eligibility lapses, service denials and other unknown factors.

We request more detail regarding the outcomes-based performance strategy. We believe that community-based organizations should be involved in identifying the “metrics” for these quality payments. We strongly encourage the department to design an Outcome and Value Based workgroup inclusive of provider voices.

Enhanced Case Management

Proposed as an alternative to Whole Person Care and Health Home Services, the new ECM has the potential to transform the delivery system. By including behavioral health in the provider types, our members will be part of the array of provider types specializing in serving the target populations. We are supportive of the general changes to the new ECM services but would like further detail on beneficiary enrollment. Specifically, we would like to understand default provider determination.

Additionally, request explanation on the expected variations across the State including staffing, documentation and rate setting. If the service system does not have consistency in care, providers will continue to have problems serving multiple counties. A fragmented system of requirements, at the discretion of regional Managed Care Organizations, will only add to an already burdensome billing system. We are also mindful that a statewide strategy for performance measures, rate setting and incentives will only exist if the State realigns this responsibility to a statewide Medicaid entity or requires uniformity across all Managed Care Organizations. Without strong guidance and requirements from the State, there will be differing policies as it relates to payment rates, staffing, network access and services varying by zip code.

We also request that the State mandate a standard method of assigning patients to an ECM provider. We support a model that makes clear that clients retain choice despite the auto-assignment system that may give preference to previously treating providers.

Billing

The current billing process for providers is unsustainable. As reported during statewide meetings with Department staff, at Capitol hearings and other meetings, *paperwork reduction contributes significantly to workforce shortages*. We are cautiously optimistic that the CalAIM process will help streamline the process for all county billing to only be what is federally required by CMS. We ask that this new federal minimum standard be memorialized in statue through trailer bill legislation. Without this codification, the state will see "paperwork creep" occur in the upcoming years. *The current system where each county requires different forms does not work for patient centered care.*

Additionally, we would like further information on the county peer rate billing process. Attention should be paid to the propensity to compare counties against atypical sized counties such as Los Angeles and San Francisco to guarantee proper rate setting. Please share with us the methodology used to set the peer rates. We are concerned that absent a system that takes into account the variations in counties, the potential exists for providers to be under reimbursed.

HCPCS and CPT Codes

Due to system changes related to coding and rates, the transition between payment systems is integral to payment reform and provider retention. We are especially concerned about interoperability between the CPT codes for non-licensed professionals and the lack of billing codes for Medicaid behavioral health services. *We continue to request that DHCS provide consistency in codes used for billing and works closely with Managed Care Organizations to crosswalk levels and services across county service systems.*

In addition to operational changes, we are also requesting that DHCS mandate that billing best practices are employed during the system migration. This includes regular claims testing and rebilling quarterly billing control groups with shadow claims.

Early and Periodic Screening Diagnostic and Treatment (EPSDT)

National trends, in addition to the effects of COVID, have shown the impacts of childhood suffering. In fact, research shows the clear nexus of childhood trauma and the risk of developing future mental health conditions. CalAIM language is inconsistent in the interpretation of EPSDT protections, and we request clarifications. We believe medical necessity and protections should be clearly extended to all eligible clients under age 21 and providers should be allowed to bill for services prior to diagnosis. Eligibility criteria should be made clear and based on a list of

evidence-based practices to address factors including, but not limited to, involvement in the child welfare system, homelessness, risk of mental illness and childhood trauma.

In Lieu of Services (ILOS)

Providers are supportive of the ILOS framework; however, we remain concerned about the comprehensiveness of the list of services as ILOS is a framework that has been used in the older adult system of care and may not be inclusive of services for other client groups. Also, per our letter dated December 2, 2019, we strongly recommend that the State put into place contractual agreements and develop key performance measures to ensure that existing program funding does not become the default funder for services that should be provided through Managed Care Plans.

Targeted Case Management Services (TCM)

According to the CalAIM proposal, Medi-Cal managed care plans in counties with TCM programs will be required to submit information in the transition and coordination plan describing how they will work with the Local Government Agency to ensure that members receiving enhanced care management services do not receive duplicative TCM services. CBHA requests clarification about how DHCS is operationally defining "duplication." Also, please outline how DHCS plans to monitor duplication and address the occurrence of duplication of services across multiple systems.

CBHA appreciates the opportunity to share our comments and we look forward to continued engagement with DHCS.

On behalf of the CBHA Board of Directors and its members,

[redacted]

Le Ondra Clark Harvey, Ph.D.
Chief Executive Officer

[redacted]

Robb Layne
Senior Advocate, Policy and Legislative Affairs

cc:

Kelly Pfeifer, MD, Department of Health Care Services
Jim Kooler, Department of Health Care Services
Lindy Harrington, Department of Health Care Services
Autumn Boylan, Department of Health Care Services
Erika Cristo, Department of Health Care Services
Marlies Perez, Department of Health Care Services
Stephanie Welch, Health and Human Services Agency
Secretary Mark Ghaly, MD, Health and Human Services Agency

To whom it may concern,

The First 5 Association of California thanks the Department for the opportunity to provide feedback on its proposed 1915b and 1115 Medicaid waivers. We appreciate many elements in this package of proposals, including CalAIM's population health approach to providing services, which holds the promise of holistically improving health outcomes of California's young children with low income. We also appreciate the renewal of coverage for full-scope Medi-Cal for pregnant women with low income.

We have two main comments related to our goal that all children experiencing social-emotional distress receive trauma-informed care that includes the whole family and is respectful of the child's community and background.

First, the First 5 Association is deeply concerned about restricting access to services that are mandated by the Early Periodic Screening Diagnosis and Treatment (EPSDT) benefit. California families are experiencing trauma and toxic stress, particularly as a result of isolation, depression and loss experienced during the pandemic. Even before the pandemic, too few children received mental health services through either their managed care plan or county behavioral health services, as a result of system complexity, confusion about the EPSDT benefit, and often a misunderstanding of how mental health conditions present themselves in young children, among other barriers. To reduce some of these barriers, we recommend the Department use only the broad federal EPSDT medical necessity criteria to determine referral to mental health services in either Medi-Cal managed care and specialty mental health services, and cover all services necessary to "correct or ameliorate" a mental health condition. The proposed waiver adds unnecessary layers of eligibility complexity. We fear that the proposed criteria to access specialty mental health services lend further confusion to these rules rather than clarify them.

Second, we are concerned about the proposed use of an ACEs screen as a tool to direct or qualify children for specialty mental health services. Using a population-level statistical predictor at the individual services level is inappropriate, even if used as one of several criteria. The traditional ten ACEs reflect only a fraction of those experiences demonstrated to impact the long-term activation of the stress response that leads to long-term health impacts. The quality and level of buffering available in a child's life has a direct impact on whether the stress system is activated over the long-term. We are only beginning to understand the effects of age at which stress is experienced in terms of long-term impacts, but it is clear there is a correlation between early stress and more significant impacts. For example, extreme and long-term mental illness or substance use disorder by a caregiver, beginning at an early age, in the absence of significant stress mitigation relationships (ACE score of 1), should qualify an individual for specialty mental health services even when it does not also include involvement in the child welfare system or experiencing homelessness. At the individual case level, that situation might be a dramatically stronger argument for services than a teen whose parents divorce and in the process a parent is subjected to short-term intimate partner violence, experiences depression and has a short experience with alcohol dependence

(ACE score of 4) but quickly enters recovery, while the parent or another adult provides mitigating support to the minor.

In sum, the ACEs tool is too blunt to be used in this way, and our learning about the ACEs screening tool and appropriate interventions is too new for the Department to include it in as a criteria for services.

Sincerely,
Melissa Stafford Jones
Executive Director, First 5 Association of California

Wilma Chan, SUPERVISOR, THIRD DISTRICT
ALAMEDA COUNTY BOARD OF SUPERVISORS

COMMITTEES:
Health, Chair
Unincorporated, Chair
Personnel & Legislative

May 6, 2021

Will Lightbourne, Director
Department of Health Care Services
Director's Office
Attn: Angeli Lee and Amanda Font
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Sacramento, California 95899-7413

Submitted via email to CalAIMWaiver@dhcs.ca.gov and CalAIMECMILOS@dhcs.ca.gov.

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Mr. Lightbourne:

Thank you for the opportunity to comment on the California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 & 1915(b) Waivers. ALL IN Alameda County—a county-wide, multi-sector initiative focused on eliminating poverty—recognizes the importance of these waiver proposals to improve quality outcomes for Medi-Cal beneficiaries, manage member risk using whole person care and social determinants of health approaches, and reduce complexity and variation across the Medi-Cal managed care system.

ALL IN Alameda County's Food as Medicine initiative aims to prevent, treat, and reverse chronic diseases by addressing the social determinants of health, specifically food insecurity and social isolation. Our Food as Medicine program builds three important pieces of innovative infrastructure at our clinically integrated Federally Qualified Health Centers (FQHCs) sites:

1) Food Farmacy: Patients are prescribed food prescriptions by their healthcare team to treat, prevent, and reverse chronic disease, which can also reduce ER visits, hospitalizations, and medication usage. Food prescriptions are fulfilled by Dig Deep Farms, an urban farm utilizing regenerative practices, and include sixteen weeks of vegetables fulfilled at onsite "food farmacies" which are currently being delivered to patients' doorsteps during shelter-in-place.
2) Behavioral Pharmacy: Group Medical Visits bring together patients with various medical conditions to "move, nourish, connect, and be" through weekly visits that include physical activity, healthy food, social connection, and stress reduction. The behavioral group support, provided by Open Source Wellness, is currently delivered virtually and occurs weekly for four months.
3) Provider Training: Providers and healthcare staff receive state of the art trainings on how to use "food as medicine" to treat, prevent, and reverse chronic disease. Staff also receive training on how to implement universal food insecurity screening, how to optimize CalFresh referrals, and how to refer to the Food Farmacy and/or the Behavioral Pharmacy.

We applaud DHCS's decision to include medically supportive food and nutrition services in the revised CalAIM proposal under the In Lieu of Services (ILOS) Meals/Medically Tailored Meals option (page 217, bullet number

4). As a provider of medically supportive food and nutrition services, we plan to be an ILOS provider under this ILOS option and are working closely with our local, public Medi-Cal managed care plan, Alameda Alliance for Health, to prepare for implementation. We are concerned, however, that despite the inclusion of medically supportive food and nutrition services in the revised proposal, the exclusive reference to "meals" and/or "medically tailored meals" (MTM) in the CalAIM Section 1115 & 1915(b) Waivers' draft documents, applications, associated policy bills like SB 256 (Pan), as well as the FY22 Budget Health Trailer Bill Language currently pending in the State Legislature will preclude Medi-Cal Managed Care Plans from contracting with providers of medically supportive food and nutrition services like us as part of ILOS implementation.

As you work to refine this comprehensive proposal, ALL IN Alameda County respectfully offers the following feedback for the DHCS's consideration:

- Rename the ILOS category in the final CalAIM 1915(b) wavier "Medically-Supportive Food/Meals/Medically Tailored Meals" to clarify that the broad range of medically supportive food and nutrition services, including food prescriptions, behavioral coaching, and nutritional coaching, are authorized and reimbursable under this ILOS.
- Ensure all final ECM and ILOS documents, including the DHCS-MCP ECM and ILOS contract template, ECM and ILOS Standard Provider Terms and Conditions, CalAIM ECM and ILOS Model of Care Template, and ECM and ILOS Coding Guidance, consistently refer to medically supportive food and nutrition services as well as meals and medically tailored meals.
- Expand the "Meals/Medically Tailored Meals" ILOS Coding Options to allow for the billing of medical food, behavioral coaching, and nutritional coaching. Specifically, please consider including the following changes in the final ECM and ILOS Coding Options document:
    - Page 5: rename "Meals/Medically Tailored Meals Category" to be "Medically-Supportive Food/Meals/Medically Tailored Meals"
    - Page 5: In the Meals/Medically Tailored Meals category add a new code with HCPCS Description "Medical food; per service"
    - Page 5: In the Meals/Medically Tailored Meals category add "S5170: Home delivered meals, including preparation, per meal"
    - Duplicate code "H2014: Skills training and development; per 15 minutes" (page 4) in the Meals/Medically Tailored Meals category (page 5) in recognition of the available behavioral, cooking and/or nutrition education and coaching.
    - Duplicate code "H2016: Comprehensive community support services; per diem" (page 2) in the Meals/Medically Tailored Meals category (page 5) in recognition of the available administrative, application, and enrollment support to help with transportation to food and linkages to additional food supports.

We are encouraged to see the inclusion of more comprehensive food-based benefits in the CalAIM proposal and the focus on addressing the social determinants of health. Offering this broader range of medically-supportive food and nutrition services and interventions allows for increased patient autonomy and more culturally relevant support in addition to improved health outcomes. To secure these positive outcomes and to enable medically supportive food and nutrition service providers like ALL IN Alameda County's Food as Medicine program to successfully contract with our Medi-Cal managed care plans to provide these ILOS to eligible Medi-Cal managed care members, we strongly encourage the above changes as California moves from policy to implementation.

Thank you again for the opportunity to provide comment during the public stakeholder process. For questions or clarifications, please contact Vanessa Cedeno at vanessa.cedeno@acgov.org or (510) 272-6693. Thank you for your consideration of these comments.

Wilma Chan, SUPERVISOR, THIRD DISTRICT
ALAMEDA COUNTY BOARD OF SUPERVISORS

COMMITTEES:
Health, Chair
Unincorporated, Chair
Personnel & Legislative

Sincerely,

[redacted]

Supervisor Wilma Chan, Chair
ALL IN Steering Committee
Alameda County Board of Supervisors, District 3

Cc: Larissa Estes, ALL IN Alameda County
Dr. Steven Chen, ALL IN Alameda County
Amy Costa, County Administrator's Office
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May 6, 2021
Will Lightbourne, Director
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Sacramento, California 95899-7413

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

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Mr. Lightbourne:

Thank you for the opportunity to comment on the California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 & 1915(b) Waivers. Open Source Wellness – a 501(c)3 nonprofit based in Oakland focused on increasing health equity, recognizes the importance of these waiver proposals to improve quality outcomes for Medi-Cal beneficiaries, manage member risk using whole person care and social determinants of health approaches, and reduce complexity and variation across the Medi-Cal managed care system.

At Open Souce Wellness, we are a core partner in All-In Alameda County's Food as Medicine program, an initiative which aims to prevent, treat, and reverse chronic diseases by addressing the social determinants of health, specifically food insecurity and social isolation. The Food as Medicine program builds three important pieces of innovative infrastructure at our clinically integrated Federally Qualified Health Centers (FQHCs) sites:

1) Food Farmacy: Patients are prescribed food prescriptions by their healthcare team to treat, prevent, and reverse chronic disease, which can also reduce ER visits, hospitalizations, and medication usage. Food prescriptions are fulfilled by Dig Deep Farms, an urban farm utilizing regenerative practices, and include sixteen weeks of vegetables fulfilled at onsite "food farmacies" which are currently being delivered to patients' doorsteps during shelter-in-place.
2) Behavioral Pharmacy: Group Medical Visits bring together patients with various medical conditions to "move, nourish, connect, and be" through weekly visits that include physical activity, healthy food, social connection, and stress reduction. The behavioral group support, provided by Open Source Wellness, is currently delivered virtually and occurs weekly for four months.

3) Provider Training: Providers and healthcare staff receive state of the art trainings on how to use "food as medicine" to treat, prevent, and reverse chronic disease. Staff also receive training on how to implement universal food insecurity screening, how to optimize CalFresh referrals, and how to refer to the Food Farmacy and/or the Behavioral Pharmacy.

We applaud DHCS's decision to include medically supportive food and nutrition services in the revised CalAIM proposal under the In Lieu of Services (ILOS) Meals/Medically Tailored Meals option (page 217, bullet number 4). As a provider of nutrition services, we plan to be an ILOS provider under this ILOS option and are working closely with our local, public Medi-Cal managed care plan, Alameda Alliance for Health, to prepare for implementation. We are concerned, however, that despite the inclusion of medically supportive food and nutrition services in the revised CalAIM proposal, the exclusive reference to meals or medically tailored meals (MTM) in many of the CalAIM ILOS draft documents and associated CalAIM policy bills pending in the State Legislature as well as the FY22 Budget Health Trailer Bill Language will preclude Medi-Cal Managed Care Plans from contracting with providers medically supportive food and nutrition services as part of ILOS implementation.

As you work to refine this comprehensive proposal, Open Source Wellness respectfully offers the following feedback for the DHCS's consideration:

- Rename the ILOS category in the final CalAIM 1915(b) wavier "Medically-Supportive Food/Meals/Medically Tailored Meals" to clarify that the broad range of medically supportive food and nutrition services, including food prescriptions, behavioral coaching, and nutritional coaching, are authorized and reimbursable under this ILOS.
- Ensure all final ECM and ILOS documents, including the DHCS-MCP ECM and ILOS contract template, ECM and ILOS Standard Provider Terms and Conditions, CalAIM ECM and ILOS Model of Care Template, and ECM and ILOS Coding Guidance, consistently refer to medically supportive food as well as meals and medically tailored meals.
- Expand the "Medically-Supportive Food/Meals/Medically Tailored Meals" ILOS Coding Options to allow for the billing of medical food, behavioral coaching, and nutritional coaching. Specifically, please consider including the following changes in the final ECM and ILOS Coding Options document:
    - Page 5: rename "Meals/Medically Tailored Meals Category" to be "Medically-Supportive Food/Meals/Medically Tailored Meals"
    - Page 5: In the Medically-Supportive Food/Meals/Medically Tailored Meals category add a new code with HCPCS Description "Medical food; per service"
    - Page 5: In the Medically-Supportive Food/Meals/Medically Tailored Meals category add "S9470: Nutritional counseling, dietitian visit"
    - Page 5: In the Medically-Supportive Food/Meals/Medically Tailored Meals category add "S5170: Home delivered meals, including preparation, per meal"
    - Duplicate code "H2014: Skills training and development; per 15 minutes" (page 4) in the Medically-Supportive Food/Meals/Medically Tailored Meals category (page 5) in recognition of the available behavioral, cooking and/or nutrition education and coaching.

- Duplicate code “H2016: Comprehensive community support services; per diem” (page 2) in the Medically-Supportive Food/Meals/Medically Tailored Meals category (page 5) in recognition of the available administrative, application, and enrollment support to help with transportation to food and linkages to additional food supports.

We are encouraged to see the inclusion of more comprehensive food-based benefits in the CalAIM proposal. Offering this broader range of medically-supportive food and nutrition interventions allows for increased patient autonomy and more culturally relevant support in addition to improved health outcomes. To secure these positive outcomes and to enable medically supportive food and nutrition service providers like us to successfully contract with our Medi-Cal managed care plans to provide these ILOS to Medi-Cal managed care members, we strongly encourage the above changes as California moves from policy to implementation. Thank you again for the opportunity to provide comment during the public stakeholder process. For questions or clarifications, please contact Dr. Benjamin Emmert-Aronson at Ben@OpenSourceWellness.org or (330) 807-5754. Thank you for your consideration of these comments.

Sincerely,

Benjamin Emmert-Aronson, Ph.D.
Co-Founder, Director of Operations
Open Source Wellness

California Pan-Ethnic HEALTH NETWORK

May 6, 2021

Jacey Cooper, Chief Deputy Director Department of Health Care Services
1501 Capitol Avenue
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Sacramento, CA 95899-7413
Via email: Jacey.Cooper@dhcs.ca.gov

Re: CalAIM Section 1115 & 1915(b) Waiver

On behalf of the California Pan-Ethnic Health Network, we thank you for the opportunity to comment on the Administration's CalAIM Section 1115 waiver application & 1915(b) waiver overview. CPEHN is a statewide health advocacy organization dedicated to eliminating health disparities and achieving health equity for California's diverse communities of color. CPEHN was actively engaged in the Cal-AIM discussions as a member of the Population Health Management and NCQA Accreditation workgroups and has submitted numerous comment letters to the Department of Health Care Services on the comprehensive set of proposals in Cal-AIM including Behavioral Health integration, Enhanced Care Management and In Lieu of Services. We provide the following comments below:

Detailed comments:
Section 3.2 – DMC-ODS

Tribal Healers and Natural Helpers: We strongly support the state's proposal to seek expenditure authority to allow federal reimbursement for all DMC-ODS services that are provided by traditional healers and natural helpers. California has one of the largest American Indian populations in the United States, and is home to 723,225 individuals of American Indian sole and mixed-race descent (2010 U.S. Census). Existing systems of care do not appropriately serve the American Indian and Alaska Native (AI/AN) communities, who, as the Department of Health Care Services recently noted, experience death rates involving opioid pain medication higher than among any other racial or ethnic minority group. AI/ANs are eligible to receive health care services on or near Indian reservations and in urban Indian communities from the Indian Health Service (IHS), a federally funded payer of last resort. However California's delivery system is fragmented and IHS, chronically underfunded.

In fact, other state Medicaid programs have either approved or are in the process of seeking approval for reimbursement of services to traditional healers and natural helpers. Arizona is also asking CMS to reimburse for tribal healing practices as part of their recent waiver applications. Arizona has recently submitted their 1115 Waiver Renewal request to CMS and in it, they requested to implement the reimbursement for traditional healing services to facilities and clinics operated by Indian Health Services.[1] In New Mexico, the AI/AN population is eligible to receive payment for tribal healing practices offered by managed care organizations (MCOs) but this provision only applies to those who are

enrolled in their health plan and receive services through Centennial Care. The MCO's offer this benefit as a "Value-Added Service," and the benefit is paid to the member by the MCO.[2]

However, if included, California would have to be careful to avoid creating perverse incentives and outcomes caused by conforming services provided by traditional healers and natural helpers to the Medi-Cal framework. For this to be achievable, we urge the state to work directly with AI/AN communities to ensure the spirit and the integrity of the services provided by traditional healers and natural helpers are not altered to fit within the Western medical model framework that is historically lacking in its ability to provide culturally or linguistically responsive care. Moreover, we ask that the state (1) continue to work with AI/AN communities on what constitutes evidence-based practices for Indian Health Care Providers and (2) maintain the option for the Indian health care delivery system to scale up operation of the Indian Health Program Organized Delivery System (IHP-ODS), a pilot program that has been developed over the past few years. The IHP-ODS will provide critical benefits to the AI/AN community.

We also believe the state has an opportunity through Cal-AIM to seek additional amendments or waivers to integrate community-defined evidence practices (CDEPs) through Medi-Cal reform for all other racial and ethnic groups. Though traditional healing practices are distinct to the culture, history and teachings of Native American/Indigenous communities, we believe the State's efforts to seek federal reimbursement for all DMC-ODS services that are provided by traditional healers and natural helpers is a pioneering example of what California could do in the area of community-defined evidence practices for Tribes but also other racial and ethnic groups who have their own cultural practices that could be reimbursed through Medicaid. For example:

- The State could expand the scope of services available and see that CDEPs are reimbursed in Medi-Cal through a State Plan Amendment as an additional service under the Medi-Cal preventive services benefit.

- As part of the demonstration's evaluation, the State could assess whether CDEP programs can be adapted to Medicaid requirements without compromising the services' integrity.

- Alternatively, the State could invite or encourage Medi-Cal managed care plans to provide community-defined evidence practices (CDEPs) as a 'value-added" service beyond the standard benefits to adults to improve the overall health of plan enrollees.[3]

While the Office of Health Equity in the California Department of Public Health has invested significantly in these types of services through the California Reducing Disparities Project (CRDP) in order to build an evidence-based for their effectiveness, CDEPs have not yet been tested as a statewide benefit or service under the MHSA or the Medi-Cal program and it is our belief they would fit into the demonstration requirements.

Integration of DMC-ODS with Specialty Mental Health: While we strongly support continuation of the DMC-ODS program, many of the additional services that have become available in the past five years, and the state's proposal to seek reimbursement for DMC-ODS services that are provided by traditional healers and natural helpers, we have general concerns about the state's proposals to improve cultural and linguistic access in behavioral health for all other racial and ethnic groups.

We believe special consideration will need to be given to the State's administrative proposal to integrate cultural competence standards given that the state has for years failed to provide oversight of existing county cultural competence requirements.

Under existing regulation, county mental health plans are required to develop and submit cultural competency plans to the Department of Healthcare Services (DHCS) every three years. However, the state has not reviewed the findings of these plans for many years to ensure they meet basic requirements or reduce racial, ethnic, cultural, and linguistic behavioral health disparities, despite the requirement to do so.

Currently mental health plans are required to have a plan for culturally responsive care for specialty mental health services. DMC-ODS plans are also required to have a culturally responsive care plan. *Under Cal-AIM's integrated system, counties would have only one integrated plan for culturally responsive care instead of two, separate plans. We appreciate DHCS' recognition of the importance of integrating cultural competence standards between mental health and SUD in their Cal-AIM proposal but more detailed information is needed regarding the concrete steps the State will take to ensure a strong final set of updated standards.* We have provided the Department with detailed comments regarding their proposal to integrate cultural competence standards. As part of our comments, we recommended DHCS:

- Ensure Cultural Humility Plans are a vehicle for anti-racist work by explicitly incorporating Community Defined Evidence Practices (CDEPs) as requirement.
- Convene stakeholders, including consumer advocates, to, identify best practices at the local level, including best practices to reduce racial and ethnic disparities such as community-defined evidence practices
- Expand internal capacity to provide meaningful leadership anti-racism as part of their responsibilities to advance cultural and linguistic competence
- Expand internal capacity to evaluate the impact of behavioral health services on the health and wellbeing of communities of color.
- Clarify how the request of funds through BCP: 4260 duplicates or adds to the goals of the DHCS's Community Mental Health Equity Project.
- Clarify long-term plans to work with the Office of Health Equity in the California Department of Public Health (CDPH)

We also recommend the Department:

- Review these plans on a timeline determined by stakeholders
- Interact with these plans and measure county performance against the existing standards
- Ensure counties submit integrated CHPs to the Department of Health Care Services on a timeline determined by stakeholders
- Develop a statewide public report on the local experiences of local communities and recommendations for the replication of evidence-based and community-defined best practices implemented at the local level
- Publically report to the Legislature and key stakeholders, on an annual basis, updates on plans to integrate cultural competence standards between mental health and SUD.

Section 3.3 – Peer Support Specialist Services

Currently, counties provide some peer support services as a component of other services, such as Intensive Care Coordination services, or Wraparound. Legislation passed last year (SB 805) directed DHCS to allow counties to certify peer support specialists and pay for their services for individuals receiving specialty mental health or SUD services. We agree that peer support is an important component of mental health and substance use disorder services. We are concerned, however, that this service will not reach its full potential

in the way DHCS is currently proposing to implement it, based on counties opting in, through a combination of state plan, 1115, and 1915(b) authorities.

Instead, this service should be available to all of California's diverse Medi-Call consumers who need it throughout the state, in the state plan, and not contingent on whether the person's county of residence has opted in to providing the service. We understand that the authorizing legislation directs DHCS to "seek any federal waivers it deems necessary to establish a demonstration or pilot project for the provision of peer support services in counties that agree to participate and provide the necessary nonfederal share funding for the demonstration or pilot project." WIC 14045.19(a). However, allowing the service to be offered piecemeal based on particular counties' willingness to contribute the non-federal share is not an appropriate way to extend such important services to California's diverse Medi-Cal consumers. It simply is not good policy that a beneficiary's access to this important service should depend on the county in which they live. We recommend that DHCS work with CMS to obtain authority to add peer support services as a state plan service, available statewide to people with mental health conditions or SUDs when clinically appropriate. That is consistent with Medicaid's purpose of being a statewide program.

We also urge the state to provide more detail about their policies and procedures to address racial, ethnic and LGBTQ+ behavioral health disparities through the peer certification law. While we support implementation of the peer certification model, we are concerned that many Black, Indigenous, and People of Color (BIPOC) communities who could be candidates for peer certification might not in practice obtain peer certification due to the impact of structural racism on the behavioral health workforce. The cultural and linguistic expertise of BIPOC peers must be explicit incorporated and required as part of the peer certification standards, and requirements that are too onerous, unreasonable or discriminatory should be removed. The peer certification law in California should include a component on equity to ensure that practitioners implementing CDEPs can also act as certified peers, which would result in greater inclusivity and reaching more BIPOC and LGBTQ+ consumers.

Section 3.8 – Providing Access and Transforming Health (PATH) Supports:

CPEHN strongly supports DHCS' request for expenditure authority to broaden and scale collaboration arrangements between health plans, counties, public hospital systems and community-based organizations. An investment in data infrastructure and health information exchange is critical for moving beyond Whole Person Care pilots and addressing Social Determinants of Health (SDOH) statewide. A federal investment will also be helpful in the state's efforts to strengthen the effectiveness of Medi-Cal in addressing the significant gaps in health outcomes across beneficiaries based on race and ethnicity.

CPEHN works with community-based organizations including groups that were actively engaged in the state's WPC pilot projects and are interested in providing care coordination and services as part of Cal-AIMs Enhanced Care Management and In Lieu of Services (ILOS) components. A key finding and request from our CBO partners is for an investment in capacity building, infrastructure and IT systems in order to facilitate broad adoption of the new benefits and services under ECM and ILOS.

More specifically:

- An investment in capacity building will particularly allow smaller and mid-sized CBO providers unfamiliar with Medi-Cal Per-Member-Per-Month (PMPM) based contracting to build the infrastructure necessary to contract with health plans, counties, and public hospital systems as part of the new ECM and ILOS benefits and services.

- An investment in infrastructure and IT will allow for better integration of medical record-based electronic HIE with the emerging concept of electronic "community information exchanges" or CIEs such as those developed as part of the Whole Person Care Pilot projects. These CIEs may include data from housing, food, education and other sectors in order to better address the social determinants of health. There is some foundation for this data sharing and integration on the enrollment side with "no wrong door" enrollment channels. Careful thought however, must be given to the API (Application, Programming and Interface) of an HIE so that it is capable of extracting only the data that is necessary for non-medical providers such as Community Health Workers (CHW), to schedule asthma home visits (an In Lieu of Service under Cal-AIM) with a patient diagnosed with asthma.

Section 4. We appreciate DHCS' proposal to discontinue or transition initiatives under the Medi-Cal 2020 demonstration to either the consolidated 1915(b) waiver or Medi-Cal State Plan authority. We raise the following questions as the state discontinues or transitions these initiatives:

Section 4 - PRIME: In California, health disparities are well-documented and often linked to race, ethnicity, language, sexual orientation, and gender identity, among other socio-economic factors. Under the state's PRIME program which was part of the state's Medi-Cal 2020 demonstration, all of California's public health care systems were required to improve the collection and stratification of detailed Race, Ethnicity, and Language (REAL) data and to collect Sexual Orientation and Gender Identity (SOGI) data.

California has chosen to transition PRIME to Medi-Cal managed care. As a result, applicable performance measures for PRIME were transitioned to, and public hospitals may now qualify to receive managed care directed payments through, the Quality Incentive Program (QIP) for the reduction of racial and ethnic disparities. Moving forward plans will be required to stratify 6 measures by OMB Race & Ethnicity categories:

- Q-BCS: Breast Cancer Screening
- Q-CMS130: Colorectal Cancer Screening
- Q-CBP: Controlling High Blood Pressure
- Q-CMS147: Preventive Care and Screening: Influenza Immunization
- Q-CMS2: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- Q-CDC-H9: *Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%) (CDC-H9)

We would appreciate additional clarification as to why public hospitals are no longer being required to stratify quality data by sexual orientation and gender identity (SOGI). More broadly, as part of this transition, we would like to see a commitment from the state and all plans to comprehensive demographic data collection and reporting utilizing the federal 2015 Office of National Coordinator for HIT standards for electronic health records. This includes full disaggregation of race, ethnicity, language, sexual orientation, gender identity and disability status. The 2015 ONC standards also include data on behavioral and social risk factors including topics like ACES, social isolation, domestic violence, food and/or housing insecurity which have also been shown to impact health outcomes. Collection and reporting of this data will allow DHCS to set year-over-year targets for quality improvement and disparities reduction in Medi-Cal managed care and provide greater oversight of managed care plans under the new Population Health Management requirements in Cal-AIM.

Section 4 - Dental Transformation Initiative (DTI): We support DHCS' proposal to establish a new, statewide dental benefit for children, encompassing the services included in domains 1 through 3 of the DTI

as well as DHCS' proposal to offer new dental benefits statewide for children and certain adult enrollees, as well as expanded pay-for-performance initiatives including:

- A Caries Risk Assessment Bundle for young children
- Silver diamine fluoride for young children and for adults in specified high-risk and institutional populations, including those living in a skilled nursing facility/intermediate care facility or who are part of the Department of Developmental Services population
- Expanded pay-for-performance initiatives that a) reward increasing the use of preventive services and b) reward establishing/maintaining continuity of care through a dental home

DHCS' continued focus on achieving a 60 percent dental usage rate for Medi-Cal eligible children in alignment with CMS' Oral Health Initiative is laudable. However we remain concerned about the discontinuation of The Local Dental Pilot Projects (LDPPs) under Domain 4 of the DTI which connected Medi-Cal children ages 0 to 20 to dental care, established dental homes, and provided culturally and linguistically appropriate oral health education. Through their efforts, LDPPs were able to accomplish the following[i]:

- Increase access to dental care by providing robust, locally driven care coordination services led by trusted community partners.
- Bring dental care to community settings, including schools, WIC sites, and medical offices.
- Increase the number of dental providers willing to provide services to Medi-Cal children.
- Improve community oral health literacy and local capacity through strong community partnerships.
- Decrease the number of dental appointment no-shows.

Due to the successful outcomes of the Domain 4 LDPPs, we hope the Cal-AIM initiative will choose to support an integration of the LDPP model and expand the project to include adults. With evidence to prove their project's effectiveness, this is an initiative the Medi-Cal program can count on improving the oral health of Medi-Cal beneficiaries.

Expanded pay-for-performance: We support comments by the California Dental Association on the importance of extending pay-for-performance beyond an established list of benefits. We would like to see greater flexibility in an incentive program for providers to authorize dental services based on medical necessity instead of remaining stringently committed to an established list of benefits. Medi-Cal beneficiaries are a diverse population with equally diverse needs. If the goal is to improve the oral health of Medi-Cal beneficiaries, simply "integrating" with a managed care plan is not enough. Of the top five treatment codes, three of those codes are for extracting teeth for adult beneficiaries.[ii] It is unclear whether these teeth would have been saved with a posterior laboratory-processed crown (an uncovered benefit) or an implant (also an uncovered benefit). These patients' only recourse is to get partial dentures, which are known to be an imperfect solution to missing, necessary teeth or complete dentures, which are known to cause painful blisters if posterior implants (again, an uncovered benefit) are not there to stabilize the denture. For these reasons, we recommend the Department consider extending dental coverage to include medically necessary procedures versus strictly adhering to a limited menu of benefits.

Strengthening Care Coordination: Additionally, as with the PATH proposal, which will be targeted to scaling of the WPC pilot projects, we would like to see further federal and state investment in capacity building, infrastructure and IT to ensure better coordination of care across the continuum of medical, behavioral health, developmental, oral health and long-term services and supports, including tracking referrals and outcomes of referrals. I If DHCS' Oral Health proposal hopes to improve oral health outcomes for Medi-Cal beneficiaries, there must be adequate tracking and evaluation of establishment of dental homes

of dental homes. AB 2207, a bill signed by Governor Brown in 2016, requires Medi-Cal managed care plans to provide dental health screenings for eligible beneficiaries and refer them to appropriate Medi-Cal dental providers. Unfortunately there was no requirement for Medi-Cal managed care plans to track the screenings and referrals they were providing; therefore, there is no evidence that managed care plans have the experience and capacity to coordinate oral health care for Medi-Cal beneficiaries. If the Cal-AIM oral health proposal is to be successful, there must be an active supervising body consisting of diverse stakeholders to monitor health plans and keep them accountable.

Conclusion:
We appreciate DHCS' commitment to reforming and further innovating the state's Medi-Cal program through Cal-AIM. We look forward to partnering with the state to ensure it can meet the aspirational goals of this initiative and ensure California's most vulnerable communities can continue to access critical services and benefits at this time of greatest need. Please contact Cary Sanders/CPEHN at csanders@cpehn.org with any questions.

Sincerely,

[redacted]

Caroline B. Sanders

Senior Policy Director/CPEHN

NLSLA

Neighborhood Legal Services
of Los Angeles County

May 6, 2021

Via Email

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: Protecting essential legal services that address entrenched health disparities in California

Dear DHCS Director Lightbourne, Ms. Lee, and Ms. Font:

Neighborhood Legal Services of Los Angeles County (NLSLA) appreciates the opportunity to comment on behalf of the Medical Legal Community Partnership – Los Angeles legal collaborative regarding DHCS' CalAIM 1115 Demonstration & 1915(b) Waiver, California Advancing & Innovating Medi-Cal (CalAIM). We commend DHCS' approach to improving health holistically by addressing the social determinants of health and its commitment to building upon the successes and lessons learned from the Whole Person Care and Health Homes Program pilots. However, NLSLA is concerned about the lack of publicly available information on CalAIM's goals, metrics, and processes to dialogue with key stakeholders.

Medical Legal Community Partnership – Los Angeles (MLCP-LA) is a groundbreaking collaboration led by NLSLA, with the Legal Aid Foundation of Los Angeles (LAFLA), Mental Health Advocacy Services (MHAS), and Bet Tzedek Legal Services through the Los Angeles County Department of Health Service's Whole Person Care program. NLSLA provides free legal services to more than 100,000 people each year. Our staff of more than 160, including 80 attorneys, specialize in areas of the law that disproportionately impact low-income people, including affordable housing and eviction defense, access to public benefits, support for domestic violence survivors, access to healthcare, worker and consumer rights, and employment and training.

In particular, DHCS should clarify whether and how legal services are explicitly enumerated within the new CalAIM framework. If not, these services may disappear altogether—and the state would be abandoning its most effective tool for addressing devastating disparities in health.

In the last year, a global pandemic made clear what health advocates have known for decades: race and poverty have a direct—and devastating—impact on health. As COVID-19 made its way across the nation, it did not exact an equal toll; Black Americans have been 3.5 times as likely as white Americans to die from the disease. In California, Latinos between the ages of 35 to 49 have died of the virus at more than 5½ times the rate of white people the same age. And people living in poverty across the state have experienced far higher rates of infection, serious illness and death than those living in nearby wealthier areas.

What accounts for these disparities? A lack of economic opportunity, a dearth of affordable housing, widespread food insecurity, and a persistent lack of meaningful access to healthcare. These are the social determinants of health, and they are the reason the Los Angeles County Department of Health Services partnered with legal services organizations to improve health outcomes in low-income neighborhoods through Medical Legal Community Partnership–LA.

Launched in 2018, MLCP-LA's innovative partnership provides legal assistance to the most vulnerable patients, seeking sustainable improvements in the lives of individuals who suffer multiple social and economic stressors. In just 3 years, MLCP-LA has helped more than 4,000 people in Los Angeles County access critical benefits, avoid eviction, find safety and stability after domestic violence, eliminate medical debt, and address habitability issues like lead paint. MLCP-LA has removed barriers to stability, allowing patients to adhere to treatment plans and reduce emergency department use. This has alleviated patient stress and improved their health. MLCP-LA has supported the healthcare team to operate more efficiently and truly practice at the top of their license. MLCP-LA's successes have also been recognized through numerous accolades including the National Center for Medical Legal Partnership's inaugural Impact Award, a National Association of Counties Achievement Award, and two Los Angeles County program awards.

While NLSLA supports DHCS's commitment to ensuring Medi-Cal beneficiaries have access to supportive services beyond those already provided by the managed care plans, we are concerned that the shift to Medi-Cal managed care will inadvertently eliminate medical legal community partnerships. Ensuring patients have access to housing-related services, recuperative care, environmental accessibility adaptions and personal care services is important. But a complex structure of individual and systemic legal barriers undermines meaningful access to these services.

Medical Legal Community Partnership Services as Part of ILOS and ECM.

DHCS must clearly enumerate legal services as part of its ILOS and ECM strategies. A failure to do so may be seen as a strict prohibition against leveraging CalAIM funding for this essential resource. To ensure that patients benefit from ILOS, adhere to preventative treatment to avoid more costly modes of care, and ultimately improve health outcomes, DHCS should explicitly list medical legal community partnership services as part of the ILOS framework. Embedding trusted non-profit legal aid partners within the healthcare system will amplify the reach and success of DHCS's strategies.

For instance, offering housing supportive services is critical, but without addressing the many underlying causes of housing instability, these investments will fall short. Landlords may unlawfully discriminate against patients with fixed incomes, previous criminal justice system involvement, and prior evictions on their records. A lawyer could work alongside a managed care plan's housing navigator to ensure that the tenant's rights are protected throughout the application process, significantly improving successful long-term housing stability. The legal team can also work with tenants to expunge criminal records, prevent eviction, and ensure that eviction records are sealed, limiting adverse impacts in the future.

Attorneys also eliminate mold- or vermin-related housing issues for patients whose numerous emergency room and specialty care referrals were ultimately linked to these dangerous housing conditions, and secure reasonable accommodations for patients with disabilities. Even in cases where DHCS's proposed Environmental Accessibility Adaptations could finance the cost of modifications, legal advocacy is frequently needed to ensure that a landlord agrees to the changes—regardless of who pays for them.

Each time the legal team contacts a patient, they will benefit from a "legal checkup" to identify and address a broad spectrum of barriers impacting health. Patients presenting with housing instability would not have their longer-term financial stability addressed through DHCS' proposed ILOS or ECM structure. However, through the integrated legal service, a patient would be screened and connected to public benefits, would receive support in troubleshooting their EDD unemployment claim and could have barriers to employment, such as records of prior criminal justice system involvement, expunged. In another scenario, a survivor of intimate partner violence may benefit from advocacy obtaining a restraining order to ensure their immediate safety. Their child, also a Medi-Cal beneficiary, similarly needs extended advocacy to receive the special care they are entitled to at school to address what initially seems like a behavioral issue but is actually the manifestation of an untreated disability.

Integrating legal services within the CalAIM structure will ensure the collaboration, coordination, and accountability needed to address patient's complex needs in a way that simply providing an external legal referral cannot. In addition to serving patients directly, the legal teams offer individualized technical assistance to members of the healthcare and managed care staff to help them identify and case-manage patients' legal needs. The legal team also conducts system-wide trainings on key legal areas of interest such as housing rights, public charge concerns, and public benefits. The legal team will work with the managed care plans and broader health system to build upon existing screening tools to ensure that all members are screened for legal needs. The legal team will also remain accountable to the larger system by sharing data around patient referrals and outcomes, subject to rules protecting the attorney-client relationship.

Medical Legal Community Partnership Services as Part of GPP.

NLSLA supports DHCS' commitment to GPP because the program financially incentivizes medical providers to better engage with particularly vulnerable persons: those who are uninsured or on restricted-scope Medi-Cal. These persons typically either do not have the requisite immigration status to qualify for health insurance, or these persons might be navigating various financial and logistical challenges that lead to lapse in health insurance coverage (especially for those who lack regular access to telephone or internet services).

As DHCS is already aware, the Rand Corporation's 2019 "Evaluation of California's Global Payment Program" reported that GPP has consistently served 525,000+ persons on an annual basis throughout California through a variety of clinic care services made available to patients. This report also found that "provid[ing] a diverse mix of non-traditional complementary and technology-based services supports the notion that the GPP promoted allocating resources wisely." NLSLA believes this is particularly compelling information because GPP's reported statewide benefits are consistent with the experiences of localized medical legal community partnership efforts. For example, in Los Angeles County, the MLCP-LA collaborative's advocacy for uninsured and undocumented patients in Los Angeles County have profound economic and health-related benefits for marginalized communities.

Accordingly, NLSLA also proposes that DHCS explicitly consider how legal services could be incorporated within the GPP framework, especially if DHCS ultimately determines that other funding sources (like ILOS) are unavailable.

Safeguards Should be Implemented to Ensure that that Medical Legal Community Partnership Services are Widely Available and Without Restraint.

Medical legal community partnership services should be available to all Medi-Cal beneficiaries who need it throughout the state, without being contingent on the randomness of whether a person's county of residence opted in to providing the service. For example, Los Angeles County Department of Health Services (DHS) engages the MLCP-LA program to offer free legal help to every patient in the DHS healthcare delivery system. However, patients who live in other counties do not receive these life-changing services.

If DHCS cannot obtain the necessary legislative or regulatory authority to include legal services as part of the state plan, NLSLA proposes that legal services, (regardless of whether through ILOS or other means) be offered as a county option, rather than as an individual plan option. Despite seeing the value in offering essential legal services to members, health plans may consider other financial or liability interests in declining to contract with legal services providers to offer these services. Consequently, until DHCS determines that networks are adequate enough such that all plans are required to provide all ILOS services, the provision of legal services should remain a county option.

Alternatively, plans opting to incorporate any ECM or ILOS services should also be required to contract with legal services providers and offer this benefit to members. ECM or ILOS without a legal services component will offer an incomplete and suboptimal service to patients. Whether it be housing or any of the other enumerated services, unless a patient's underlying complex legal issues are addressed, the full impact of the service will not be achieved.

A fee-for-service option should be available for patients to receive these essential legal services where health plans or counties decline to provide them. Legal services providers can contract directly with DHCS to offer this essential benefit even in instances where plans opt to not offer any ILOS. Even absent the broader ECM or ILOS structure, legal services can meet DHCS's goals by preserving housing, promoting income and food stability, and eliminating other barriers driving patients to seek more expensive emergency and inpatient services.

Finally, DHCS must consider how GPP funding could bridge any gaps in CalAIM's ability to fund legal services for populations focused on Medi-Cal eligibility (given the large number of uninsured and undocumented persons who are living in California).

Regardless of the structure through which legal help is offered, in order to ensure that patients are addressed as a whole person and that the entirety of their legal issues can be addressed, it is imperative that the scope or approach to legal services not be constrained. Legal services through a medical legal community partnership are an effective and fiscally sound way to address DHCS's goals of identifying and managing member risk through a whole person care approach.

On behalf of Neighborhood Legal Services of Los Angeles County, Legal Aid Foundation of Los Angeles, Mental Health Advocacy Services, and Bet Tzedek Legal Services, we thank you for considering these recommendations. We look forward to working with DHCS to ensure the continued access to these essential services. Please contact Gerson Sorto at (818) 834-7536 or at gersonsorto@nlsla.org if you have any questions or require additional information concerning the above.

Sincerely,

[redacted]

Gerson Sorto
Supervising Attorney
Neighborhood Legal Services
of Los Angeles County

[redacted]

Elisa Carino
Staff Attorney
Neighborhood Legal Services
of Los Angeles County

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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:

Shingletown Medical Center (SMC) 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, SMC 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.

Shingletown Medical Center is an FQHC that cares for Medi-Cal and uninsured patients in Shingletown/Shasta County. Our mission is to provide comprehensive, high-quality health care services to those who need it most. The majority of our Medi-Cal patients are among the 11 million beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through two contract pharmacies.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows SMC 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, Shingletown Medical Center annually saves an estimated $40,000 through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow SMC 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, Shingletown Medical Center patients have better access to more services, just as Congress intended in enacting the 340B program.[1]

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

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

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

In conclusion, Shingletown Medical Center urges DHCS not to include implementation of Medi-Cal Rx as part of CalAIM, to fully analyze the impact it will have on the Medi-Cal program, and to provide a transparent process for stakeholders to provide meaningful input and alternatives for DHCS' consideration. Doing so will enable SMC 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. Shingletown Medical Center looks forward to working with DHCS on this critical issue that affects over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

Tami Fraser
Chief Executive Officer
Shingletown Medical Center

[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

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

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

Dear Director Lightbourne,

Shingletown Medical Center appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

Shingletown Medical Center 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 vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

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

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

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

Shingletown Medical Center 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, Shingletown Medical Center 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 me at tfraser@shingletownmedcenter.org or (530) 474-3390.

Sincerely,

[redacted]

Tami Fraser
Chief Executive Officer
Shingletown Medical Center

May 6, 2021

CalAIM Team
Will Lightbourne, Director, Department of Health Care Services
Jacey Cooper, Chief Deputy Director & State Medicaid Director
California Department of Health Care Services
1500 Capitol Mall
Sacramento, CA 95814
CalAIMWaiver@dhcs.ca.gov

Re: Comments on CalAIM 1115 Medicaid Renewal Application & 1915(b) Application

Dear Mr. Lightbourne, Ms. Cooper, and CalAIM Team—

On behalf of the above organizations, who work to promote the health and stability of Californians experiencing homelessness, we are writing to offer comments and recommendations on the California Advancing & Innovating in Medi-Cal (CalAIM) proposed applications for 1115 Medicaid Renewal and for the 1915(b) Waiver, released in April 2021.

Background on Needs of Beneficiaries Experiencing Homelessness

In a January 2021 State Health Official letter, the Centers for Medicare and Medicaid Services (CMS) acknowledged a growing body of evidence that shows social determinants of health, including

homelessness, lead to poor health outcomes.[1] People experiencing homelessness incur Medi-Cal costs that are two to three times the costs of other beneficiaries, with the top 10% of homeless beneficiaries incurring costs in excess of $75,000 per year.[2] Despite this high level of healthcare spending, people experiencing homelessness die, on average, 25-30 years younger than housed people with similar health conditions.[3] Even before COVID-19, Californians died on the streets every day from causes directly attributable to homelessness.[4]

The CalAIM proposal rightfully acknowledges that housing support services reduce Medicaid costs. Indeed, 30+ years of evidence and experience prove housing support services that use evidence-based approaches help people access housing and maintain housing stability. In turn, housing stability dramatically improves health outcomes and avoids and reduces per-beneficiary Medicaid costs.[5]

Because **housing support services are essential** for beneficiaries experiencing homelessness to access meaningful care, as acknowledged in the CalAIM proposal, **these services should be funded through a benefit:**

- **Housing navigation and tenancy transition services** to meet beneficiaries where they are, form trusting relationships, engage beneficiaries to want to participate in services, connect beneficiaries to local homeless systems, assess beneficiaries' preferences for and barriers to living in the community, assist beneficiaries with housing search and completion of housing applications, connect beneficiaries to landlords willing to rent to people with subsidies, help beneficiaries review and sign leases, ensure housing is safe and ready for move-in, and assist beneficiaries in arranging for move-in through moving and transportation expenses**.**
- **Housing deposits** to help people move into and stabilize in housing, including one-time costs of housing move-in, like security deposits, payment of utility arrears, and essential furnishings.
- **For those with significant barriers to housing stability, tenancy sustaining services,** to help beneficiaries stabilize and maintain housing stability, connect people with community-based resources, plan for housing support, identify and intervene in behaviors that may jeopardize housing stability, educate and train in landlord-tenant responsibilities and relationships, provide non-medical transportation, provide evidence-based employment services, and offer individualized case management and care coordination.[6]

Housing support services relate to each other: housing navigation leads to needing move-in assistance which, for certain beneficiaries, leads to needing tenancy support services. If any one of these services is

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[1]Centers for Medicare & Medicaid Services. State Health Official Letter, #21-001. *Opportunities in Medicaid & CHIP to Address Social Determinants of Health (SDOH).* Jan. 7, 2021.

[2]*See, for example,* Katherine A. Koh, Melanie Racine, Jessie M. Gaeta, et. al. "Health Care Spending And Use Among People Experiencing Unstable Housing in the Era of Accountable Care Organizations." *Health Affairs.* Vol. 39, No. 2. Feb. 2020. Health Care Spending And Use Among People Experiencing Unstable Housing In The Era Of Accountable Care Organizations | Health Affairs; Joel C. Cantor, Sujoy Chakravatry, Jose Nova, et. al. "Medicaid Utilization and Spending Among Homeless Adults in New Jersey: Implications for a Medicaid-Funded Tenancy Support Services." *Milibank Q.* Vol. 98, No. 1. Mar. 2020; Daniel Flaming, Patrick Burns, Gerald Sumner. "Getting Home: Outcomes from Housing High Cost Homeless Hospital Patients." *Economic Roundtable*. Sept. 2013.Economic Roundtable | Getting Home (economicrt.org).

[3]Carol Caton Et Al., Nati'l Symposium On Homelessness Research, Characteristics And Interventions For People Who Experience Long-Term Homelessness (2007), *available at* http://aspe.hhs.gov/hsp/homelessness/symposium07/caton/index.htm; Margot Kushel, M.D., Associate Professor of Medicine in Residence, UC San Francisco, Testimony to Legislative Forum on Homelessness in California, Jul. 18, 2007, *available at* http://www.housingca.org/resources/Joint_Ctte_on_Homelessness_Testimony_Kushel.pdf.

[4] Harriet Blair Rowan. "Homeless Deaths Surge in Los Angeles County." *California Healthline*. Apr. 2019.

[5]*See, for example*, Maria Raven, K. Doran. "An Intervention to Improve Care & Reduce Costs for High-Risk Patients with Frequent Hospital Admissions: A Pilot Study." *BioMed Central Health Services Research.* 2011; Mary Larimer, Daniel Malone. "Health Care & Public Service Use & Costs Before & After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems." *Journal of American Medical Association.* 2009; Laura Sandowski, Romina Kee. "Effect of Housing & Case Management on Emergency Room Visits and Hospitalizations Among Chronically Ill Homeless Adults." *Journal of American Medical Association* (2009); Karen Linkins, Jennifer Brya. *Frequent User of Health Services Initiative, Final Evaluation* (2008).

[6]Identified as eligible Medicaid-funded services in the State Health Official Letter, #21-001.

unavailable, the beneficiary can lose their housing and their health can decompensate. Keeping a beneficiary stably housed is less expensive than for that beneficiary to cycle in and out of homelessness.

Given this background, we offer the following recommendations to ensure beneficiaries experiencing homelessness can access housing support services in a meaningful way:

Create a Benefit to Fund Housing Support Services

We again urge DHCS to include a benefit to fund housing support services as part of a stated long-term goal under the CalAIM proposal. We agree with the goals of ECM to provide, "a whole-person, interdisciplinary approach to care that addresses the clinical and non-clinical needs of high-cost and/or high need Members" through providers who offer a "community-based, interdisciplinary, high-touch, and person-centered" approach. However, ECM, as proposed, will not address the whole person care needs of people experiencing homelessness because ECM will only fund care coordination. Care coordination for beneficiaries who are experiencing homelessness is unsuccessful in reducing costs or improving health outcomes. Indeed, studies show emergency department visits, inpatient days, and costs among beneficiaries experiencing homelessness continue to increase so long as a beneficiary remains homeless, even when they are receiving intensive, quality care coordination services.[7] Similarly, ILOS, as optional services that can be added or ended, are unlikely to result in any ongoing, scalable funding for housing support services. While both the Whole Person Care and Health Homes Programs offered funding for housing support services as part of an integrated package of services, designed to address the whole needs of each beneficiary, CalAIM instead proposes to offer the most important component of these programs for people experiencing homelessness—housing support services—as optional, and allow plans to design or limit them as they see fit.

Because study after study shows housing support services are highly effective in reducing Medicaid costs and health outcomes for people experiencing homelessness,[8] we recommend seeking federal approval for a benefit specifically for people experiencing homelessness and for formerly homeless supportive housing residents. A benefit should fund housing support services on a supplemental per person, per month rate, through providers with experience successfully housing people experiencing homelessness through evidence-based approaches. These services incorporate care coordination/management, while ensuring beneficiaries obtain the housing supports they need to access and maintain health stability. Beneficiaries experiencing homelessness have highly unique needs, and a benefit should address their specific challenges.

The recent CMS State Health Officer letter encourages states to use existing Medicaid authorities to fund high-quality services that are sufficient in amount, duration and scope to reasonably achieve their purpose. The letter describes ways in which states can fund services to help beneficiaries secure housing, housing and

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[7]Karen Linkins, Jennifer Brya. *Frequent User of Health Services Initiative, Final Evaluation* (2008); E. Latimer, D. Rabouin, et. al. "Cost Effectiveness of Housing First Intervention with Intensive Case Management Compared with Treatment as Usual for Homeless Adults with Mental Illness." *J. Amer. Medical Assoc.* Aug. 21, 2019; M. Larimer, D. Malone, et. al. "Health Care & Public Service Use & Costs Before & After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems." *J. Amer. Medical Assoc.* Apr. 1, 2009.

[8] Joel C. Cantor, Sujoy Chakravatry, Jose Nova, et. al. "Medicaid Utilization and Spending Among Homeless Adults in New Jersey: Implications for a Medicaid-Funded Tenancy Support Services." *Milibank Q.* Vol. 98, No. 1. Mar. 2020; E. Latimer, D. Rabouin, et. al. "Cost Effectiveness of Housing First Intervention with Intensive Case Management Compared with Treatment as Usual for Homeless Adults with Mental Illness." *J. Amer. Medical Assoc.* Aug. 21, 2019; Sungwoo Lim, Qi Gao, Tejinder P. Singh, et. al. "What Do Medicaid Spending Patterns Reveal About the Impact of Supportive Housing." *Housing Matters, Urban Institute*. 2018; M. Larimer, D. Malone, et. al. "Health Care & Public Service Use & Costs Before & After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems." *J. Amer. Medical Assoc.* Apr. 1, 2009; Karen Linkins, Jennifer Brya. *Frequent User of Health Services Initiative, Final Evaluation* (2008).

tenancy supports, non-medical transportation, and individualized supported employment services, which could all be offered in a single benefit. The letter identifies potential Medicaid authorities to fund these services, including waivers under Section 1905(a)(13), 1915(b)(3), or Section 1915(c), or a Section 1915(i) State Plan Amendment by adding housing-related services through alternative payment models, including a supplemental rate.[9] Indeed, at least 15 states, including a number of rural states, are now funding or planning on funding housing support services through a benefit offered to all experiencing homelessness, administered through a set of standardized guidelines. These states are using either a 1915(i) State Plan Amendment or 1115 Waiver. Congress is now considering legislation to to strengthen federal support for home and community-based services.

In a recent letter, DHCS staff indicated DHCS intends to seek federal approval for a benefit to fund housing support services once staff believe enough statewide capacity exists to offer these services. Further, DHCS staff expects managed care plans to have sufficient capacity to have a robust network of service providers able to offer services as a benefit *by 2024*.[10] **We therefore recommend DHCS establish a date certain of January 2024, by which DHCS will seek federal approval of a housing support services benefit as part of the CalAIM proposal.** Promoting a date certain will entice providers to develop their capacity to be able to receive reimbursement from managed care plans, and for managed care plans to build capacity toward an adequate network statewide, and is consistent with other provisions in CalAIM. DHCS could do an assessment of network capacity before implementing the benefit fully. The benefit would also allow people experiencing homelessness to receive care coordination from providers with cultural competency to address their care coordination needs.

A statewide benefit with a supplemental per person, per month rate as part of CalAIM would—

- Allow the state to standardize the services interventions based on evidence-based housing support services practices,
- Avoid adverse selection by creating a mandated benefit available to all beneficiaries in a single county,
- Avoid problems of churn in connecting beneficiaries to services they need, as a single plan would not determine whether a beneficiary can access services,
- Attract providers with successful experience helping people get and stay housed, with certainty that the benefit will be available and remain in place, so long as a beneficiary needs the services,
- "Scale up" supportive housing and other evidence-based homelessness interventions, consistent with the Administration's priorities to reduce homelessness and foster Homekey success,
- Tap into and further develop the capacity of managed care plans and providers,
- Help managed care plans identify people experiencing homelessness and access housing for members experiencing homelessness, and
- Provide for future opportunities to coordinate Medi-Cal funding for services with housing made available through homeless systems. The state, for example, could align eligibility for the benefit and eligibility for state-funded housing projects, and provide plans with assistance aligning services and county-, state-, or federally-funded housing subsidies through a benefit.

In implementing a benefit, we recommend the following design:

- Offering a separate, specialized benefit that meets the unique needs of beneficiaries experiencing homelessness through a per member, per month supplemental payment as part of CalAIM,

[9] State Health Official Letter #21-001.
[10] Jacey Cooper. "CalAIM Role in Addressing Homelessness." *Letter to Sharon Rapport & Linda Nguy.* April 9, 2021.

- Requiring plans to contract with counties, homeless continuums of care, and community-based organizations with deep experience and expertise ***in providing these services*** to, rather than just experience serving, people experiencing homelessness. We saw in the Health Homes Program that even community clinics with deep health care expertise serving people experiencing homelessness often struggled to provide housing navigation and tenancy transition and support services. These providers often had difficulties even finding and enrolling these beneficiaries into the program.[11]

Strengthening PATH (Providing Access and Transforming Health Supports) Through State Funding to Community-Based Providers with Cultural Competency

We support the proposal for Providing Access and Transforming Health Supports (PATH) training and technical assistance to develop ECM and ILOS provider networks. In fact, we believe this support could help the state build an adequate network of providers for a housing support services benefit.

Through the WPC pilots, counties have successfully partnered with non-traditional providers who do not bill Medi-Cal but have experience working with populations targeted for ECM and ILOS. These partnerships include community-based organizations that provide housing support services. We are concerned that the shift in delivery systems to Medi-Cal managed care plans may result in many of these partnerships discontinuing. Rather than terminating these contracts and losing the valuable lessons learned from WPC pilots, we agree with the intent of supporting these providers in their move to contracting with Medi-Cal managed care plans.

Even if the federal government approves PATH, we urge DHCS to consider state funding to build a provider network of homeless service providers who can receive reimbursement from Medi-Cal, regardless of federal approval. Because the Department has indicated housing support services is the ILOS that is closest to being a statewide benefit, we encourage specific funding be set aside for homeless service providers with the cultural competency to provide evidence-based housing support services. While technical assistance and capacity building funding under PATH will help our communities continue to build more effective systems, homeless service providers need funding to create infrastructures that will enable them to meet the requirements of a future benefit. We therefore recommend a state grant go directly to community-based providers to help them build the staffing and infrastructure needed to bill, report, and contract with Medi-Cal plans or subcontract with existing Medi-Cal contractors.

Change the ECM/ILOS Requirements Documents

Regardless of whether DHCS incorporates a benefit for beneficiaries experiencing homelessness, we recommend the following changes to ECM and ILOS (explained in further detail below):

- Clarifying the ECM benefit as a benefit that does not end when a beneficiary's condition improves, but increases or decreases in intensity, according to the beneficiary's recovery.
- Eliminating administrative burdens the federal government does not require, such as billing or reporting encounters in 15-minute increments.

[11] Nadereh Pourat, Xiao Chen, Brenna O'Masta, et. al. "First Interim Evaluation of California's Health Homes Program (HHP)." *UCLA Center for Health Policy Research*. Sept. 2020.

- Changing eligibility to focus on beneficiaries experiencing homelessness, rather than risk of homelessness, and beneficiaries who previously experienced homelessness but are now residing in supportive housing.
- Requiring plans to contract with counties or providers that subcontract with homeless continuums of care (CoCs) and community-based organizations with demonstrated success in housing beneficiaries experiencing homelessness through housing support services. The Health Homes Program demonstrated the challenges of providing services through traditional providers who may have expertise in offering medical treatment to people experiencing homelessness, but do not have expertise in successfully providing housing support services.
- Recommending staffing ratios of 20 beneficiaries per staff person, on average, for those beneficiaries experiencing chronic homelessness or beneficiaries experiencing homelessness with co- or tri-morbidities, or providing other means of ensuring beneficiaries are receiving the intensity of services they need to get and stay healthy.
- Allowing for peer-provided services, as identified in the CMS State Health Official Letter, even if that peer has a history of arrest or conviction (given the link between homelessness and past incarceration).
- Providing an "outreach rate" for the first three months of service provision, to offer incentives for providers to find and engage people often distrustful of the health care system.
- Requiring managed care plans and providers serving beneficiaries experiencing homelessness establish a homeless coordinator to foster partnership with homeless continuums of care, which are best equipped to refer members to housing, similar to a standard New Hampshire enacted in their plan contracts.[12]

Clarifying Language Around ECM as a Flexible Benefit

The populations eligible for ECM have, by definition, complex conditions and long-term needs. The provider standards include language that would transfer beneficiaries off of ECM services as soon as an assessment indicates a beneficiary can "graduate" to less intensive services. Yet, recovery is not a straight line, but a circle; beneficiaries with chronic behavioral health or medical conditions cycle between recovery and crisis or decompensating health. We recommend framing the ECM benefit as not a benefit that people transition off of or onto, but a benefit that is flexible enough for beneficiaries to have seamless increases and decreases of intensity of services, with regular assessments of their needs. Some beneficiaries may eventually no longer need ECM, but ECM should be framed as a long-term benefit that offers whatever level of intensity beneficiaries require. As an example, the Los Angeles County Department of Health Services' Housing for Health program offers high and low acuity models, with easy movement between these models to adjust to the participant's needs at any given time.

Better Defining Eligibility for Beneficiaries Experiencing Homelessness

Any benefit intended to offer services to people experiencing homelessness should focus eligibility on—

- Beneficiaries experiencing homelessness, as defined by HUD,
- Beneficiaries being discharged from an institutional setting, who were experiencing homelessness upon institutional admission and therefore "at risk" of being discharged into homelessness, and
- Beneficiaries who were formerly homeless and are now residing in supportive housing.

[12]New Hampshire Medicaid Managed Care Services Contract, Section 4.11.5.7.2. Feb. 2019.

"At risk of homelessness" is difficult to define. Research indicates even programs singularly focused on serving people experiencing homelessness have difficulties successfully identifying people truly at risk.[13] Managed care plans have varying definitions of "at risk" in the Health Homes Program (or do not define at all), which often leaves providers to define "at risk" in a haphazard and inconsistent way. A provider can find any beneficiary experiencing poverty, struggling to pay rent, as at risk, even though over 1.5 million Californians fit this description. Further, experience with national homeless programs shows homeless programs targeting "at risk" populations tend to prioritize or serve more frequently people who are housed over people experiencing homelessness, because people who are housed are easier to locate and serve,[14] even though data shows people experiencing literal homelessness drive high health care costs, and are able to reduce their Medicaid expenditures once housed. Finally, people experiencing homelessness have very different needs than households at risk of homelessness. For these reasons, and particularly because the state's proposed investment in CalAIM is limited, we propose ensuring people with the greatest vulnerabilities get served by limiting eligibility to people experiencing homelessness. Alternatively, we recommend defining "at risk" as those who are residing in an institutional setting, or being discharged from that setting, and who were homeless when admitted.

Eligibility for ECM and ILOS housing services is at the same time too narrow because it does not allow for continuous eligibility for beneficiaries once they are no longer homeless. Even though ECM and ILOS tenancy support services most logically would be offered to beneficiaries recently housed, they are currently not eligible for services under the definitions included in the requirements documents. People in recovery from chronic conditions, including homelessness, require ongoing services. Services intended to end after a brief period once someone is no longer homeless will result in returns to homelessness and potentially other dire consequences. For these reasons, we recommend allowing residents of supportive housing to continue to receive these services, or to include language that allows beneficiaries who get housed to remain eligible for services until the beneficiary's health conditions fully stabilize, at least two years after move-in.

Plans Should Contract with Providers Offering Housing Support Services, Including Non-Medicaid Providers

The State Health Officer letter acknowledged that non-traditional providers that do not have existing Medicaid contracts, but specialize in serving people experiencing homelessness, may achieve better outcomes than traditional Medicaid providers.[15] Indeed, many Health Homes Program providers struggled to offer housing navigation and tenancy support services to people experiencing homelessness, or even find these beneficiaries, despite their deep expertise in treating this population in most cases. To achieve success, community-based organizations that are "homeless service" and "housing providers," Healthcare for the Homeless providers, and health centers with strong, longstanding success in outreaching to and serving people experiencing homelessness, are able to achieve better outcomes than traditional Medicaid providers who hire staff to fill a housing navigator role for the purpose of ECM or ILOS. A provider should not only have experience serving beneficiaries experiencing homelessness, but should also have *experience providing housing support services and achieving successful outcomes in getting people and keeping people stably housed*. In the

[13] *See, for example,* Till Von Wachter, Marianne Bertrand, Harold Pollack, Janey Rountree. "Predicting & Preventing Homelessness in Los Angeles." California Policy Lab. Sept. 2019.

[14] A U.S. Department of Housing & Urban Development program designed to provide services and housing subsidies to people at risk of and experiencing homelessness resulted in over 70% of the funds being used to serve the "at risk" population. For this reason, HUD modified the program to remove the availability of prevention services and subsidies to those at risk, and limited the program to people experiencing homelessness. Office of Special Needs Assistance Programs, Office of Community Planning & Development, HUD. *Homelessness Prevention & Rapid Re-Housing Program (HPRP): Year 3 & Final Program Summary.* Jun. 2016.

[15] State Health Official Letter #21-001.

alternative, plans should contract with counties or providers who will subcontract with community-based organizations that successfully provide housing support services.

The recent UCLA interim evaluation of the Health Homes Program showed over 84% of Community-Based Care Management Entities primarily offered medical models of care coordination, hiring in-house staff to provide housing navigation. As a result, only an estimated 3.5% of HHP beneficiaries among Group 1 and 2 plans ever experienced homelessness and only 38% of *this* small percentage received any housing support services.[16] The managed care plan with the highest percentage of enrolling HHP beneficiaries experiencing homelessness was the Inland Empire Health Plan, which had a direct contractual relationship with homeless service providers, Brilliant Corners and Step Up on Second, to identify beneficiaries experiencing homelessness and provide housing navigation and tenancy support services.[17]

Administrative Requirements

The administrative requirements articulated in the provider standards will dissuade many homeless service and housing providers from enrolling as ECM or ILOS providers. Community-based organizations are typically not equipped to dedicate more dollars on administrative requirements than on service delivery. In fact, funding for these providers often "starves" these programs of administrative resources. For managed care plans to develop and grow their capacity in serving this population, we recommend the following:

- *Remove billing & reporting requirements in 15-minute increments*: Encounter reporting and billing in 15-minute increments impedes a person-centered model. These reporting requirements not only interfere with the relationship between clients and providers, in having to document every 15 minutes, they are highly burdensome and will prevent many providers from accessing ILOS or ECM. This billing and reporting requirement also serves little purpose. A 15-minute reporting requirement in the Health Homes Program has failed to result in frequent in-person units of service (the average number of units of service was less than 2 per month).[18] We recommend offering a supplemental per person, per month rate instead, and requiring monthly reporting on the types of services and the total number of contacts with beneficiaries. Simpler reporting and billing will allow managed care plans to foster capacity.
- *Remove requirements based on a medical model of care:* As ECM and ILOS are intended to offer services to beneficiaries with social determinants of health and medical models have typically not served these beneficiaries well, we recommend removing requirements that are hold-overs from medical models:
    - *Remove requirement for providers to create and staff a telephone line available 24 hours per day, 7 days a week*: We recommend instead requiring providers to offer beneficiaries the ability to contact their case manager or care coordinator directly. For providers serving beneficiaries experiencing homelessness, staffing a telephone line 24/7 would add significant administrative cost and little benefit for beneficiaries who are far more likely to reach out to a case manager they know than a staffed phone line.
    - *Remove distinctions in payment between traditional Medicaid providers and other providers:* We recommend requiring managed care plans to provide payment within 30 days for providers that are not individual or group practices or health facilities, the same as payment deadlines for traditional medical providers, as providers without large medical practices may have less capacity, not greater, to wait 90 days for payment.

[16]Nadereh Pourat, Xiao Chen, Brenna O'Masta, et. al. "First Interim Evaluation of California's Health Homes Program (HHP)." *UCLA Center for Health Policy Research*. Sept. 2020.
[17]First Interim Evaluation of California's Health Homes Program (HHP).
[18] *Ibid*.

- *Modify requirements for outreaching to beneficiaries:* The ILOS Provider Standards require providers to outreach to members within 24 hours of assignment, yet acknowledge that beneficiaries experiencing homelessness may be difficult to find. The 24-hour outreach requirement will spur many providers to send a letter to "check the box" of beginning outreach, which will fail to engage beneficiaries experiencing homelessness. Instead, we recommend clarifying that providers must begin in-person outreach *efforts* within 24 hours or attempting to locate "difficult to reach" beneficiaries.
- *Remove requirements for providers to enroll as Medicaid providers:* The Provider Standard Terms and Conditions requires providers to become enrolled Medicaid providers where an enrollment pathway exists, or to undergo managed care plan enrollment and background checks. We instead recommend following federal law that allows for contracting with non-traditional providers in serving beneficiaries experiencing homelessness.[19]

Staffing Ratios & In-Person Services

While DHCS clearly intends to fund primarily in-person services through ECM and ILOS, providers were more than two times more likely to engage beneficiaries telephonically than in-person in the Health Homes Program.[20] For these reasons, we recommend identifying ways to connect with beneficiaries suitable for the beneficiaries' unique needs, and promoting staffing ratios that work for the beneficiaries being served. For beneficiaries experiencing homelessness and co- or tri-morbidities, or chronic homelessness, we recommend staffing ratios of 1:20 to ensure the intensive, in-person nature of the services DHCS is expecting under ECM and ILOS, and clarifying the specific circumstances in which services may be offered telephonically. The standard DHCS identifies of "sufficient experience and expertise" is broad and undefined, and therefore is not meaningful for managed care plans or providers.

Outreach Services

Managed care plans typically struggle to identify members experiencing homelessness and traditional providers often struggle to enroll beneficiaries experiencing homelessness. One reason for the latter is often because providers do not begin receiving payment unless and until the beneficiary consents to participate in the program. Beneficiaries experiencing homelessness are less likely to walk into a community health center or primary care physician's office seeking care, and so are harder to enroll, often requiring providers to find beneficiaries, build trusting relationships, and engage the beneficiaries to want to participate in the program, sometimes taking months of in-person outreach and engagement efforts.

For these reasons, we appreciate that the CalAIM requirements allow managed care plans to fund past initiation of outreach services once beneficiaries enroll in ECM, and encourage managed care plans to offer incentive payments for hard-to-find beneficiaries. However, these remedies do require providers to wait the significant time it could take to enroll beneficiaries experiencing homelessness before receiving payment. For this reason, we recommend paying plans and providers for a three-month outreach period for beneficiaries eligible, prior to a beneficiary's enrollment, following a New York Health Homes Program model. This three-month period would allow providers to receive payment while finding and engaging beneficiaries experiencing homelessness, and would allow providers to get paid for these services when they are providing them, even if the managed care plan does not offer incentive payments. DHCS could also allow managed care plans to pay incentives for providers who enroll a specific percentage of beneficiaries

[19]State Health Officer Letter #21-001.
[20]Interim Evaluation of California's Health Homes Program (HHP).

experiencing homelessness (i.e., 25% or higher beneficiaries experiencing homelessness), and incentives for moving those beneficiaries into housing.[21]

Further, we recommend clarifying when a provider may conduct outreach through letters, e-mails, texts, and other methods that are not in-person. Currently, the Model of Care Template suggests that a provider must conduct in-person outreach to eligible beneficiaries, but switch to other methods of outreach, "if in-person outreach is unsuccessful." Because the requirements documents do not define "in-person attempts" or "unsuccessful attempts," we recommend further guidance that requires at least three attempts from staff, such as peers with lived expertise of homelessness, who have outreach experience in successfully identifying and engaging beneficiaries experiencing homelessness.

Peer Support Services

We appreciate your proposal for an integrated peer support specialist pilot to assist Medi-Cal beneficiaries with behavioral health conditions to access and receive meaningful care. As beneficiaries with lived experience of homelessness have expertise unique to their experiences, **we recommend including beneficiaries with lived experiences of homelessness and behavioral health conditions in the pilot to serve other beneficiaries currently experiencing homelessness.** Peers with lived experience of homelessness have rare expertise in outreaching to and engaging people experiencing homelessness, assessing the goals and needs of beneficiaries experiencing homelessness, and coordinating care and connecting people to homeless systems.

The undersigned organizations continue to call for Medi-Cal funding for services that would meet the unique needs of beneficiaries experiencing homelessness. We look forward to working with the Administration to heed the example of other states, the guidance of CMS, and the recommendations of experts to fulfill the promise and intent of CalAIM for this population. We can ensure systems discharging people into homelessness become instead responsive to homelessness, if Medi-Cal can meet the unique needs of this fragile population. Thank you for considering our recommendations.

Sincerely,

[redacted]

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Conard House

[redacted]

Michael Blecker
Swords to Plowshares

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Rose Ceja

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[21] 42 CFR Section 438.6.

National Health Care for the Homeless Council

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May 6, 2021

Director Will Lightbourne
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413
Submitted via: CalAIMWaiver@dhcs.ca.gov

RE: SEIU California Comments on CalAIM Section 1115 Demonstration Application and Section 1915(b) Waiver Overview

On behalf of our 700,000 members, the Service Employees International Union State Council (SEIU California) welcomes this opportunity to comment on the Department of Health Care Services' (DHCS) proposed CalAIM Section 1115 Demonstration Application and Section 1915(b) Waiver Overview. SEIU California represents county workers across all county departments and healthcare systems, who lead the way in addressing the social determinants of health, social services, public health, health care, and behavioral health needs. SEIU California generally support this CalAIM initiative, which intends to improve the quality of life and health outcomes of the 13 million beneficiaries by implementing broad delivery system, programmatic and payment reforms to create a more seamless, coordinated and patient-centered Medi-Cal program. We support CalAIM's vision to revitalize behavioral health care through a person-centered, trauma informed, and recovery-based services approach that offer people with behavioral health care needs an avenue to wellness and quality of life.

Section 1115 Demonstration Application Proposal:

SEIU California generally supports DHCS' 1115 demonstration 5-year renewal and amendment request through CalAIM. The continued success of California's 1115 Waiver is instrumental to the Medi-Cal Program, and California's public safety-net hospital and health care systems, as well as the behavioral health care system.

- ***Global Payment Program Renewal*** - California's county public safety-net hospitals must treat any patient, who comes through their doors, independent of the patient's health insurance or financial status. The Global Payment Program and Safety-Net Care Pool funding offered financial incentives to provide uninsured and underinsured individuals with more appropriate care in outpatient settings. They also served to facilitate public health systems in offering new services, which were previously not reimbursable, but have shown to help improve health outcomes. These focused programs have strengthened the delivery of both primary care and specialty outpatient care. Continuation of both programs is imperative in order to solidify the stability of California's public safety net hospitals, especially as 3.5 million Californians remain uninsured due to

lack of health care affordability or due to their immigration status. We support this renewal.

- ***New Equity Sub-Pool Funding –*** This proposal seeks to expand the Safety Net Care Pool (SNCP) funding to establish a *separate* "Equity Sub-pool" through which eligible Designated Public Hospitals would "earn" points in order to receive payment for services and activities to address health inequities and social determinants of health and respond to the impacts of racism and inequities on the uninsured populations these hospital systems serve. We strongly support this proposal and look forward to working with DHCS to ensure existing skilled public sector workforces are rendering such services and activities.
- ***Providing Access and Transforming Health (PATH) Supports –*** DHCS seeks expenditure authority under the 1115 Waiver to support services and capacity building, including payments for supports, infrastructure, IT systems, interventions, and services to complement care that will be under the 1915b. It would be for those items that are not otherwise covered under the State Medicaid Plan. This would also help with the justice-involved populations for the 30-day pre-release proposal. We support this proposal.

Section 1915(b) Waiver Overview Proposal:

- ***Creation of a Statewide Enhanced Care Management (ECM) Benefit*** – County workers and providers have an existing and explicit role in serving the proposed Enhanced Care Management benefit (ECM) target populations, including children and youth with complex needs (CCS, Foster Care, and first episode of psychosis), individuals experiencing homelessness or who are at risk of becoming homeless, high utilizers of medical care, individuals with behavioral health needs, and others.[1] Of the 26 WPC Lead Entities in operation providing and coordinating non-medical supports, 22 are Counties. Further, Counties employ diverse staff, such as outreach workers, multi-lingual community health workers, social workers, public health nurses (in-home visits) and many other professional and clinical personnel. As such, we have the bandwidth to address the many different needs and approaches to serving diverse ECM beneficiaries. We are reliable and expert partners.

  Therefore, SEIU strongly recommends the inclusion of mandatory contracting language within the ECM and ILOS sections in the implementing legislations of CalAIM. Both of the infrastructure, as well as expertise for this new benefit is at the local county level. We believe this approach would ensure a more rapid deployment of the needed benefit, offer stronger outcomes for Medi-Cal enrollees, and strengthen local economies through workforce development. It would also eliminate any potential confusion across different delivery systems.

- ***Voluntary In-Lieu of Services (ILOS) Provision*** – CalAIM proposes to create a voluntary and new menu of ILOS, but at the discretion of a Medi-Cal Managed Care Plans (MCP), albeit with a beneficiary's approval. Managed care plans will

[1] See page 3 of CalAIM Enhanced Care Management and In-Lieu of Services Model of Care Template.

be responsible for administering both ECM and ILOS by contracting with local, community-based providers. The new menu of ILOS ranges from housing transition navigation services; housing deposits; housing tenancy and sustaining services; short-term post-hospitalization housing; recuperative care (medical respite); respite; day habilitation programs; nursing facility transition/diversion to assisted living facilities, such as residential care facilities for the elderly or adult residential facilities; nursing facility transition to a home; personal care and homemaker services; environmental accessibility adaptations (home modifications); and others. Most if not all of these services are already being provided by our public sector county workers and In-Home Support Services (IHSS) providers. They have the skills, training, subject matter expertise and knowledge of locally available resources to make timely and direct referrals connecting people to critical services.

Therefore, SEIU believes county behavioral health, public health, health services, house, social services departments, as well as our In-Home Support Services (IHSS) providers need to have a more definitive role in any ILOS offered service. We recommend DHCS to require managed care plans to contract with county departments for select ILOS, which would ensure a more cohesive linkage with local and available resources and services. For example, through the IHSS program, the state already has a cost-efficient system and trained workforce for personal, homemaker, and respite services and our IHSS providers can be appropriate ILOS providers. For existing IHSS beneficiaries, the implementation of ILOS personal care and homemaker services may instead create more fragmentation, more disruption, and less consumer choice by asking beneficiaries to navigate an additional delivery system, i.e., private home care agencies via managed care plans approval and offering. Another example is our county housing workers that already identify housing and prepare individuals for securing and maintaining not only stable housing, but also stable lifestyle. We also request DHCS limit managed care plans' wide discretion and authority in determining the core portfolio of services within ILOS - or at a minimum provide some standard guidance that would inform how MCPs should determine or offer ILOS.

- ***Behavioral Health Care Delivery System Transformation*** – The proposed 1915(b) waiver overview offers a plan that finally transforms our behavioral health care system, both with regards to delivery of critical services and also payment for such services, which we support. CalAIM makes changes to the behavioral health medical necessity criteria that will allow behavioral health providers to meet the patient/client's mental and/or substance use disorders prior to determining whether the individual has a covered diagnosis under current policy. SEIU is supportive of the CalAIM goal to improve access to Specialty Mental Health services for both children and adults, including where a co-occurring Substance Use Disorder is involved. The specific improvements include, among other things:
    - Standardized delivery screening tool to be used by MCPs and Behavioral Health Plans, including a no wrong door policy;

- Eliminating the diagnosis requirement to access Specialty Mental Health services;
- Streamlining mental health documentation requirements; and
- Clarifying that children and youth (under 21 years) can obtain Specialty Mental Health services regardless of impairment level, including open access for those experiencing trauma (through ACEs screening).

SEIU supports the shift from CPE to IGT which will facilitate quality improvement and enable a value-based payment approach to services. ***However, when establishing reimbursement rates for counties, DHCS should also consider the number and quality of investments in the workforce, training, and infrastructure needed to provide high-quality services to its residents.*** These are critical factors that will help counties expand and maintain strong programs in the long-term.

- ***MCP Population Health Strategy Requirement*** – CalAIM proposes to work on health equity and population health issues by requiring managed care plans to develop and maintain a population health management strategy. Some Med-Cal managed care plans have a population health management strategy, often in response to NCQA requirements, but many do not. In the absence of a strategy, care can be driven by a patchwork of requirements that can lead to gaps in access and a lack of coordination, which we agree with. But, permitting managed care plans to develop their own individual population health strategy without consultation subject-matter and field experts, such as county public health departments, is problematic. MCPs not experienced nor equipped to undertake these core public health roles. County public health departments have led community public health assessments, population health management and related-analysis, prevention, and equity efforts for our communities regardless of health care coverage for decades.

  Therefore, SEIU we recommend that County Public Health be directly consulted and viewed as an integral partner in the development of MCP population health management programs. There needs to be a recognition of these natural linkages in the public health and health care systems, which is one of the real ways both systems can work alongside to improve overall healthcare and population health outcomes. The State needs to better identify and propose concrete ways in which public health fit in the broader health care delivery system, and this would be one way.

Conclusion

SEIU California generally supports the 1115 and 1915(b) waiver proposals, but we also identify key changes and improvements that must be made in order for our Medi-Cal program to transform for the better and for its 13 million beneficiaries to fully receive patient-centered care with good health outcomes. SEIU California supports DHCS' goal of meeting Medi-Cal beneficiaries/patients where they are – both from a plan of care perspective and with the use of our county public sector workforce. Our public sector workers are the most qualified and competent to provide timely direct care provision, as well as to do outreach, program enrollments, care coordination services, case

management and other wrap around services. Our membership has found time and time again that these strategies are essential to ensuring that patients receive effective care and adhere to the treatment plans designed by their providers. We thank you for your consideration and look forward to working with you on additional policy changes.

Sincerely,

[redacted]

Mary June G. Diaz
Government Relations Advocate

CC:

Dr. Mark Ghaly, Secretary, CA Health and Human Services Agency
Michelle Baass, Undersecretary, CA Health and Human Services Agency
Brendan McCarthy, Assistant Secretary, CA Health and Human Services Agency
Jacey Cooper, Chief Deputy Director, Health Care Programs & State Medi-Cal Director
Dr. Kelly Pfeifer, Deputy Director, Behavioral Health
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May 6, 2021

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

RE: CalAIM Section 1115 & 1915(b) Waivers

Dear Director Lightbourne,

The American Academy of Pediatrics, California (AAP-CA) representing over 3,000 pediatrician members appreciates the broad goals of DHCS' proposed 5-year CMS Waiver. However, we are deeply concerned that the proposal in its current form may unintentionally limit, rather than expand, access to behavioral health care for children and youth in California.

Eligibility for Behavioral Health Services

The draft proposal uses unclear criteria to define which children and youth should receive behavioral health services. Federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) regulations state that children and youth are eligible for services if an "appropriate" clinical provider determines services are needed, but it is not clear who is an "appropriate" clinical provider. EPSDT rulings have determined that if a competent medical provider finds specific care to be "medically necessary" to improve or ameliorate a child's condition, services must be covered. Without clarifying who is or isn't an "appropriate" provider, children and youth may not qualify for services until they undergo a secondary assessment of the need for care. **The guidelines should clearly state that when a primary care provider or licensed behavioral health provider determines that services are necessary and submits or makes available documentation that substantiates that eligibility, the child or youth is eligible for behavioral health services**.

Timeliness of Behavioral Health Services

The draft proposal does not clarify the process for receiving behavioral health services within the DHCS-required timely access to care standard of 10 business days from the date of the request for a non-urgent appointment and 48 hours for an urgent appointment. Past policies and practices, lack of workforce capacity, and unclear responsibilities of the behavioral health systems upon referral have resulted in substantial delays in receipt of care. **Medi-Cal Managed Care Plans (MCP) should be responsible for assuring that the timely access standard is met for all referrals for service unless the patient has previously received services in the County Mental Health Plan's (MHP) specialty mental health system. The MHP is responsible for assuring access to timely care for previous enrollees who received specialty mental health care in any County mental health plan, regardless of location.**

Eligibility for Specialty Mental Health Services through County Mental Health Plans

The draft proposal specifies that beneficiaries under age 21 are eligible to receive specialty mental health services if they meet particular criteria, with "scoring in the high-risk range on a DHCS-approved trauma screening tool" as one of the criteria. According to an article by Dr. Robert Anda, author of the ACEs study, "ACE scores are being misappropriated as a screening or diagnostic tool to infer individual client risk and misapplied in treatment algorithms that inappropriately assign population-based risk for health outcomes from epidemiologic studies to individuals."[1] Furthermore, the proposal does not take into account the way ACEs are experienced in the BIPOC population or take into account the systemic racism and inequality that lie beneath these issues.[2] **DHCS should convene an advisory workgroup to consider the**

[1] https://psycnet.apa.org/record/2020-54827-019
[2] https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-10091-y

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appropriate role of trauma screening in determining mental health access for children and teens.

Initial Intervention services

The CalAIM proposal states there should be "No Wrong Door" for entry to care and that reimbursement and services can be offered before a diagnosis is clearly established, yet how can non-urgent services be provided in a timely manner or which system pays for the interim services is not clear. The behavioral health workforce shortage makes it impossible for MCPs and MHPs to obtain the information needed for a referral and arrange a continuity behavioral health provider within 10 business days, let alone complete a baseline evaluation to determine the needs of the patient. **A plan for delivering initial intervention services for non-urgent referrals, either through the primary care provider, the referring behavioral health provider or a member of a pool of behavioral health providers incentivized and available to deliver care to children and youth in a timely manner is needed.**

Plans could authorize initial intervention services with the referring behavioral health provider or primary care provider, possibly through contract arrangements with local education agencies and medical providers. Specifications regarding the content of brief initial intervention services, along with credentialing to deliver these services to children and youth would need to be developed.

An appointment for initial intervention services should be provided within 10 business to support the child/youth and complete the evaluation for new non-urgent referrals if a continuity behavioral health provider is not available. The Medi-Cal Managed Care Plans (MCP) are responsible for providing initial intervention services for patients who have not previously received care in the County Mental Health Plan until an evaluation has been completed and an appointment is made with a continuity provider. The MHP is responsible for providing initial intervention services for nonurgent referrals to enrollees who had previously received specialty mental health care in any County mental health plan, regardless of location.

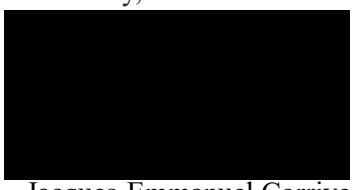
Support of Preventive Services

Federal EPSDT funding covers preventive services as well as therapeutic services for children and youth, however DHCS has not proposed funding services targeted specifically towards behavioral health early intervention and prevention.

Implementation of statewide preventive services could be made available through the EPSDT funding stream, such as enhanced school-based services working in partnership with mental health and primary care providers, enhanced implementation of integrated behavioral health in primary care practices, and enhanced dissemination of dyadic care for parents and young children in need of support.

AAP-CA respectfully opposes the proposed CMS waiver unless amended due its potential clinical impacts. Thank you for your public service and leadership on behalf of the health and wellbeing of children, youth, and families in California.

Sincerely,



Jacques-Emmanuel Corriveau, MD, FAAP
Chair, State Government Affairs Committee
American Academy of Pediatrics, California

cc: AAP Leadership

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December 15, 2019

California Advancing & Innovating Medi-Cal (CalAIM) Proposal 10.28.2019
Input to the California Department of Health Care Services
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CalAIM@dhcs.ca.gov

RE: Input into Department of Healthcare Services' "CalAIM" Proposal – Rare Blood Disorders

Dear DCHS CalAIM Leadership:

We are writing to you on behalf of: 1) California's ten Federally and State recognized Hemophilia Treatment Centers (HTC), and 2) as leaders in creating California's first Sickle Cell Disease (SCD) State Action Plan (2018) who are developing the Plan's recommended statewide clinical network for adults with SCD, and implementing the Plan's goals to expand workforce, surveillance and awareness.

Thank you for the opportunity to review and provide this initial input into the California Advancing & Innovating Medi-Cal (CalAIM) Proposal released 10.28.2019. We represent the expert specialist teams who, in tandem with our community-based organization (CBO) partners, use a value framework[1] to provide integrated health and social services to reduce health disparities for Californians with catastrophic rare genetic blood disorders. These California's are among the State's most medically vulnerable populations, are among the higher users of costly healthcare services, and are at high risk very poor health and shortened lifespans. In short, they are the very populations that this new CalAIM initiative directly targets. Yet the CalAIM proposal inadequately addresses these populations' specific needs. We respectfully submit these initial comments and recommendations which speak directly to the CalAIM guiding principles and goals. We commit to monitor CalAIM stakeholder meetings and provide further input as CalAIM evolves.

OVERVIEW

Californians with rare complex blood disorders are extremely medically vulnerable and high utilizers: Californians with Hemophilias, Thrombophilias, Thalassemias, von Willebrand Disease (VWD) and Sickle Cell Disease (SCD) represent some of our state's most medically vulnerable residents. These disorders are present at birth and harm multiple organ systems. They are progressively debilitating and last a lifetime. They are familial, rare, and difficult to both diagnose and treat. Internal bleeding is horrifically painful and frequently spontaneous. This pain often requires high (but time limited) doses of narcotics to control; doses that are often inappropriately denied, partly in reaction to the current opioid crisis. When sufficient pain medications are prescribed, narcotic withdrawal occurs, but often without adequate home supports, thus prolonging return to full functioning. Internal bleeding to the head, throat, abdomen, and -- in SCD -- chest, can be fatal. Silent strokes frequently occur, limiting executive brain function. Due to multiple failures of the health care system to address these conditions using preventive whole person approaches, Californians with these blood disorders become 'high utilizers' of costly healthcare services (e.g. emergency room visits and hospital stays), at risk for very poor functioning and health outcomes, diminished quality of life, shortened survival.

Health disparities are dire, particularly in SCD, where most affected individuals are African American and, secondarily, Latinx. Though few clinicians and the public know that Latinx are at risk. The race/ethnic backgrounds of Californians with hemophilia, VWD and thrombophilias generally reflect our State's demographics of a majority plurality. Over half of Californians with hemophilia and over 70% of those with SCD are primarily insured by either Medi-Cal, California Children's Services (CCS) or the Genetically Handicapped Persons Program (GHPP). Their safety is highly dependent upon Medi-Cal, CCS, and GHPP policies that ensures continued access to California's long-standing network of CCS and GHPP blood disorder "Specialty Care Centers (SCC)". All these blood disorders are CCS and GHPP eligible conditions.

[1]O'Mahony et al. International Journal of Technology Assessment in Healthcare, 2018

Simultaneously, there is a **severe shortage of expert hematologists** practicing in California who provide evidence informed care for these populations, especially for adults with SCD and Thalassemia. Reimbursement for preventive team-based services that Californians with these rare chronic complex disorders need in the outpatient setting is lacking, particularly for community health workers (CHW) who are specifically trained in these blood disorders. CHWs provide essential care coordination services throughout delivery systems and beyond the healthcare setting. These workforce gaps exacerbate social determinants of health.

BACKGROUND – California's 40-year-old Rare Blood Disorder Network – Improving health/Reducing costs:

We are submitting these recommendations behalf of eleven California's Federally and State recognized Hemophilia Treatment Centers (HTC). These HTCs provide multi-disciplinary team based clinical care, research, and outcomes monitoring services to over 10,000 residents with suspected or diagnosed rare inherited bleeding (e.g. hemophilia and VWD) and clotting disorders (e.g. genetic thrombophilias). HTC services include diagnosis, treatment, prevention, education, care coordination, surveillance, and low-cost pharmacy. Services span the outpatient, inpatient and community settings. The 10 HTCs are all CCS and GHPP Hemophilia *Special Care Centers. The majority also sees patients with inherited blood disorders such as Sickle Cell Disease and Thalassemias*.

Access to Specialty Centers Improves Health and Productivity, reflecting a Value Framework: HTCs and SCD Centers are key to reducing morbidity, mortality, emergency room visits and hospitalization. **CDC data document 60% reduced deaths[2], 60% fewer hospitalizations and lower costs[3] when males with hemophilia obtain care at HTCs as compared to care outside the US HTC Network**. HTC patients complete high school by age 25 higher than the general population despite having a chronic complex disorder, increasing the chances for higher paying jobs than counterparts with less education.[4] Unfortunately, Californians with SCD, particularly those in Los Angeles[5] die at younger ages (median age 45.7)[6] than their counterparts and African-Americans without SCD living elsewhere in the US.[7] The lack of knowledgeable sickle cell providers in California drives these poor healthcare outcomes.[8]

Federal Specialty Center Enhanced Quality Requirements: To further ensure the safety and longevity of Californians with rare blood disorders, all 10 California SCC/HTCs are also members of the federally recognized US HTC Network (USHTCN)[9]. The USHTCN is comprised of 140+ regionally organized specialty centers. The USHTCN fulfills Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) requirements for integrated team based clinical care and quality improvement, and conduct complications surveillance under oversight of regional core centers***. No Managed Medi-Cal Health Plan provides these services.*** Five of California's HTCs are among the original 26 HRSA supported Centers dating from the late 1970's.

Blood Disorders Networks in CA Transforming Health: About half of California's HTC teams also provide integrated team-based diagnosis and treatment to persons with SCD and Thalassemias. CIBD serves as Prime Grantee for HRSA's and CDC's four state Western States Regional Hemophilia Center Network for the past two decades. Similarly, CIBD serves as Prime Grantee for HRSA's 13 State Pacific Sickle Cell Regional Collaborative (PSCRC) whose main focus is SCD healthcare systems access to care and knowledgeable providers. In these roles, CIBD provides regional leadership, strategies, and oversight to build rare blood disorder clinical expertise, improve access to guideline informed care, strengthen complications and outcomes surveillance, and sparks and sustains regional healthcare delivery systems transformation, in collaboration with community-based organizations. In its PSCRC role, CIBD annually convenes with HHS Regional Leaders, fostering access to blood disorder specialty care for acutely underserve populations through partnerships with the Offices of Refugee Resettlement, and builds the clinical workforce via tele-education using Project ECHO.[10] CIBD is contracted with the California Department of Public Health to implement the Governor's new three year appropriation to build a statewide network of adult SC centers, and expand surveillance, workforce and outreach/education.

Health Disparities in Sickle Cell Disease: Institutional racism, the shortage of clinicians who are knowledgeable about SCD – particularly adult providers – the lack of specialty SCD clinics for adults, and the nations opioid crisis tragically synergize. In California, this results in affected individuals delaying needed treatment. Reluctantly using emergency rooms as the primary locus of

[2] Soucie et al, Blood, 2000.
[3] Soucie et al, Haemophilia, 2001
[4] Drake et al, American Journal of Preventive Medicine, 2010
[5] Powars et al, Medicine, 2005
[6] Paulukonis and Hagar, Blood, 2017
[7] Paulukonis et al. Public Health Reports 2016
[8] Paulukonis et al. Longitudinal Data Collection for Sickle Cell Disease in California. 2015
[9] Baker et al, American Journal of Public Health, 2005
[10] See https://pacificscd.org/project-echo/

SCD 'care'. And inaccurately being labelled as 'drug seekers' when requesting needed short courses of narcotics in to resolve SCD pain crises.

Indeed, SCD represents one of our nation's most catastrophic health disparities. Tragically, this is occurring at the same time of today's unprecedented advances in new therapeutics. And simultaneous to new national attention on SCD – from the Surgeon General Jerome Adams, MD; Assistant Secretary of Health Brett Giroir, MD; The NIH's new Cure Sickle Cell Initiative, the National Academy of Science's forthcoming national blueprint for SCD; the American Society of Hematology, the Office of Minority Health, in addition to HRSA and CDC. **Health policies are needed to redress the mounting failures that result in all too many Californians with SCD and hemophilia being denied access to the rare disorder specialty teams they need to live long healthy productive lives.** DHCS' The CalAIM proposal provides an opportunity to create policies that can address the needs of California's populations with rare complex chronic inherited disorders.

RECOMMENDATIONS for the CalAIM Proposal to increase health, systems, reduce avoidable costs.

1. *We recommend that Californians with rare genetic blood disorders who have CCS and GHPP eligible conditions, <u>including adults, be explicitly eligible for all CalAIM proposed population health service enhancements</u>.*

<u>Rationale</u>: The physical, social, emotional, and behavioral manifestations of these blood disorders makes affected individuals of all ages the exact medically vulnerable, high utilizers of high cost services that is the priority of the CalAIM proposal. The CalAIM proposal recognizes this high level of medical vulnerability among CCS eligible individuals, and frequently references "children with special healthcare needs" as a priority population. However nowhere the CalAIM proposal must recognize that children with CCS eligible conditions are not automatically cured when they age out of CCS upon their 21st birthday. Indeed the CA Department of Healthcare services created GHPP in the 1970's recognizing that many such children were living to age 21, but private insurance would not cover them. Without GHPP, these medically vulnerable young adults would only know a life of under/unemployment so they could be Medi-Cal eligible to afford their expensive medications and retain access to the knowledgeable care only available at the expert Special Care Centers. <u>By explicitly including adults with CCS and GHPP eligible conditions</u>, CalAIM's population health innovations will reach the medically vulnerable adults it helped as CCS eligible children. This recommendation also encompasses 1) the <u>Case management and Enhanced Care Management</u> (pp 29-31) proposed services for basic and complex case management and enhanced care management, and 2) the "In Lieu of services" (p.32) which are flexible wrap around services provided as a substitute to or to avoid inappropriate hospital discharges, emergency room visits, inpatient stays and pain medication.

2. *We recommend that the CalAIM proposal allow all Californians with rare blood disorders <u>of all ages</u> to have <u>uninterrupted access to California's long-standing network of Subspecialty Care Centers (SCC), regardless of the client's county of residence.</u>*

<u>Rationale</u>: This population health strategy will remedy the unintended consequences of current DHCS policy for Californians with rare genetic disorders with CCS and GHPP conditions. Doing so will **<u>also increase patient safety</u>** by ensuring that <u>risk identification and therapeutic response</u> is conducted by clinicians who are expert in rare disorder diagnosis and management aligned with a whole person approach to patient goals (CalAIM Report p 25). It aligns with CalAIM Report regarding general requirements to address risk and need (CalAIM Report p. 28). It will enhance downstream benefits of continued access to new therapies, long standing national quality metrics, and proposed innovations in value based reimbursement.

Uninterrupted SCC access will promote opportunities for the proposed CalAIM initial and one year risk assessment (Report p.25) to align with blood disorder specific risks that evolve throughout the lifespan. Uninterrupted SCC access will also address major gaps in the report under Wellness and Prevention Services (p.29), which only reference the American Academy of Pediatrics (AAP) and US Preventive Service Task Force (USPSTF) Grade A and B recommendations. Unfortunately, with the exception of recommending Newborn Screening for Hemoglobinopathies, the AAP and USPSTF recommendations completely ignore NIH Evidence Based Guidelines for VWD[11], SCD[12], as well as those published for Hemophilia[13], and Thalassemia[14]

Without SCC experts guiding care, what evidence-based criteria will the Managed Medi-Cal Health Plans use to identify and manage ongoing and emerging risks, assess patient needs, devise and monitor treatment plans related to members' rare blood disorders

[11] NIH, The Diagnosis, Evaluation and Management of von Willebrand Disease, 2007
[12] NIH, Evidence based management of Sickle Cell Disease, 2014
[13] Srivastava Haemophilia 2013
[14] Chonat, Adv Ex Med Biol 2017

(P28-29?) What blood disorder quality metrics will the Plans use to benchmark performance? What uniform standardized blood disorder surveillance systems will Plans use to monitor blood safety, mortality, complications, morbidity, healthcare utilization and costs? What specific predictive modeling or specific algorithms will Plans use that address rare blood disorder members' needs in general and those who are 'outliers' (p. 29)? This is concerning, given the Plans' lack of expertise in rare disorders in general, and in light of the recent report in Science regarding racial bias in algorithms used to manage population health.[15]

Current Medi-Cal care coordination policy now limits Medi-Cal, CCS, and GHPP[16] insured person's access to their SCC for only one year after initial Plan enrollment, with no future access guarantees. This varies from county to county at the discretion of local Plans resulting in disparities of care delivery. This is contrary to the CalAIM proposal's guiding principles of increased flexibility and reducing variability across counties. Furthermore, there are no data to support the Department's position that these medically vulnerable clients would receive better care or experience improved outcomes under the Plans. Thus, the current CalAIM proposal jeopardizes rare blood disorder client health and safety.

Using County borders as basis for access to care for complex, chronic rare blood disorders jeopardizes patient safety and functioning. **We advocate CalAIM to recognize the state's long-standing network of SCCs, which can be used by multiple counties regardless of whether the SCC's are located in the county of patient residence.** Moreover, access to the SCCs advances CalAIMs' efforts to build on the past success of the SCCs in enhancing health outcomes, reducing morbidity, mortality and costs. SCC access also builds on current and long-standing SCC quality improvement initiatives. Realistically, clinicians at county-based plans cannot be expected to automatically have or quickly acquire expertise in rare blood disorder diagnostic and management. Rare blood disorders are not evenly disbursed geographically throughout the State. Applying county borders as the criteria for network adequacy and geographic access – the current practice - is suited to high prevalent conditions. Such policies pose risk to rare disorder client health and safety.

Uninterrupted Client Access to SCCs **protects health and safety, reduces high utilization and reflects a value framework, a guiding CalAIM principle**: Ideally, Managed care plans would use the SCC as part of their regional medical resources and encourage these plans to use the **SCC as the provider of choice for multi-disciplinary care of rare blood disorders.** Before Managed Medi-Cal expansion, GHPP and CCS insured clients were required to be seen at the SCCs at least annually for a comprehensive visit, and submit an annual comprehensive treatment plan**.** Annual treatment plans would be used to guide SARS for the upcoming year, and be updated, as client medical needs changed. This practice, in place since GHPP's inception in the early 1970's, and likely before in CCS, reflects DHCS recognition that expertise in the SCCs managing genetically catastrophic conditions is critical for patients with rare chronic diseases. We encourage CalAIM to innovate by requiring the Plans to allow uninterrupted access to the SCCs to ensure that the rare blood disorder care needs are met.

The costs of hemophilia medication are exceptionally high, and the costs of future SCD medications may also be great, given that SCD affects five times more people than hemophilia. SCC team members typically conduct lengthy and frequent phone calls with clients and families to increase care access by reducing geographic barriers, as an adjunct to in person clinic visits. Increasingly, SCCs are providing clinical care via tele-health and tele-medicine technologies. Collectively, these innovations help reduce avoidable emergency room visits[17] and hospitalizations, reduce per-capita costs, and lower school and work absenteeism, all key metrics in value frameworks, and part of the CalAIM guiding principles. We encourage CalAIM to support policy innovation that adequately reimburses SCCs for team based care provided at clinics that are in person, via audio and teleconferencing.

California's SCC leaders are working with international blood disorders health economists on introducing the concept of value-based reimbursement model pilots.[18] These models are already implemented in several European countries, reducing costs while simultaneously improving access to therapies with enhanced patient adherence to regimens. CalAIM support for access to SCCs therefore aligns with CalAIM guiding principles of value based care transformation, accelerating California becoming a national leader in value-based reimbursement for rare costly disorders.

[15] Obermeyer, Science, 2019
[16] GHPP insured are part of "Seniors and Persons with Disabilities" and required to be enrolled in Managed Medi-Cal Health Plans.
[17] Kulkarni, Haemophilia, 2018
[18] O'Mahony et al. International Journal of Technology Assessment in Healthcare, 2018.

Transitional Services: Uninterrupted access to SCCs will help ensure high quality transition across service settings and levels as transition will include guidance from SCC expert clinicians and CBO led CHWs. It is critical that the proposed CalAIM 'standardized discharge risk assessment tool' (p. 33) include blood disorder specific components.

Skilled Nursing Facility Coordination (p. 34): Policy innovation is needed to open up SNF access to people with blood disorders who rely on medication that requires intravenous infusion (e.g. factor concentrate). Currently, no intravenous infusions are allowed for SNF residents. People with severe hemophilia and VWD rely on routine use of factor concentrates to live normal lives, and have been 'self-infusing' for decades. As this population ages, disqualification to live in a SNF on this basis alone presents a serious access to care barrier, placing enormous burden on the family.

Quality Metrics, Health Information Technology, and Interoperability (p. 35): Currently DHCS has no rare blood disorder metrics to monitor rare blood disorder care quality: to measure access, processes, utilization, blood safety, and outcomes. This is in contrast to SCCs for both hemophilia and SCD. California's 10 HTCs participate in a 20-year-old CDC surveillance system those tracks bleeding disorder complications with a focus on inhibitor development. When inhibitors to medications develop, current blood clotting medications are not effective, and patients can bleed daily, placing them at high risk of death and tripling the cost of care. HTCs also participate in HRSA required quality improvement projects; areas include adolescent transition to adult care, aging in hemophilia and thrombophilia detection. Several HTCs teams caring for clients with SCD also participate in HRSA required quality improvement projects that promote NIH evidence based guidelines, to promote Hydroxyurea adherence, pneumococcal immunizations, and stroke monitoring using transcranial Doppler.[19] **Therefore, allowing uninterrupted access to SCCs would improve patient health and safety by continued client involvement in these rare disorder uniform quality metrics and surveillance programs**.

High Patient Satisfaction with SCC Care and National Recognition: Individuals with hemophilia and von Willebrand Disease who obtain care at SCCs in California report very high satisfaction with care and services, as reported in national patient satisfaction surveys. Therefore, maintaining access to SCCs for these rare blood disorders populations aligns with the CalAIM guiding principles of enhancing the member experience, and providing patient centered care.[20] Our pilot Jefferey Smith Adult Sickle Cell Clinic at MLK Jr. Outpatient Center has garnered an award from the National Association of Counties, and attention from the CDC.

Workforce crisis: Very demanding time commitments and low Medi-Cal reimbursement rates for outpatient care result in very few physicians caring for patients with rare complex disease. Few Managed Medi-Cal Health plans can afford to support the required team of nurses, social worker, and specialists for relatively few complex and rare disorder patients. Finally, few healthcare providers outside of the SCCs accept GHPP insured clients because 1) the eligible diseases are rare, and 2) GHPP does not bill electronically, and reimbursement from the State is delayed, posing unacceptably high administrative costs to practices.

Access to New Therapies: CalAIM proposals to limit access to SCCs for clinical care, also would limit access to clinical trials, to the detriment of patient health, taxpayer dollars, and the economy. There are dozens of new medications in the hemophilia and sickle cell disorders pipeline, more than in recent memory. The 10 HTCs have consistently large patient populations (on average 250/year) and conduct research to test the safety and efficacy of drugs in development. Many SC centers do as well.

However, managed Health Plans do not have this capacity. Therefore, limiting access to SCCs poses negative clinical consequences. It slows scientific advancement and inhibits California's involvement in scientific advancement economy. It increases costs to the state because during clinical trials, drug manufacturers pay for the costs of medications. And it reduces client access to potentially improved medications that could improve health and functioning.

3. *We recommend that all SCCs that care for Californians with rare genetic blood disorders of all ages be explicitly eligible for CalAIM proposed shared risk/savings and incentive payments as well as non-clinical interventions, such as community health workers (CHW) and care coordinators, to enhance care coordination across delivery systems and thereby address social determinants of health. Furthermore, we recommend that CalAIM require CHWs be a required care coordination service, build in adequate CHW reimbursement into contracts, and require the CHW training and certification that is required of the California Department of Public Health's Newborn Screening genetic counselor educators for those disorders that are part of Newborn Screening.*

[19] NIH Evidence based management of Sickle Cell Disease: Expert Panel Report, 2014.
[20] National and regional trends from the National Patient Satisfaction Survey of US Hemophilia Treatment Centers: http://www.htcsurvey.com/news

Rationale: California's SCCs for rare blood disorders have an extensive history and track record of taking on the risks of caring for medically vulnerable Californians, improving patient health, quality of life, and lifespan; reducing hospitalizations and costs. SCC rare disorder expertise, commitment to multidisciplinary team-based care, active engagement in regional networks with oversight,[21] partnership with CBOs, commitment to quality improvement, adherence to federal goals, participation in uniform registries[22], and high levels of patient satisfaction, demonstrates their value to patients, families, healthcare delivery systems, and payors. Therefore the CalAIMS shared risk/savings and incentive payments should be available to them.

Community Health Workers that have explicit and ongoing training in blood disorders, and which report to CBO's that are independent from the clinics in which they are physically embedded, offer essential health services that maximize patient adherence to treatment recommendations. Being accountable to a CBO enhances client trust and expands the CHW's access to community resources which are essential to enhancing health equity, but which may not be viewed as valuable by typical hospital leadership[23].

Recommendations in Summary:

- Californians with rare genetic blood disorders who have CCS and GHPP eligible conditions, including adults, be explicitly eligible for all CalAIM proposed population health service enhancements.
- The CalAIM proposal allow all Californians with rare genetic blood disorders of all ages to have uninterrupted access to California's long-standing network of Subspecialty Care Centers (SCC), regardless of the client's county of residence.
- All SCCs that care for Californians with rare genetic blood disorders of all ages be explicitly eligible for CalAIM proposed shared risk/savings and incentive payments as well as non-clinical interventions, such as community health workers (CHW) and care coordinators, to enhance care coordination across delivery systems and thereby address social determinants of health. Furthermore, we recommend that CalAIM require CHWs be a required care coordination service, build in adequate CHW reimbursement into contracts and require the CHW training and certification that is required of the California Department of Public Health's Newborn Screening genetic counselor educators for those disorders that are part of Newborn Screening.

We understand that the CalAIM October 2019 Proposal will likely undergo revision based on stakeholder input. We look forward to continued engagement with the CalAIM stakeholder process.

Respectfully submitted,

[redacted]

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HRSA Western States Regional Hemophilia Treatment Centers: Center for Inherited Blood Disorders; Children's Hospital Los Angeles; Rady Children's Hospital San Diego; City of Hope National Medical Center; Guam Department of Public Health and Social Services; Hemostasis and Thrombosis Center of Nevada; Orthopaedic Institute for Children; Stanford University Medical Center; UCSF Benioff Children's Hospital Oakland; UCSF Medical Center; University of California, Davis; University of California, San Diego; Valley Children's Hospital

[21] Baker, Am J Public Health, 2005
[22] Soucie AM J Preventive Medicine 2010 and Baker Haemophilia 2013
[23] Hsu, Am J Preventive Medicine, 2016.

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May 6, 2021

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RE: Input into Department of Healthcare Services *CalAIM Section 1115 & 1915(b) Waiver* – Rare Chronic Blood Disorders

Dear DHCS CalAIM Leadership:

We are writing to you on behalf of 1) California's ten Federally and State recognized Hemophilia Treatment Centers (HTC), and 2) the leadership team for Networking California for Sickle Cell Care (NCSCC), an innovation funded through the Governors 2019 budget appropriation, to create a statewide clinical network for adults with Sickle Cell Disease (SCD), a priority in California's inaugural Sickle Cell State Action Plan (2018), in partnership with our Community Based Organizations (CBO).

Our networks' expert specialist teams and CBO allies, use a value framework[1] and evidence based organizational structures.[2] Together we provide integrated health and social services. Patients are highly satisfied, enhancing adherence to treatment plans.[3] Our work is noted in the National Academy of Science's new Strategic Blueprint for Sickle Cell Disease[4] and in Congressional Reports.[5] This innovative rare disorder model can reduce health disparities and costs statewide for Californians with catastrophic rare genetic blood disorders that are complex, are incurable, life threatening.

Thank you for the opportunity to provide input into the April 2021 California Advancing & Innovating Medi-Cal (CalAIM) Proposal. Today's input builds upon comments we submitted to you on 12.15.2019 (Attachment A) regarding the 10.28.2019 CalAIM proposal. Attachment A described the healthcare needs, high health services utilization, health disparities, and costs faced by the medically and socially vulnerable Californians we serve. These Californians are diagnosed with hemophilia, von Willebrand Disease, Thalassemia, Sickle Cell Disease, or genetic clotting disorders. All should be automatically eligible for CalAIM Enhanced Care Management and In Lieu of Services benefits, to fulfill CalAIM goals of reducing health disparities by improving identification and management of member risk; increasing consistent and seamless systems alignment across delivery systems; and to improve health outcomes and via systems transformation that includes value-based initiatives, modernization, and fiscal reform.

Our 12.15.2019 input offered three recommendations. We restate them below, note status per April 2021 CalAIM proposal, and then provide additional input.

Review of 12.15.2019 Recommendations, Status per April 2021 Proposal, and New Recommendations

1. Californians with rare genetic blood disorders who have California Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) eligible conditions, including adults, be explicitly eligible for all CalAIM proposed population health service enhancements. Original rationale – see Attachment A.
    - Status per April 2021 Proposal: Recommendation not addressed.

[1]O'Mahony et al. Patient-centred value framework for haemophilia**.** *International Journal of Technology Assessment in Healthcare*, 2018
[2]Kantar et al. Building access to care in adult sickle cell disease: defining models of care, essential components, and economic aspects**.** *Blood Advances*. 2020
[3]Riske et al. Patient satisfaction with US Hemophilia Treatment Center Care, Teams and Services: The First National Survey**.** *Haemophilia,* 2020.
[4]National Academies of Sciences, Engineering, and Medicine. Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Action, 2020
[5]National Institute for Child Health Quality. Sickle Cell Disease Treatment Demonstration Program, Congressional Report. 2017.

- While 'children and youth with complex physical behavioral or developmental health needs' are listed as one of the seven target mandatory populations for Extended Care Management (ECM) in some parts of the proposal, elsewhere the proposal indicates that such children are 'among the proposed target populations.' This conflicts with page 5 which states that children with complex medical conditions are among the state's most vulnerable residents, and page 23 which states that '…CalAIM ensures that medically complex children and adults get their physical, behavioral, developmental, and oral health needs met.'
- GHPP is mentioned only once, on page 198, indicating that an eligibility subset for the In Lieu of Services (ILOS) Respite services '…may include' persons enrolled in CCS and GHPP. This, too, conflicts with the page 23 statement above. Giving no assurance that CalAIM benefits will be available to GHPP insured.
- Additions to original rationale regarding our populations' needs to be automatically eligible for CalAIM benefits – A 2020 Data Brief from Tracking California (our Statewide SCD Surveillance System) report new findings regarding high Emergency Department (ED) visits among residents w/SCD: Californians with SCD go to the ED more than twice per year on average, compared to 0.4 times per year for all Americans. Children with SCD who are covered by public insurance have more ED encounters on average than those with private insurance. And Californians with SCD are more likely to live in low income zip codes than other state residents. This high ED visit utilization for Californians with SCD can be mitigated by CalAIM partnership with our rare blood disorder networks.

2. The CalAIM proposal allow all Californians with rare genetic blood disorders of all ages to have uninterrupted access to California's long-standing network of Subspecialty Care Centers (SCC), regardless of the client's county of residence. Rationale – see Attachment A.
    - Status per April 2021 Proposal: Recommendation not addressed.
        - The April 2021 CalAIM report is completely silent on access to CCS and GHPP SCCs. Managed Medi-Cal Health Plans do not have sufficient caseload of rare blood disorder clients, do not have dedicated rare blood disorder teams, and are not part of rare blood disorder networks – innovations that are essential to build or maintain expertise in rare blood disorder diagnosis and management. Rare disorder CCS and GHPP Centers – and the new NCSCC Adult Sickle Cell Centers -- do. For all the April 2021 CalAIM proposal's emphasis on reducing health disparities, identifying, and managing member risk, increasing consistencies across delivery systems, building on existing innovations, this silence is only disheartening, but threatens to jeopardize the very health and longevity of California's most medically vulnerable rare blood disorders residents insured by Medi-Cal.
3. All SCCs that care for Californians with rare genetic blood disorders of all ages be explicitly eligible for CalAIM proposed shared risk/savings and incentive payments as well as non-clinical interventions, such as community health workers (CHW) and care coordinators, to enhance care coordination across delivery systems and thereby address social determinants of health. Furthermore, we recommend that CalAIM require CHWs be a required care coordination service, build in adequate CHW reimbursement into contracts and require the CHW training and certification that is required of the California Department of Public Health's Newborn Screening genetic counselor educators for those disorders that are part of Newborn Screening. Rationale – see Attachment A.
    - Status per April 2021 Proposal: Recommendation not addressed.
        - The April 2021 CalAIM report is completely silent on our recommendation three. This despite the CalAIM goal of system innovation, fiscal reform, and value-based initiatives as ways to address reducing disparities.

Additional Input: **we reiterate recommendations 1-3 and add these new recommendations**:

4. Experts in rare blood disorder care from our Federal/State recognized CCS/GHPP Centers, Western States Regional Hemophilia Center Network, Pacific Sickle Cell Regional Collaborative, Networking California for Sickle Cell Care, plus our lead CBO partners, the Sickle Cell Disease Foundation, and four CA chapters of the National Hemophilia Foundation be part of stakeholder working groups that:
    - advise CalAIM on its Risk stratification methodology for rare genetic blood disorders. Rationale: the proposed risk stratification categories (low, medium and rising, high and unknown) are not diagnostic specific, input from patient

leaders and experts is needed to ensure criteria are evidence informed, and consistent across all Managed Medi-Cal Health Plans. Per Pages 27-31 of the CalAIM proposal, the individual Risk Assessment of 10-15 questions may include a metric of ED visits in the past six months. For hemophilia, where disease can be well managed at home, but where catastrophic bleeds can occur with trauma and sometimes spontaneously, how might that risk metric be tailored? For SCD, some adults get historically such poor treatment they avoid ED's even during horrific pain crises, accelerating their health status due to historic lack of access to knowledgeable care. How might the absence of ED visits as a metric be tailored for Californians with SCD? How will medication adherence to rare blood disorder therapies be assessed in CalAIM risk assessments?

- Advise CalAIM on its compliance program to ensure that monitoring, oversight, goals and metrics, audit tools specific are scientifically robust and appropriate for evaluating quality of care provided by Managed Medi-Cal Health Plans to Californians with rare genetic blood disorders. Rationale: Per Page 36 of the CalAIM proposal, eligibility for complex case management, NCQA will allow Managed Health Plans to define 'complex' in determining eligibility for complex case management. How does that flexibility enhance consistency? How will that flexibility address population needs?

Summary: Californian's with rare genetic blood disorders are among the State's most medically vulnerable populations, are among the higher users of costly healthcare services, and are at high risk very poor health and shortened lifespans. In short, they are the very populations that this new CalAIM initiative directly targets. Yet the CalAIM proposal inadequately addresses these populations' specific needs.

We look forward to continued engagement with the CalAIM stakeholder process.

Respectfully submitted,

[redacted]

Diane J. Nugent, MD
President/Medical Director, Center for Inherited Blood Disorders
Regional Director, Western States Regional Hemophilia Network
Principal Investigator, Pacific Sickle Cell Regional Collaborative
Principal Investigator, Networking California for Sickle Cell Care

[redacted]

Judith R. Baker, DrPH, MHSA
Public Health Director, Center for Inherited Blood Disorders
Regional Administrator, Western States Regional Hemophilia Network
Policy Director, Pacific Sickle Cell Regional Collaborative
Policy Director, Networking California for Sickle Cell Car

Cc: Mary Brown, Sickle Cell Disease Foundation
Marsha Treadwell, PhD and Elliot Vichinsky, MD, UCSF Benioff Children's Hospital Oakland
HRSA Western States Regional Hemophilia Treatment Centers: Center for Inherited Blood Disorders; Children's Hospital Los Angeles; Rady Children's Hospital San Diego; Guam Department of Public Health and Social Services; Hemostasis and Thrombosis Center of Nevada; Orthopaedic Institute for Children; Stanford University Medical Center; UCSF Benioff Children's Hospital Oakland; UCSF Medical Center; University of California, Davis; University of California, San Diego; Valley Children's Hospital.

Networking California for Sickle Cell Care: Center for Inherited Blood Disorders; Kern Medical Center, Loma Linda University Medical Center; Martin Luther King Jr. Outpatient Medical Center; UCSF Benioff Children's Hospital Oakland; UCSF Fresno; UCSF Medical Center; University of California, Davis; University of California, San Diego.

Western Sierra Medical Clinic
Better Health Together

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May 6, 2021

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

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

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

Dear Director Lightbourne,

Western Sierra Medical Clinic appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications.

Western Sierra Medical Clinic 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.***

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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 vender, we recommend the department delay the pharmacy transition and consider removing the transition from its waiver proposal.

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

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

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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 Western Sierra Medical Clinic 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).***

Western Sierra Medical Clinic 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.

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****

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

Again, Western Sierra Medical Clinic 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 feel free to contact me at jenniferm@wsmcmed.org.

Sincerely,

[redacted]

Jennifer Malone
Chief Executive Officer

ALCOHOL JUSTICE®
The Industry Watchdog

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

RE: "CalAIM Section 1115 & 1915(b) Waivers" - Alcohol Use Disorder (AUD) Services: Access to All FDA-Approved Medication Assisted Treatment (MAT)

To the Department:

We have concerns regarding the proposed change in language to Drug Medi-Cal – Organized Delivery System (DMC-ODS). We believe the language will continue to limit access for patients dealing with alcohol use disorder (AUD) and their health care professionals in accessing all FDA-approved forms of Medication Assisted Treatment for AUD.

Alcohol Justice brings research, policy, media, and advocacy together to mobilize coalitions that include youth, adults, and various community leaders. We organize to enact, support, and advocate for alcohol policies that keep youth and communities safe and healthy.

We recognize the Department has recently made public statements to CalAIM stakeholders supporting patient access to all forms of MAT.

However, the Department's current proposed language includes the "requirement" that "all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to, medication assisted treatment."

We recommend the Department includes simple and straightforward, patient-centered language. We have provided our recommendation below.

> ***Additional Medication Assisted Treatment***
>
> *Counties are required to cover opioid treatment program services, also called Narcotic Treatment Programs. Currently counties may elect to cover additional medication assisted treatment, which includes the ordering, prescribing, administering, and monitoring of all medications for AUD treatment.*
>
> *DHCS proposed in the 12-month extension request to keep the additional medication assisted treatment (MAT) services as an optional benefit but clarified the coverage provisions to require that all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to medication assisted treatment. For the period of this requested Waiver, DHCS proposes that additional medication assisted treatment (MAT)*

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alcoholjustice.org

services for AUD be a required benefit and is clarifying that the coverage provisions require that all substance use disorder managed care providers demonstrate that they either directly offer, or have referral mechanisms to all FDA-approved medication assisted treatments for AUD. The goal is to have a county-wide multi-delivery system of coverage.

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

Sincerely,

Bruce Lee Livingston, MPP
Executive Director/CEO
Alcohol Justice
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415-515-1856

DEPARTMENT OF HEALTH & SOCIAL SERVICES
Behavioral Health Services Division

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Memorandum

TO: DHCS CalAIM Stakeholder Feedback

FROM: Gerald Huber, Director, Health and Social Services
Sandra Sinz, Behavioral Health Director

CC: Honorable Bill Dodd, Member, California State Senate
Honorable Cecile Aguiar-Curry, Member, California State Assembly
Honorable Tim Grayson, Member, California State Assembly
Honorable Jim Frazier, Member, California State Assembly
Solano County Board of Supervisors
Karen Lange, Legislative Advocate, SYASL Partners, Inc.
Birgitta Corsello, County Administrator
Nancy Huston, Assistant County Administrator
Debbie Vaughn, Assistant Director, Health and Social Services

DATE: May 6, 2021

Solano County looks forward to implementing many aspects of system change and improvement associated with the State's CalAIM waiver proposal. The CalAIM proposal is responsive to several issues brought to the State's attention by the County Mental Health Plans.

Solano County is opposed to the DHCS proposal to end the carve-in specialty mental health benefit for Medi-Cal beneficiaries assigned locally to Kaiser. We acknowledge this is a unique carve-in in Solano and Sacramento Counties in partnership with Kaiser but also one that has worked effectively to provide coordinated medical and mental health services to these beneficiaries through the Kaiser system. We are aware of DHCS's desire for a uniform statewide approach but dismantling Kaiser's comprehensive treatment system into two, separate and distinct systems will negatively impact Solano County beneficiaries, both existing Solano County Mental Health Plan beneficiaries and those currently under Kaiser's care absent a modification of the current proposal.

In Solano County, Kaiser has 34,000 (29%) of the County's approximately 117,000 Medi-Cal beneficiaries. Kaiser's most recent estimate of the number of clients that would transfer is 2,800 beneficiaries based upon the utilization of mental health services in 2019 and 2020 (an 8% penetration rate). Solano annually serves 5,000 Medi-Cal beneficiaries; the addition of 2,800 beneficiaries is a 56% increase in caseload and is proposed without any additional funding support or recognition of the challenges in Solano County associated with hiring licensed mental health professionals and the lack of community-based contractors available to provide subcontracted services. We estimate the need for $11.1 million in new funding for the Solano County Mental Health Plan which includes increased staffing, inpatient beds, and infrastructure expansion. This estimate is based on a detailed analysis of our existing client utilization data applied to the estimated 2,800 Kaiser beneficiaries. DHCS staff provided 2011 Realignment documentation from FY2012/13 to demonstrate that Kaiser patients were incorporated into Solano County's 2011 Realignment allocation; however, the additional funding of $500,000 in State General funds added in FY2012/13 was based on Partnership HealthPlan capitation rates from 2012 at a time when Partnership's membership was approximately 63,000, nearly half of the current number of beneficiaries. There is also no data to show how the Kaiser capitation amount in FY2012/13 was calculated or the number of beneficiaries served at that time.

Additionally, the proposed transition timeline of 2,800 beneficiaries from Kaiser to Solano County effective January 2022 is not feasible. On April 27, 2020 Solano County DHCS requested a work plan between Kaiser and Solano County Mental Health Plan detailing the transition steps. On May 17, 2020, DHCS informed CBHDA that it could communicate to Solano and Sacramento counties that "there is no need for Solano and Sac counties to submit workplans by June 1,..so the counties do not worry about missing a deadline." This is the last communication from DHCS that Solano County received regarding the proposed transition.

For purposes of comparison, the Solano County Mental Health Plan typically admits (and discharges) about 1,500 individuals a year. This proposal requires a January 2022 transition date which equates to nearly two years' worth of new clients entering the County Mental Health system at once. There is no viable way for the system to expand that quickly given the resources (transition planning, staffing, infrastructure) required. With the timeline as proposed, we have grave concerns about the ability to transition care appropriately. To be feasible, the transition would need to implement in stages by transitioning smaller cohorts of clients over a timeline of 24 to 36 months.

While we believe that the Solano County Mental Health Plan provides a strong continuum of care for the specialty mental health population, we are very concerned that the service system will be quite negatively impacted by such an increase in demand and request that DHCS work with Solano County to develop an alternate proposal with adjusted timelines that can effectively support the overall health and well-being of Solano County beneficiaries .

DAY OUT
Adult Day Health Care

Comments on the Proposed CalAIM #1115 Demonstration Application

By Aimee Mattson / May 6, 2021

As a director for a Community Based Adult Services (CBAS) program I am writing to express my appreciation for the opportunity to share some insights into the value of Section 1115 Demonstration Application. As beneficiaries expand into dual eligibility, programs like ours will not have the capacity to serve some who could most benefit from our program. We need to restructure what we do, how we define delivery of service, and take a close look at the budget that would be associated with this necessary industry growth. I am writing to share ideas on solutions that could deliver a quick increase in access to / and definition of; person-centered-care. The innovation and collaboration of community resources can provide a wealth of ideas and information, and I appreciate your taking the time to sincerely evaluate the benefit of allowing them to impact the next 5 - year waiver.

I, along with industry peers, supports the CDA proposal to use the renewal of 1115 waiver through CalAIM to update the current Medi-Cal CBAS model. We have learned a lot during this public health emergency, and there is a direct connection to using what we've learned to deliver ideas for change that aligns with the goals of the Master Plan for aging; that being, to increase access to community-based programs throughout the state.

During this public health emergency, we have stayed open, working creatively to create a TAS that would continue to serve our populations via tele-health. We have learned a lot, most importantly was discovering how we could use flexibility to create a tele-health service that truly delivered person centered results. In real-time this was the definition of "meeting people where they are" and bringing services "to them". I am humbled to say that our partnership with those we serve has been deeply changed by adding the flexibility of tele-health. We are more strongly connected, serving the participant as well as their support person(s) in meaningful ways. Staying close and continuing to serve has enriched us all. We have been creative and dedicated, with strong involvement from our entire inter-disciplinary team… and we are all the stronger for it.

An important area to review is how to expedite access for CBAS services critical to immediate care needs. During TAS we learned that the most vulnerable in our population could discharge from an acute setting, and there would be an immediate benefit to have been able to access our services. Our goal is to support their greater independence, which in this case would be physical and mental recovery and being connected to good care management. The usual process can be quite lengthy, taking several weeks to complete. If they were

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within criteria guidelines (perhaps 60 days post discharge) and with skilled needs, they should be automatically eligible for enrollment in a CBAS program.

Complex challenges face these vulnerable populations, not the least of which is the fact that this population is growing faster than we can support it under the current model. There is a marked increase for those struggling daily with homeless, or the fear of pending homelessness. We need to develop a plan to support high-needs and hard-to-reach populations. We would engage in the same "whole person care" approach, allowing the results to improve their health outcomes... and stabilize their role within their communities.

Currently most managed care programs are individually supported. Our targeted populations have multiple teams delivering care; the result is a high risk of service gap as these individuals struggle to manage the complex system all on their own.

Three high goals associated with these modifications are:

1. Manage individual risk through the application of person-centered care, including steps to include the mental / social detriments of health.
2. Reduce complexity in providing care / and increase flexibility for how we define it.
3. Improved outcomes for each area identified and reduce associated health disparities.

It feels important to be proactive in developing committed partnerships NOW with our Managed Care Organizations (MCO) to ensure that we position ourselves to meet the surging interest of dual eligible transition to Medi-Cal managed care. To help address that goal we would like to see CBAS transition back to a state plan by the end of the next 1115 waiver period.

Our targeted populations face strong vulnerabilities and having clear access to services that are defined with flexibility could greatly impact their need to seek institutionalized care / services.

Thank you again for considering these opinions. Standing in the trenches day after day I assure you, what we do makes a big difference... and now we look to you in shaping what that looks like in the bigger picture.

Respectfully submitted,

[redacted]

Aimee Jo Mattson / Director

DayOut ADHC - Merced

May 6, 2021

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

VIA ELECTRONIC MAIL
CalAIMWaiver@dhcs.ca.gov

RE: California Advancing and Innovating Medi-Cal-Section 1115 and 1915(b) Waiver Applications Comments

Dear Director Lightbourne,

On behalf of Inland Empire Health Plan (IEHP), Molina Healthcare, Riverside University Health Systems (RUHS), Arrowhead Regional Medical Center (ARMC) and the County of San Bernardino Behavioral Health Department, we thank you for the opportunity to collectively comment on the proposed California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 and 1915(b) waiver applications, which we believe have the potential to completely transform the level and quality of care of those served by the state's Medicaid program, Medi-Cal.

The Inland Empire, comprised of Riverside and San Bernardino counties, is larger than 10 states and is home to more than 4 million people—of which 1.7 million are enrolled in the state's Medi-Cal program. The region's Medi-Cal program is coordinated by two managed care plans, IEHP and Molina, and is largely served by the safety net hospitals in each county, RUHS and ARMC, which play an important role in providing primary and specialty care for a large portion of the managed care patient population. We are also grateful for the symbiotic relationship that exists between the counties, health plans and safety net hospitals to collectively support the managed Medi-Cal population through behavioral health, public health and social service programs, which allows for a more comprehensive and interrelated approach to coordinating care to improve health outcomes.

Working together, we are confident that CalAIM will be the driver for transformational change in the state's healthcare delivery system. We are in the planning stages to streamline CalAIM processes, drive efficiencies and collectively improve health outcomes for the region.

We support the Enhanced Care Management (ECM) and In Lieu of Service (ILOS) programs that will improve care coordination, integrate services, and address Social Determinants of Health (SDOH), all of which will help improve health outcomes and quality of life. Working together, we are excited for the opportunity to further collaborate to carry out this important work, including the transition from Whole Person Care Pilots to ECM.

However, in order to build a meaningful foundation for this work, we respectfully request that transparent financial information (rates) be sufficient to support the person-centered care model serving our most complex Medi-Cal residents in the setting of ECM and provided as soon as possible, to allow as much lead time as possible for meaningful conversations around program design and contracting. We would also request the state, in

developing these rates, to consider financial data from counties and health plans who have modeled ECM costs to ensure there is sufficient funding to deliver the benefit in its intended form and would offer our collective experience to support the state in this regard.

We appreciate recent pre-decisional policy guidance on the target populations and would offer that data sharing will remain a challenge without clear guidance from DHCS that requires criteria data be made readily available to plans (e.g., county mental health data needed to determine SMI/SUD ECM eligibility).

We also appreciate the Department's public acknowledgment of the need for better data sharing and look forward to a single source of truth document that clarifies the department's overarching data sharing expectations for counties and plans.

We believe the ILOS program to expand available services has great potential to improve health outcomes and savings, particularly in light of the recent announcement that DHCS will eliminate the county-wide ILOS requirement in the CalAIM proposal documents, allowing plans to begin to serve members in areas with available and established providers. The geography of the Inland Empire creates unique service delivery challenges that must be considered, such as the proposed carve-in of excluded and voluntary zip codes into managed care plan responsibility. We are grateful that DHCS has made this important adjustment to earlier proposal documents.

In the Inland Empire, in addition to key county partners and providers, we will rely on many Community Based Organization (CBO) partnerships to carry out the ECM and ILOS work. While we look forward to collaborating to streamline operations for efficient program execution, including data sharing, program administration, and provider enrollment, we seek the department's support in ensuring CBOs receive technical assistance needed for provider enrollment and reporting. We request that as the department develops the CalAIM Performance Incentive Program that program flexibility and local control to build needed capacity and infrastructure be secured and assured as soon as possible to support meaningful local planning discussions.

We thank you for the opportunity to comment and look forward to engaging in these groundbreaking design and implementation discussions.

Sincerely,

[redacted]

William L. Gilbert
Hospital Director
Arrowhead Regional Medical Center

[redacted]

Jarrod B. McNaughton, MBA, FACHE
Chief Executive Officer
Inland Empire Health Plan

[redacted]

Abbie Totten
Plan President
Molina Healthcare of California, Inc

[redacted]

Jennifer Cruikshank
Chief Executive Officer
Riverside University Health System
Medical Center & Clinics

[redacted]

Veronica A. Kelley, DSW, LCSW
Director
San Bernardino County Department of
Behavioral Health

From: Jeffreyanddaly <jeffreyanddaly@gmail.com>
Sent: Thursday, May 6, 2021 11:09 PM
To: DHCS Cal AIM Waiver <CalAIMWaiver@dhcs.ca.gov>
Subject: [External]CalAIM Section 1115 & 1915(b) Waivers

Dear DCHS officials,

Please support CAADS (CA Adult Day Services) comments on the Proposed CalAIM Section 1115 Demonstration Application. We are one of the CBAS providers. We strongly suggest the following comments to be included in the CalAIM section 1115 Waiver extension application as CAADS has outlined below:

1. Adopt TAS Modalities as an Ongoing Feature.

2. Add Research Component for CBAS.

3. Define Presumptive Eligibility for CBAS to Expedite Access to Needed Care.

4. Encourage Enhanced Care Management as a Feature of CBAS and CBAS Plus.

5. Create a CBAS STCs & SOP Work Group.

6. Transition to State Plan.

There are many underserved or unserved frail elderly through out the State who needs CBAS and CBAS Plus (powered with TAS as a Hybrid program), which has been proved to be effective and efficient during the Public Health Emergency and will also be a quick way to increase access to those underserved and unserved's needs for person-center care and to be cost savings on government health care expenditures on institutional cares.

Your adoption of the CAADS proposal is very much appreciated!

Thank you!

Daly Chin, Administrator
SunnyDay ADHC/ CBAS
10530 Lower Azusa Road,
El Monte, CA 91731
Tel (626) 350-3886

Hello,

I implore you to REFRAIN from using ACEs as threshold criteria for the 1915(b) waiver. This not only halts the critical work done to acknowledge and address social determinants of health and explicitly in addressing racism and inequity, it is a dangerous and harmful retrenchment of metrics that pathologize Black and Brown and poor communities. AND it continues to enable and reify the conditions of harm and distress that DCHS claims to be committed to. The requirement of "proof of pain" to access and utilize resources and services is unjust. It is dehumanizing. It is system serving, not community-centered or caring. Please refrain.

RYSE Center in Richmond employs an integrative community mental health model, grounded in racial justice, and based on the priorities, needs, and interests identified by young people. They have shared trauma, violence, and distress as pervasive, multi-layered, and perpetuated by stigma, judgment, and punishment from the adults and systems responsible for them. RYSE understands trauma and violence as historical and structural, relational and embodied, and therefore, supports young people though culturally-rooted holistic supports and services, while also engaging with the systems and institutions responsible for their well-being.

Clinical mental health services are at RYSE provided within key praxes of restorative justice, harm reduction and healing, and trauma-informed adolescent development and leadership. RYSE had to extricate ourselves from the cage of Medi-Cal years ago because it was choking our ability to serve our young people in the ways needed and wanted, which is without diagnosis and in the modalities and platforms they chose. We spent too much time trying to contort to a system that did not try to make room for us, but which burdened us in rigid demands to prove pain in order to procure miniscule funds that keep BIPOC community providers in survival mode as well. We stay tethered, and our young people don't get rightly treated. This is what the ACEs threshold criteria will do.

Please remember that these resources belong to our communities and should be in our communities, more freely and flexibly. If the ACEs threshold is put into place with 1915(b) waiver, the chokehold of compliance and control will only become tighter.

Please refrain,

Kanwarpal Dhaliwal
Associate Director
pronouns: she/her

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c: 510.579.1922

205 41st Street
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www.rysecenter.org

*** Please note, RYSE will be working remotely until further notice, visit our website for a list of virtual programming and resources ***

A Public Entity
Inland Empire Health Plan

May 6, 2021

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

VIA ELECTRONIC MAIL
CalAIMWaiver@dhcs.ca.gov

RE: California Advancing and Innovating Medi-Cal-Section 1115 and 1915(b) Waiver Applications Comments

Dear Director Lightbourne,

On behalf of the Inland Empire Health Plan (IEHP), I thank you for the opportunity to comment on the proposed California Advancing and Innovating Medi-Cal (CalAIM) Section 1115 and 1915(b) waiver applications, which we believe have the potential to completely transform the level and quality of care of those who served by the state's Medicaid program, Medi-Cal. As you may be aware, IEHP is one of the ten largest Medicaid health plans and the largest Medicare-Medicaid Plan in the country. Guided by our vision to never rest until our communities enjoy optimal care and vibrant health, IEHP believes that the provisions of CalAIM will be the driver for transformational change in the state's healthcare delivery system and will allow IEHP to fulfil that vision for the Medi-Cal beneficiaries we serve. Additionally, IEHP believes that CalAIM has the potential to raise the quality of care for all patients as well as the expectations and standards for health plans operating across California. Without question, IEHP fully supports CalAIM and is working diligently to prepare to implement the provisions of the proposal which are applicable to our plan.

In the spirit of IEHP's commitment to CalAIM we offer the following recommendations and considerations that we believe will better position the state and plans to successfully implement CalAIM.

MEDI-CAL MANAGED CARE SYSTEM CHANGES

1. Enhanced Care Management (ECM)

IEHP supports the proposed ECM program as it aims to improve care coordination, integrate services, and address Social Determinants of Health (SDOH), all of which have the goal of improving member health outcomes. In line with the technical recommendations IEHP submitted to the Department on March 12, 2021, we cannot overstate the need for DHCS to allow health plans the maximum flexibility possible to design and implement their respective ECM programs. We would also reiterate our deep concern around the lack of financial information, rates, needed to frame up our programs, realize our model of care and begin contract negotiations with partners and emphasize the importance of

realistically aligning the criteria used for rate setting and the criteria used on the programmatic side for each of the various populations of focus, these two components must be coupled.

We appreciate recent pre-decisional policy guidance on the target populations and would offer that data sharing will remain a challenge without clear guidance from DHCS to require that criteria data be made readily available to plans, i.e., county mental health data needed to determine SMI/SUD ECM eligibility.

In areas without robust Primary Care Provider networks and many single PCP offices, IEHP is confident that plans like ours have the internal staff to effectively serve as ECM Providers. IEHP is locally rooted in our community and many of our staff have extensive experience in direct member service, including staffing 10 Health Homes Care Teams, and therefore would request the flexibility to leverage plan resources for these purposes, including the use of telehealth to reach beneficiaries in the state's most rural areas.

2. In Lieu of Services (ILOS)

Historically, IEHP has been proud to champion the provision of wraparound services, beyond required plan benefits to our members, as we have long recognized the importance of a whole person-centered approach to care. IEHP believes that the ILOS program has great potential and we are very pleased to hear the recent announcement that DHCS will eliminate the county-wide ILOS requirement in the CalAIM proposal documents.

IEHP enjoys close partnerships with a host of Community Based Organizations (CBOs) who serve our two-county region, many of these organizations operate only in portions of our region and even in those areas, transitioning to effectively operate as a state ILOS provider will take time and technical guidance. IEHP would welcome the Department's assistance in ensuring that CBOs are successful and can meet provider enrollment and service delivery requirements.

While it is our intent to do all that we can to expand our ILOS provider network, the reality is that it will take time, especially in the existing rurally-excluded territories that CalAIM will carve-in to plan service area responsibility, which for our plan will include areas that represent some of the most rural parts of our two-county region, with limited resources. The geography of the Inland Empire, larger than 10 states, creates unique service delivery challenges that may not exist in other areas of the state that must be considered and for these reasons we are very appreciative of the DHCS accepting our earlier recommendation to allow us to provide ILOS where we can, with the goal to expand throughout the region.

3. Expanding Access to Integrated Care for Dual Eligible Californians

IEHP is proud to have the largest Medicare-Medicaid plan in the country and recognizes the need for greater integration of care for the dual population statewide. IEHP is working diligently to develop a new IEHP D-SNP to supersede our CMC plan and have identified and offer the following recommendations for a successful transition.

IEHP encourages all efforts be made to allow for the passive enrollment of Medicare FFS beneficiaries into Medi-Cal aligned D-SNPs to ensure the least amount of disruption for members. We also encourage all efforts be made to enroll dual eligible beneficiaries into the D-SNP plan that is aligned with their Medi-Cal benefits for care coordination to achieve greater health outcomes. From our CMC experience, this is important to support the dual eligible population as it allows plans to leverage and coordinate the care and resources provided by both Medicare and Medicaid, eliminating fragmented care.

IEHP recommends that DHCS ensure that aligned enrollment for dual eligible beneficiaries remain at the prime plan level to ensure that any delegation of D-SNP services only be allowed with the coordination of the aligned Medi-Cal plan. By mandating that enrollment occur with the Medi-Cal plan, greater coordination of care and visibility into a beneficiary's condition can be provided and maintained.

Lastly, recent CMS actions have demonstrated, too often D-SNP "look-alike" plans are enrolling dual eligible beneficiaries by claiming that their offerings provide better care; regrettably, these claims are often unsubstantiated much to the detriment of beneficiaries, and so much so that CMS is now taking concrete steps to phase out these "look-alike" plans. IEHP supports the state's efforts to do the same, sunsetting existing contracts and not entering into new contracts with D-SNPs that are not directly contracted with Medi-Cal managed care plans.

4. Major Organ Transplant Carve-in to Medi-Cal Managed Care

Scheduled to be carved-in to managed care plans on January 1, 2022, IEHP is working diligently to coordinate the care for our members that may need major organ transplant (MOT) services, that are currently provided through the Medi-Cal FFS delivery system. IEHP is fortunate that our service area (as well as adjacent areas), include several transplant Centers of Excellence and/or Specialty Care Centers that provide MOT services. We appreciate the foresight of DHCS to stipulate in draft trailer bill language that MOT providers accept FFS rates for services even after the services are transitioned to managed care. However, IEHP's preparation continues to face challenges due to the lack of utilization data and costs for these services within the FFS system. This data is critical to understanding the financial resources needed to ensure a successful transition. In addition, while we appreciate the deference to FFS rates for MOT services, often these services can incur travel, meals, and lodging costs which are not reflected in existing FFS rates. Therefore, IEHP would recommend that DHCS consider allowing the provision of meal and lodging costs associated with MOT services when overnight stays are required.

5. Reconsideration of Pharmacy Drug Managed Care Carve Out (Medi-Cal Rx)

CalAIM seeks to standardize benefits and breakdown the operating silos within the Medi-Cal program and IEHP remains concerned that carving out the pharmacy benefit could have the direct opposite impact, as it would construct an additional silo within the system. Additionally, with recent developments surrounding the pause to the carve-out (Medi-Cal Rx) implementation and uncertainty around the stated fiscal savings, coupled with existing concerns regarding care coordination, and member satisfaction, IEHP's concerns about the carve-out's promise and feasibility have escalated.

At IEHP, we believe, the provisions of CalAIM ECM/ILOS will rely on the pharmacy benefit remaining with the plan and, minimally, recommend the DHCS integrate Comprehensive Medication Review, Targeted Medication Review, and regularly scheduled Medication Reconciliation into a plan's ECM/ILOS program.

IEHP continues our request that DHCS reconsider further advancement of Medi-Cal Rx and instead, in partnership with plans, providers, and patients, consider alternatives to a full carve out, that would still allow the state to flex the Medi-Cal prescription drug buying power, while allowing plans to retain the clinical management of the benefit, ensuring the benefit is fully leveraged particularly as part of ECM/ILOS to ensure the best health comes for beneficiaries.

6. Behavioral Health

IEHP applauds the Department for efforts to enhance and improve access and quality of care for mental health and substance use disorder services for Medi-Cal beneficiaries as part of the CalAIM proposal. With the responsibility of coordinating mild-moderate mental health services for Medi-Cal members in our region, IEHP recognizes that a patient cannot truly be cared for unless both their physical and mental health conditions are addressed and support approaches to care that address the "Whole Person" and are pleased that CalAIM and the proposed waiver requests also subscribe to this position. We thank the Department for language in the proposed 1915(b) waiver that would provide needed clarification on the treatment of co-occurring conditions.

IEHP supports the intent of the CalAIM proposal to develop and implement a universal screening and transition tool for MCPs and counties to determine the appropriate services needed to treat a patient's mental health needs and look forward to further engaging to ensure the tools are appropriately tested and their application is understood by plans, counties, and the clinical and nonclinical staff tasked with their use.

The proposal to develop and implement a "No Wrong Door" requirement for children and adults who seek to receive mental health services, regardless of whether they present to a county mental health plan or to their managed care plan is so important to IEHP. We appreciate DHCS working to ensure that managed care plans and counties understand their respective administrative and financial responsibility for specific Specialty Mental Health Services, including Intensive-Out Patient, Partial Hospitalization, and services to treat eating disorders.

IEHP cannot underemphasize the need for additional guidance around the need for mandated data sharing for care coordination between managed care plans and county mental health plans. We appreciate the Department's acknowledgment of this issue and look forward to a single source of truth document that clarifies the Department's overarching data sharing expectations for counties and plans, and a commitment to seeking any statutory changes in state and/or federal law that would further affirm data sharing requirements under the Medi-Cal program.

7. Services for Justice-Involved Populations 30-day Pre-Release

IEHP supports the CalAIM proposal that would provide targeted Medi-Cal services to eligible incarcerated individuals 30 days prior to their release. While we understand that the initial work on this effort may initially reside with counties and the justice system, IEHP welcomes the opportunity to engage with DHCS directly and as part of the Department's Justice-Involved Population workgroup. It is our hope that these collective efforts will address key issues with the proposal, particularly in regard to early plan choice and data sharing protocol to identify needs upstream, and initiate referrals, and/or resources to address SDOH for those exiting incarceration. IEHP also requests review of the process and timeliness by which justice involved individuals receive Medi-Cal upon release. This would best position plans to serve these individuals when they become enrolled in our plan. We are also appreciative of early and ongoing engagement efforts with plans in counties transitioning Whole Person Care pilots serving this population.

8. Continuance of the Community-Based Adult Services Program

IEHP commends and thanks DHCS for their wisdom in choosing to continue the state's Community-Based Adult Services (CBAS) program which has become a foundational component to the state's Long-Term Services Medi-Cal benefit. Providing services such as mental health and personal care services, physical and occupational therapies, and nursing services, CBAS centers have transformed the lives of thousands of seniors in the state by allowing them to remain in their homes and their communities rather than being unnecessarily placed in more expensive institutional care facilities.

9. Deferment of Other CalAIM Programs/Provisions

While IEHP understands the decision to push out other provisions of the CalAIM initiative to 2023 and beyond, specifically those programs surrounding Population Health Management and Full Integration Health Plans, IEHP recognizes that the current system of care for physical, mental, and substance use disorders is complex and fragmented, which creates significant challenges for Medi-Cal Members and Providers. IEHP is open to exploring pilot models of full integration, in partnership with our counties and DHCS, to ensure that any potential design and implementation are effectively positioned to maximize the health outcomes for the members we serve, and Medi-Cal beneficiaries statewide.

IEHP truly thanks the Department for the thoughtful approach to CalAIM and appreciates the opportunity to comment on the waiver proposals. We look forward to working with you to implement CalAIM. If you have any questions, please contact me at (909) 890-2010 or mcnaughton-j@iehp.org.

Sincerely,

[redacted]

Jarrod B. McNaughton, MBA, FACHE
Chief Executive Officer
Inland Empire Health Plan

May 6, 2021

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

RE: CalAIM CMS Waiver.

Dear Director Lightbourne,

This commentary focuses on the changes proposed to the behavioral health care system in the 1915(b) Waiver proposal and how they impact children and youth. Even though the proposal has many positive components, I believe that if left unchanged, it will not improve, and will possibly decrease access to behavioral health care for children and youth in California.

My comments come from my career of serving low-income children as a primary care pediatrician in an integrated safety net system, from my 15 years of experience as the pediatric quality director for a Medi-Cal Managed Care Plan, and from my 4 years as the chairperson of the AAP Chapter 1 Mental Health Access Committee. All of these experiences have influenced my conclusion that Medi-Cal enrolled families face tremendous barriers in accessing necessary behavioral health services for their children and youth. A Chapter 1 survey that we did revealed that almost all pediatricians agreed with this conclusion - only 13% of Chapter 1 pediatricians responding to a 2018 survey felt that their patients had appropriate access to mental health services. Providers on our mental health committee regularly report wait times of 6 months for their patients to access specialty behavioral health care.

My own experience tracking physician referrals for behavioral health services when I worked for the Medi-Cal managed plan showed that less than 50% of referred children and youth ever received any necessary care. Every week, I would track high-risk patients who had been referred to the managed care plan for behavioral health services, usually after the medical provider completed an assessment and validated questionnaire, such as the PHQ9. The barriers were many, and involved problems with both providers and patients, however it was very clear that a follow-up phone call from a health plan asking vulnerable patients to once again reveal their most sensitive information in order to "assess" their needs was not an effective response to the referral. Those patients who completed the phone assessment were frequently lost to follow-up after having been given the phone numbers of therapists that may be accepting referrals and told to arrange care that in reality wasn't available because of long wait times. Oftentimes, services were not provided to the patient until a subsequent additional referral was made or a mental health crisis was documented in the school or emergency room.

My concerns focus primarily on the waiver's lack of solutions to the problems of inadequate access to the behavioral health system. If I refer a child with a heart murmur to a cardiologist, the visit would be authorized in a timely manner. I do not have to do an EKG or exercise testing or 4-limb blood pressures to prove that they need to see the cardiologist; the health plan doesn't require a phone assessment before authorizing the appointment with the specialist. With behavioral health, we should have easy access for children and teens to be assessed and begin treatment in a timely manner. This is required by law, but somehow never implemented by DHCS.

Specific concerns and recommendations regarding the waiver are:

Eligibility for Behavioral Health Services

The draft proposal uses unclear criteria to define which children and youth should receive behavioral health services. In compliance with Federal EPSDT regulations, DHCS states that children and youth are eligible for services if an "appropriate" clinical provider determines that behavioral services are needed to prevent, diagnose, or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards. They do not clarify who is an "appropriate" clinical provider, yet EPSDT rulings have determined that if a competent medical provider finds specific care to be "medically necessary" to improve or ameliorate a child's condition, services must be covered. Without clarification of "appropriate", children and youth may not qualify for services until they undergo a secondary assessment of the need for care.

The guidelines should clearly state that when a primary care provider or licensed behavioral health provider determines that services are necessary and submits or makes available documentation that substantiates that eligibility, the child or youth is eligible for behavioral health services.

Timeliness of Behavioral Health Services

The draft proposal does not clarify the process for receiving behavioral health services within the DHCS-required timely access to care standard of 10 business days from the date of the request for a nonurgent appointment and 48 hours for an urgent appointment. This is a critically important issue because past policies and practices, lack of workforce capacity, and unclear responsibilities of the behavioral health systems upon referral have resulted in substantial delays in receipt of care. The proposal does state that "Medi-Cal Managed Care Plans are required to provide nonspecialty health services to beneficiaries under the age of 21. Medi-Cal Managed Care Plans are also responsible to provide mental health services to beneficiaries with potential mental health disorders not yet diagnosed."

The proposal should state that the Medi-Cal Managed Care Plans (MCP) are responsible for assuring that the timely access standard is met for all referrals for service unless the patient has previously received services in the County Mental Health Plan's (MHP) specialty mental health system. The MHP is responsible for assuring access to timely care for previous enrollees who received specialty mental health care in any County mental health plan, regardless of location.

Eligibility for Specialty Mental Health Services through County Mental Health Plans

The draft proposal specifies that beneficiaries under age 21 are eligible to receive specialty mental health services if they meet particular criteria (See Attachment 2 in the proposal) Many of the proposed criteria have not been well-defined to date as they relate to children and youth, especially "experiencing trauma" and "significant impairment". The trauma criteria mentions "scoring in the high-risk range on a DHCS-approved trauma screening tool", which implies that an isolated score of 3 or 4 on the PEARLS screen would make the child eligible for specialty mental health services. Although most pediatricians and researchers would agree that trauma experience makes mental health disorders more likely, few would agree that a high-risk score without other co-existing mental health or behavioral concerns would justify the receipt of specialty mental health services. The impairment criteria should also specifically state that significant changes in school performance or school absenteeism is an indication of impairment.

DHCS should develop a workgroup, including California AAP to assist in developing and validating a tool that assesses the proposed criteria in an evidence-based framework and clarifies the role of trauma-screening in determining Specialty Mental Health eligibility.

Initial Intervention services

The CalAIM proposal states there should be "No Wrong Door" for entry to care and that reimbursement and services can be offered before a diagnosis is clearly established, yet DHCS does not clarify how nonurgent services are provided in a timely manner or which system pays for the interim services. The behavioral health workforce shortage makes it impossible for MCPs and MHPs to obtain the information needed for a referral and arrange a continuity behavioral health provider within 10 business days, let alone complete a baseline evaluation to determine the needs of the patient. The proposal should specify a plan for delivering initial intervention services for non-urgent referrals, either through the primary care provider, the referring behavioral health provider or a member of a pool of behavioral health providers incentivized and available to deliver care to children and youth in a timely manner. Some plans would need to authorize the services with the behavioral health provider or primary care provider, possibly through contract arrangements with local education agencies and medical providers. Specifications regarding the content of brief initial intervention services, along with credentialing to deliver these services to children and youth would need to be developed.

The proposal should state that an appointment for initial intervention services should be provided within 10 business to support the child/youth and complete the evaluation for new nonurgent referrals if a continuity behavioral health provider is not available. The Medi-Cal Managed Care Plans (MCP) are responsible for providing initial intervention services for patients who have not previously received care in the County Mental Health Plan until an evaluation has been completed and an appointment is made with a continuity provider. The MHP is responsible for providing initial intervention services for nonurgent referrals to enrollees who had previously received specialty mental health care in any County mental health plan, regardless of location. California AAP would be willing to partner with DHCS in developing content and credentialing for nonurgent initial intervention services.

Support of Preventive Services

Federal EPSDT funding covers preventive services as well as therapeutic services for children and youth, however DHCS has not proposed funding services targeted specifically towards behavioral health early intervention and prevention.

DHCS should propose implementation of statewide preventive services through the EPSDT funding stream, such as enhanced school-based services working in partnership with mental health and primary care providers, enhanced implementation of integrated behavioral health in primary care practices, and enhanced dissemination of dyadic care for parents and young children in need of support.

Thank you for your efforts to improve behavioral health care. I hope that these policy recommendations will support DHCS and instigate improvements in this proposal.

Sincerely,

Diane Dooley MD, MHS, FAAP
Associate Clinical Professor
UCSF School of Medicine
Chairperson, AAP Chapter 1 Mental Health Committee

California Coalition for Youth

TO: Will Lightbourne, Director, California Department of Health Care Services;
Dr. Mark Ghaly, Secretary, California Health and Human Services Agency

FROM: Levi Deatherage & Jevon Wilkes, The California Coalition for Youth

SUBJECT: CalAIM Waiver Proposal

DATE: May 6, 2021

On behalf of The California Coalition for Youth (CCY), we are submitting these comments in response to the CalAIM Waiver Proposal, led by the Department of Health Care Services (DHCS).

CCY is a thirty-nine-year-old grassroots non-profit organization located in Sacramento that, as a statewide coalition, takes positions on and advocates for public policies, programs and services that empower and improve the lives of all California's youth ages 12-24, with a strong focus on disconnected, runaway and homeless youth.

We have a lot to say about the complex maze that youth navigate, often at their most vulnerable moments, to get mental health services. And, if a youth manages to figure out the maze, dire workforce shortages often make it impossible to be served. This doesn't even take into account the impacts of the pandemic we've endured. The experience of navigating and trying to get access to services is, in itself, traumatic...trauma on top of trauma. We must present youth with the opportunity to heal, restore, rebuild, and thrive from the immense trauma they have experienced in their lives.

We want to commend DHCS on its intention to reform Medi-Cal through the CalAIM Waiver process. We also feel it is our responsibility to California's youth to voice serious concerns about several critical shortcomings of the CalAIM waiver proposal, which if left as is, will hinder this opportunity of rebuilding trust in a system that cares by lifting up the voices of youth beneficiaries as experts in their well-being.

"No wrong door" must mean all entry points are accessible, available, and welcoming.

We appreciate the proposal's focus on the relationship between Managed Care Organizations (MCOs) and county-run Mental Health Plans (MHPs) and their shared role in providing youth mental health services. Young people receive services in both systems and it's critical that there is improved access to both -- which is why we like DHCS' vision of no wrong door. But as written, there can still be a wrong door between these two systems. For example, if certain parts of the system leave room for local interpretation, then there will be discrepancies and inconsistencies around access. Also, long-standing workforce shortages, if unaddressed, will continue to plague the system and miss the opportunity to serve our most vulnerable and at-risk youth.

You finally identify a program, which claims they can help. Yet, when you arrive, the hope, which you struggled to develop and maintain in the first place, is quickly dashed upon hearing "you need document A,B,C,and D." You leave dumbfounded, aghast, and truly discontent, and won't seek out help again for a long-time. These are the barriers to be addressed. If a young person is eligible for Medi-Cal, it shouldn't be on them to provide more than a benefit card, at most. It should be on the system to figure out the backend and payment mechanisms as well as ensure the backend does not result in less providers participating in the system. If we do not, as a community, declare it an absolute necessity for easier access to mental health services. Then, we surely have left our future leaders, dreamers, and champions up the creek without a paddle.

When youth, or their families, reach out to access behavioral health services in Medi-Cal, it has likely taken them significant emotional effort just to ask for help. To create additional "doors" that have to be opened means more time, more questions, and the chance that there will be a wrong door as well as more opportunities for the individual to, frankly, give up and stop seeking services.

Let youth decide the level of our trauma -- in our own time and in our own way -- don't give us a "score"

The population we serve is truly one of the most vulnerable, but also one of the most resilient and impressive demographics our society has, many of whom have already fallen through cracks, been overlooked for required screenings and interventions -- the system has already failed many young people by this age. Screening tools that assign "trauma" scores and require "high scores" to see what services a young person can receive aren't a solution. No young person wants another "score" to tell them they weren't good (or severe, in this case) enough to receive access to needed services. Diagnoses that label and pathologize aren't a solution either. These simply perpetuate systemic racism and stigma.

Young people, and their support systems (be it family, relatives, peers), should be able to determine whether their experiences rise to the level of needing support without the use of an often, re-traumatizing screening tool. The system needs to be able to figure out a way to prevent young people from having to retell their stories over and over again to get care. Shouldn't their willingness to receive care, be enough to qualify them to receive care.

The workforce needs to be bigger and more like us -- youth are becoming peer support specialists and are eager to be a part of the mental health workforce.

The waivers do not address the workforce diversity or shortage problem in the Medi-Cal mental health system. This is a critical omission. What is the point of improving access if there are no available or culturally appropriate providers? We should be expanding the roles of peer support specialists and community health workers, investing in youth centered training and utilize peer-to-peer volunteers as a workforce pipeline, working with community colleges and other vocational pipelines to pave the way for people of color and those with lived experience to participate in the workforce needed by our mental health system.

We applaud the focus on homeless youth, and we must make sure at-risk youth receive the same level of support before having to experience homelessness.

The 1915(b) CalAIM waiver removes the need for a diagnosis for access to Specialty Mental Health Services (SMHS) for youth experiencing homelessness - we applaud this and are internally grateful! Same with youth in the child welfare system. While this will impact roughly 300,000+ children experiencing homelessness or in child welfare, it leaves out the remaining 5 million plus youth and children in Medi-Cal. It must go farther to eliminate access gaps for Black, Indigenous, and children of color who experience greater levels of ACES and whose families disproportionately experience compounding stressors and social determinants of health that put them **at risk for** involvement with the child welfare, juvenile justice systems, and homelessness. We must intervene before it gets to this point.

Thank you for the opportunity to weigh in on the CalAIM Waiver Proposal. This is a critical moment to positively address the systematic racism of the current system, with the opportunity to get it right for all youth. For a true California for ALL.

Sincerely,

Jevon Wilkes
Executive Director
California Coalition for Youth

Levi Deatherage
CCY Board Member, Vice Chair of Youth
Program Manager, Open Arms Youth Drop-In Center
Family Assistance

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May 6, 2021

To Director Will Lightbourne and the broader DHCS,

We write to you as child psychologists and research experts in the study of childhood adversity and resilience, advocating for effective and responsive behavioral healthcare. We are the Director and Assistant Director of the UCSF Division of Developmental Medicine, housed in the Departments of Pediatrics and Psychiatry and Behavioral Sciences.

While the initial CalAIM proposal offered ambitious, tangible, and critically needed changes for specialty mental health care for children and their families, language in the 1915(b) Waiver appears to overturn key aspects of these advancements. We assert that these erosions of the original CalAIM proposal will lead to perpetuation of a broken system of services for vulnerable families in our state. The science of healthy early childhood development and the services that promote it clearly demonstrate that behavioral health is an *essential* support for healthy development, not a response to pathology. To address these concerns and promote lasting family wellness, we urge timely revision of the proposal in the following manners:

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 request for support from a beneficiary, regardless of screening score, 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 cannot be stopped or interrupted until or if there is a transition in care.

3. Provide the public with answers to questions about the potential risks related to moving county mental health plans from a Certified Public Expenditure (CPE) methodology to Intergovernmental Transfer (IGT).

Thank you for reading this letter and considering these revisions. We believe that with concerted effort, the CalAIM proposal will make significant strides to meet the mental health needs of California's children and families.

In partnership,

[redacted]

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COMMUNITY CLINIC ASSOCIATION OF LOS ANGELES COUNTY

Member Driven. Patient Focused.

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 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne:

The Community Clinic Association of Los Angeles County (CCALAC) appreciates the opportunity to comment on the proposed Section 1115 CalAIM and Section 1915(b) Waiver Amendment and Renewal Applications. CCALAC represents 64 nonprofit community clinics and health centers that operate more than 350 sites and serve approximately 1.7 million low-income uninsured, and underserved individuals every year throughout Los Angeles County.

Collectively, the Section 1115 CalAIM demonstration and Section 1915(b) waiver, along with Medi-Cal State Plan changes, will enable full execution of the CalAIM initiative. Health centers are the backbone of the safety net delivery system in California and we stand ready to partner with the Department of Health Care Services (DHCS) and our local health plans to implement the extensive changes included in the CalAIM proposal and improve the delivery of services for millions of Californians. CCALAC commends the Administration's commitment to implementing CalAIM and we thank you for previous and ongoing stakeholder engagement around the proposal. We would like to take this opportunity to raise some broad concerns and recommendations associated with the waiver proposal.

CCALAC echoes the comments of our partners at the California Primary Care Association in urging DHCS to consider the following:

- Continue to delay the transition of pharmacy benefits from managed care into FFS. Consider removing the pharmacy transition from the waiver proposal.
- Clarify how medically necessary services can be provided and billed prior to a complete SMH/SUD assessment.
- Apply network adequacy, quality and access, and clinical performance standards to county behavioral health plans.
- Ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).
- Make certain the public has opportunity to review and comment on all policy changes.

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T (213) 201-6500. www.ccalac.org

Detailed Recommendations

1. **Continue to delay the transition of pharmacy benefits from managed care into FFS and consider removing the pharmacy transition from the 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. We urge DHCS to act quickly to further 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 contracted vendor, we recommend the department act now to further delay the pharmacy transition and consider removing the transition from its waiver proposal.

2. **Clarify how medically necessary services can be provided and reimbursed prior to a complete SMH/SUD assessment.**

The waiver proposal intends to ensure that beneficiaries receive the care they need no matter how they enter the system and where they are in the system. Currently, specialty mental health (SMH) and substance use disorder (SUD) 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 this reason, we applaud the Administration's proposal to allow treatment during the assessment period and the "no wrong door" approach that will ensure providers' ability to render necessary medical services to patients. We have questions, however, regarding how providers can comply with, and bill for, those services if they are not contracted with the county to provide such services. Health centers are often a patient's entry point into the SMH/SUD system, yet few health centers are contracted providers with their county's SMH/SUD 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. We ask DHCS to provide clarity around the intent and processes for non-contracted providers rendering medically necessary services prior to an assessment.

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

The Cal AIM proposal will integrate county specialty mental health (SMH) plans and Drug Medi-Cal Organized Delivery Systems (DMC-ODS) 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 encourage DHCS to ensure that counties throughout the state are prepared to adequately meet the demand for services and that patients/families can be assured they are receiving high quality care. Specifically, 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 the two separate programs is consolidated. Thus, while we support the intent of integrating these system components, DHCS must put in place safeguards and oversight to ensure access to timely, high-quality, and culturally and linguistically appropriate SMH/SUD services in all regions of the state.

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

CCALAC is pleased to see the inclusion of Enhanced Care Management (ECM) and In-lieu-of Services (ILOS) in the CalAIM waiver proposal and we continue to engage in stakeholder processes to provide input on these important changes. We urge the Administration to hold firm to its commitment to ensure adequate funding is allocated for these services in the state budget. To ensure successful implementation of these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to implement these changes. We are encouraged by the inclusion of the Providing Access and Transforming Health Supports, which is necessary to transition existing services and build capacity, including payments for workforce and infrastructure. Resources and support are also needed to ensure adequate and accurate data exchange, establish payment relationships, measure value and outcomes, and ensure beneficiaries remain at the center of care. Several program elements will likely impact current health center operations and infrastructure, specifically the implementation of new care management systems and process, new referral processes, new claim submission process, new patient assignment process and more. These changes, while positive in the long-run, will be resource intensive to implement. To ensure success, the Administration and DHCS must make available robust resources and support to ECM and ILOS providers, including health centers.

5. **Ensure the public has opportunity to review and comment on policy changes that are mentioned in the waiver proposals, but are not described in detail in those documents.**

While we appreciate the opportunity to comment on the 1115 and 1915(b) waivers and expect DHCS will release details of related 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.

The safety net health care delivery system continues to be on the front lines in COVID-19 response and vaccination efforts. Given the challenges of the past year and continued focus on COVID-19, we are concerned that the January 1, 2022 implementation date is incredibly ambitious. Ensuring successful implementation, and avoiding disruption to current operations, will require a thoughtful and measured approach, with a focus on transparency and ensuring adequate resources and supports for providers.

In conclusion, CCALAC appreciates this opportunity to submit comments on the waiver proposals. We look forward to working with you to implement these major changes and continuing to provide input and feedback throughout the process. Please contact me with any questions.

Sincerely,

Louise McCarthy
President & CEO

445 S. Figueroa Street, Suite 2100 Los Angeles, CA 90071
T (213) 201-6500. www.ccalac.org

CHEAC
Improving the Health of all Californians

May 6, 2021

Via Email: CalAIMWaiver@dhcs.ca.gov

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

Dear Director Lightbourne:

The County Health Executives Association of California (CHEAC), representing local health departments throughout our state, appreciates the opportunity to comment on the Department of Health Care Services' (DHCS) California Advancing and Innovating Medi-Cal (CalAIM) initiative.

Population Health Management

CHEAC appreciates the department's interest in improving the health of all Medi-Cal managed care beneficiaries by requiring health plans to adopt a population health management strategy. The pandemic has shined a light on the disparities that exist across the state, and CHEAC strongly encourages DHCS to leverage the lessons learned by incorporating public health knowledge and expertise in the creation of population health management strategies. These strategies should not be solely focused on an individual's health condition but should also incorporate local health department epidemiological data and expertise, such as the disease burden for certain zip codes and ethnicity groups and community health assessments conducted by local health departments. As such, CHEAC requests that managed care plans be required to contract with local health departments to leverage public health data and expertise to support better health outcomes and reduced health disparities.

Enhanced Care Management

CHEAC supports the requirement that managed care plans contract with counties to leverage existing knowledge and expertise from Whole Person Care pilots in the administration of enhanced care management/in-lieu of services. Counties have expertise case managing other populations that would fall under the enhanced care management benefit including children currently being served by the California Children's Services Program in non-Whole Child Model counties and individuals served through targeted case management. CHEAC would urge DHCS to require plans to contract back with counties to support continuity of care and retain the crucial expertise.

Oversight and Monitoring of CCS and CHDP

While local health departments are not opposed to enhanced oversight and monitoring of local administration of California Children's Services (CCS) and Child Health and Disability Prevention (CHDP) programs, it is critical that this process is developed in consultation with counties. CHEAC has submitted proposed modifications to the Administration's trailer bill language requiring the department to consult with stakeholders, including counties, to: 1. Review and recommend changes to current state and federal standards, policies, and guidelines; 2. Recommend statewide performance, reporting, and budgetary standards, and auditing tools; 3. Evaluate fiscal resources needed to adequately ensure CCS and CHDP compliance; 4. Determine the process for initial and ongoing updates to policies, guidelines, standards, and performance and compliance requirements; 5. Determine the method for conducting periodic quality assurance reviews and audits; and 6. Recommend a process of providing technical assistance to counties when performance is consistently below expectations and create a continuous improvement process in lieu of penalties.

For oversight and monitoring to be successful, the state must outline clear roles, expectations, and standards that all entities serving these children and families should be held to, including the state, managed care plans, and counties.

Services for Justice-Involved Populations 30-Days Pre-Release

CHEAC is supportive of expanding Medi-Cal services to incarcerated individuals. In many local jurisdictions, local health departments administer medical services within the jails and as such, we look forward to additional details related to this proposal and in the meantime have questions related to what local entity is facilitating providers to conduct the in-reach, even if through tele-health. We also would ask whether the state is assuming the incarcerated individuals would be a plan member during the 30 days before release or if the assumption is that everyone receiving these services would be fee-for-service.

Despite best efforts, we anticipate a significant fee-for-service population given it takes 30 days to enroll in a plan and it is not clear how a handoff to a managed care plan would happen. We also have questions around the logistics of ensuring that services an incarcerated person may need off-site through the Medi-Cal Inmate Claiming Program will continue to be available during their last 30 days of incarceration.

CHEAC recommends DHCS engage various stakeholders through a working group, with local health department representation, to further flesh out the proposal.

Dental Transformation Initiative (Domain 4)

Domain 4 of the Dental Transformation Initiative was the Local Dental Pilot Projects (LDPPs), created with the goal of increasing dental prevention, caries risk assessment and disease management, and continuity of care among children in the Medi-Cal program. The 13 Local Dental Pilot Projects (LDPPs) provided much needed services within their communities, including oral health education and dental care coordination. These projects have additionally increased the provider network, established dental homes in community-

based settings, and provided resources for Medi-Cal-enrolled children and their families. Many of these children—who are overwhelmingly children of color and low-income children—are now in crisis because of the COVID-19 pandemic and its disparate impact on low-income families.

Unfortunately, due to delays in implementation, LDPPs have not had the opportunity to realize the full impact of the pilots. However, because of the critical services these local dental pilot projects provide, CHEAC requests that Domain 4 be included in the CalAIM submission.

Again, we appreciate the hard work of the department as you embark on transforming the Medi-Cal delivery system and appreciate the opportunity to provide comments.

Should you have any questions regarding our comments, please feel free to contact me at mgibbons@cheac.org or (916) 327-7540.

Thank you,

Michelle Gibbons
Executive Director

Thank you for the opportunity to comment on the renewal application. I wanted to specifically call out the section related to the Global Payment Program (GPP, Section 3.1). It is laudable that one of the goals of the GPP is to "Encourage the use of primary and preventive services" and that it "addresses social needs and responds to the impacts of racism and inequities on the uninsured populations" that are served by public hospital systems. It is crucial that Medi-Cal include tobacco cessation as a key component of the GPP. Tobacco is one of the leading preventable causes of morbidity and mortality. The State of California Tobacco Education and Research Oversight Committee (TEROC) recently released its 2021-2022 plan for tobacco control in California (https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/Pages/TEROCMasterPlan.aspx), and in it notes that "Medi-Cal insures over 600,000 people who smoke. Medi-Cal covers half of the state's smokers with chronic disease and nearly three fifths of those who experience severe psychological distress. The program spends approximately $3.58 billion annually on tobacco-related health care while receiving about $1 billion annually from Proposition 56. Proposition 56 funds come entirely from tobacco users and impacts those with limited financial resources the most." While Medi-Cal has recently conducted important innovations to improve its tobacco cessation efforts, TEROC has several recommendations that align with the GPP goals, including providing a standardized, comprehensive, barrier free cessation benefit, and ensuring that coverage for cessation services are integrated as a reimbursable service among substance and mental health treatment providers given the high rate (40%) of comorbidity between tobacco use and substance use / mental health disorders. The populations that would be targeted by the GPP Equity Sub-Pool also experience higher than average rates of tobacco use, which is why the TEROC 2021-2022 plan is focused specifically on achieving health equity and eliminating tobacco-related health disparities. I am certain that California's tobacco control community would be eager to partner with Medi-Cal to address tobacco use among Medi-Cal recipients, which would increase Medi-Cal's efficiency, equity, and quality of care.

Michael Ong, M.D. Ph.D.
Chairperson, State of California Tobacco Education and Research Oversight Committee
Professor in Residence of Medicine & Health Policy and Management, UCLA
Section Chief, Hospitalist Division, VA Greater Los Angeles Healthcare System

SAN YSIDRO HEALTH

May 5, 2021

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

Department of Health Care Services
Director's Office
Attn: Director Lightbourne; 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:

We write to you today in objection to the incorporation of the "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, San Ysidro Health urges the Department of Health Care Services ("DHCS") to consider the negative effects on federally-qualified health centers ("FQHCs") and their patients. Medi-Cal Rx creates unnecessary barriers to healthcare access and hinders FQHCs' efforts to provide high-quality care to California's most vulnerable and underserved patients.

San Ysidro Health is an FQHC that cares for 108,000 people a year – primarily Medi-Cal and uninsured patients in San Diego County. Our mission is to improve the health and well-being of the communities we serve, with access for all. The majority of our Medi-Cal patients are among the millions of beneficiaries enrolled in Medi-Cal managed care. In addition to the many services we provide, we have integrated pharmacy services into our practice through two internal pharmacies and a host of contract pharmacies serving our county-wide service area.

Integrating pharmacy and medical services within the Medi-Cal managed care delivery system allows San Ysidro Health to better serve patients by eliminating additional steps in the process. 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, San Ysidro Health annually saves an estimated $7 million dollars through participation in Medi-Cal managed care and the 340B Drug Discount Program. The savings allow us 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, patients of San Ysidro Health (and other covered entities) 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.

Medi-Cal Rx will impede our 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. San Ysidro Health incorporates by reference the CHCAPA public comment letter into this letter; and we fully share CHCAPA's concerns and agrees with its conclusion that DHCS has not fully considered or examined the heavy costs of Medi-Cal Rx.

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

Thank you for your time and consideration. As your community partner, San Ysidro Heatlh looks forward to working with DHCS on this critical issue affecting over 11 million Medi-Cal beneficiaries.

Sincerely,

[redacted]

President & CEO

Encl.

[1] The purpose of the 340B program is to enable FQHCs to "stretch scarce federal resources" to provide expansive, high-quality services to the Medi-Cal patients who need them most. (H.R. Rep. No. 102-384, pt. 2, at 10.)
[2] Bipartisan Attorneys General 340B letter to former HHS Secretary Alex Azar, Dec. 14, 2020, available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-bipartisan-coalition-340b-drug-pricing-program.

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Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

May 03, 2021

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

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

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

Dear Director Lightbourne:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[4] 42 U.S.C. § 1396n(b).

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

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

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

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

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

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

Sincerely,

Anthony White
President

Encl.

KATHRYN E. DOI
PARTNER
DIRECT DIAL (916) 491-3024
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HansonBridgett

April 16, 2021

VIA OVERNIGHT DELIVERY

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

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

Dear Director DeCaro:

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

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

Avenal Community Health Center

Clinicas de Salud del Pueblo

Community Health Centers of the Central Coast

Desert AIDS Project

Family Health Centers of San Diego

Gardner Family Health Network

Golden Valley Health Centers

HealthRIGHT 360

Hill Country Health & Wellness Center

Imperial Beach Community Clinic

La Maestra Family Clinic

MCHC Health Centers

Mission Area Health Associates

Omni Family Health

Open Door Community Health Centers

Ravenswood Family Health Network

San Francisco Community Health Center

San Ysidro Health

Shasta Community Health Center

South of Market Health Center

TrueCare

United Health Centers of the San Joaquin Valley

Vista Community Clinic

WellSpace Health

Central California Partnership for Health (Affiliate Support Organization)

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

Thank you,

Kathryn E. Doi
Partner

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

Community Health Center
Alliance for Patient Access

823 Gateway Center Way, San Diego CA 92102

April 16, 2021

VIA FEDERAL EXPRESS

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

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

Dear Director DeCaro:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. Conclusion

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

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

Thank you for your time and consideration.

Sincerely,

Anthony White
President, CHCAPA

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

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

Exhibit A
to letter dated 4/16/2021

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March 18, 2021

VIA FEDERAL EXPRESS

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

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

Dear Ms. Cash:

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

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

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

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

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

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

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

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

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

Your attention to this matter is greatly appreciated.

Very truly yours,

Kathryn E. Doi
Partner

KED:KQD
Encls.

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

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

Exhibit A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Service	State Plan Service Category	Definition	Covered in GMC	Covered in 2-Plan	COHS	Regional	Imperial	San Benito
Long Term Care (LTC)		Care in a facility for longer than the month of admission plus one month. Medically necessary care in a facility covered under managed care health plan contracts	~~X~~[5]~~X~~[3,9~~65~~]	~~X~~[5]~~X~~[3,5~~96~~]	X[53]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]	~~X~~[5]~~X~~[3,5]
Medical Supplies ~~(Jan 1 – Mar 31, 2021)~~Prior to April 1, 2021	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. ~~Does not include incontinence creams and washes~~	X	X	X	X	X	X
Medical Supplies (effective April 1, 2021 onward)	Medical Supplies	Medically necessary supplies when prescribed by a licensed practitioner. Does not include medical supplies carved-out to Medi-Cal Rx that are billed by a pharmacy on a pharmacy claim including medical supplies described in the Medi-Cal Rx All Plan Letter (APL 20-020). [1] ~~Medically necessary supplies when prescribed by a licensed practitioner.~~	X	X	X	X	X	X
Medical & Non-Medical (NMT) Transportation Services	Transportation-Medical & Non-Medical ~~(NMT)~~Transportation (NMT) Services	Covers ambulance, litter van and wheelchair van medical transportation services are covered when the beneficiary's medical and physical condition is such that transport by ordinary means of public or private conveyance is medically contraindicated, and transportation is required for the purpose of obtaining needed medical care. NMT is transportation by private or public vehicle for	X	X	X	X	X	X

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Exhibit B

Reply all | Delete Junk |

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

[redacted]

Attachment N Updates ...
119 KB

Attachment N Updates ...
104 KB

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[redacted]

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

Good Morning,

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

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

Changes to Attachment N include:

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

Reply all | Delete Junk |

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

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

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

Exhibit C

Reply all | Delete Junk |

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

Reply all | Delete Junk |

[redacted]

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

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

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

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

Reply all | Delete Junk |

<Aaron.Toyama@dhcs.ca.gov>; McGowan, Benjamin@DHCS <Benjamin.McGowan@dhcs.ca.gov>; Dodson, Anastasia@DHCS <Anastasia.Dodson@dhcs.ca.gov>; Davis, Kirk@DHCS <Kirk.Davis@dhcs.ca.gov>; Cisneros, Bambi@DHCS <Bambi.Cisneros@dhcs.ca.gov>; Retke, Michelle@DHCS <Michelle.Retke@dhcs.ca.gov>; Lee, Angeli@DHCS <Angeli.Lee@dhcs.ca.gov>
Subject: CA Medi-Cal 2020 Attachment N Updates for Pharmacy Carve-out

Good Morning,

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

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

Changes to Attachment N include:

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

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

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

Exhibit D

Christopher M. House

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

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

U.S. District Court

Eastern District of California - Live System

Notice of Electronic Filing

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

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

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

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

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

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

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

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

Regina Mary Boyle rboyle@cliniclaw.com

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

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

Exhibit E

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

Dear Stakeholders,

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

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

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

DHCS anticipates providing further information in May.

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

Thank you,
DHCS

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

MCRxSS Announcement

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

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

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

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P.O. Box 2088 Rancho Cordova, CA 95741-2088, United States

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Important Update on Medi-Cal Rx

February 17, 2021

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

Exhibit B
to letter dated 4/16/2021

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

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, Francisco Castillon, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

/ / /

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Francisco Castillon

Exhibit C
to letter dated 4/16/2021

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

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, C. Dean Germano, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) The SPP would be simple to administer.

(d) The SPP will be renewed annually.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[redacted]

Exhibit D
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, Ricardo Roman, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[redacted]

Ricardo Roman

Exhibit E
to letter dated 4/16/2021

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FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

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

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

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

I, David Brinkman, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[redacted]

David Brinkman

Exhibit F
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

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

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

I, Dr. Kelvin Vu, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

Executed on this 2 day of February, 2021, in Arcata, California.

DR. KELVIN VU

Exhibit G
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

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

Plaintiffs,

v.

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

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

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

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

I, Dr. Paramvir Sidhu, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 5 day of February, 2021, in Visalia, California.

[redacted]

DR. PARAMVIR SIDHU

Exhibit H
to letter dated 4/16/2021

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COMMUNITY HEALTH CENTER ALLIANCE
FOR PATIENT ACCESS, ET AL.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

COMMUNITY HEALTH CENTER ALLIANCE FOR PATIENT ACCESS, et al.,

Plaintiffs,

v.

WILLIAM LIGHTBOURNE, Director of the California Department of Health Care Services; CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No. 2:20-CV-02171-JAM-KJN4

DECLARATION OF FRAN BUTLER-COHEN IN OPPOSITION TO MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Judge: Hon. John A. Mendez
Date: February 23, 2021
Time: 1:30 p.m.
Crtrm.: 6

I, Fran Butler-Cohen, declare:

1. I am the Chief Executive Officer ("CEO") at Family Health Centers San Diego ("FHCSD") and have held this role since 1986. I have reviewed the data and associated outcomes relevant to the impact of Medi-Cal Rx on FHCSD in connection with the preparation of this declaration. I have personal knowledge of the facts set forth

herein, and if called to do so, could and would testify competently thereto. I make this declaration in support of Plaintiffs' Opposition to Defendants' Motion to Dismiss.

2. FHCSD is a Federally Qualified Health Center ("FQHC") that receives federal grant funding under Section 330 of the Public Health Services Act. FHCSD has served the medically underserved communities of San Diego County since 1970, with the transition of the Chicano Free Clinic to Logan Heights Family Health Center, FHCSD's flagship clinic. FHCSD has since transformed into the tenth largest health center in the country, providing care to over 149,000 patients each year, of whom 90 percent are low income and 31 percent are uninsured. FHCSD serves all patients regardless of their ability to pay.

3. FHCSD staff is on the front lines of battling COVID-19. Since April 2020, FHCSD has provided free COVID-19 testing to as many patients as the staff can manage. During this time, demand for FHCSD services has skyrocketed. To try to meet our patients' testing needs, FHCSD has purchased additional lab equipment and increased the number of lab shifts, but it is still not enough. FHCSD is also piloting rapid testing and notification systems to quickly identify patients with COVID-19 and reduce community spread. Additionally, we have set up a separate obstetrics clinic for mothers who have tested positive for COVID-19. These steps have proven necessary, since, among the patients we serve, the COVID positivity rate in the second week of January 2021 was 35 percent, more than double the average statewide rate for the same time period.

4. In an effort to take care of patients and to avoid sending them to hospitals – which currently cannot handle an additional influx of patients – FHCSD has also ramped up its ability to care for the sickest, non-emergent patients. Instead, we have started Monoclonal Antibody administration for the sickest, non-emergent patients at one of our clinic sites, and are opening a second infusion site in Chula Vista, a known hot spot, as soon as possible.

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5. Despite the heroic efforts of our health care workers – who have shouldered the burden of coming to work every day risking their own health and the health of their families – FHCSD staff is stretched beyond its limits and is struggling to continue. We currently have seventy (70) members of our team out of work due to COVID, which hurts FHCSD's ability to meet patients' needs and county demands. We have started an emergency child care program to keep our workers on the job when they have no other childcare options. We have also started an Employee Food Pantry Program so that employees who have lost income can feed their families.

6. Now, with the development of a COVID-19 vaccine, San Diego County is asking FHCSD to submit information regarding how many vaccinations we could administer to the general public, which requires me and the FHCSD staff to study guidance from the Centers for Disease Control and the Department of Defense to implement massive public vaccination events, in addition to juggling the current emergency needs of our patients and community.

7. Simultaneously, FHCSD is still required to commit time to fielding government audits and meet with the State and Managed Care Organizations on metric performance. In addition, FHCSD is currently in the beginning stages of a random federal 340B audit that has already taken several hundred hours of staff time in preparation and document submission. At the same time, the Health Resources and Services Administration is requesting capital funding grantees submit previously unrequired data and qualitative information to help them design future grant programs, Moreover, FHCSD has had to make significant modifications to contract pharmacy arrangements to ensure our patients receive affordable medications due to the attack on the 340B program by pharmaceutical manufacturers. All of this comes against the backdrop of the State of California awarding a contract valued at approximately $80 million annually to a for-profit company (Magellan Medicaid Administration, Inc.) recently purchased by Centene, a publicly traded NYSE corporation worth $76 billion for $2.2 billion dollars to

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facilitate the state in their plan that will remove hundreds of millions of dollars from the state's health care safety-net.

8. It is unconscionable that during this time of perpetual crisis, when our staff and other healthcare workers have sacrificed so much to serve the communities that need them most, FHCSD and other FQHCs are required to prepare and plan for Medi-Cal Rx, which will result in drastic funding reductions due to changes in reimbursement. Additionally, the loss of 340B funding that helps stretch our resources to expand healthcare access will further reduce staff and desperately needed health services.

9. Although the "effective" date of Medi-Cal Rx has been moved to April 1, 2021, the implementation of Medi-Cal Rx has been underway for many months, requiring health centers to adjust our conduct in a number of ways. Examples of some of the activities FHCSD has had to undertake in anticipation of the "go live" date for Medi-Cal Rx include:

- A complete budget review and assessment of programs currently funded through 340B savings, including the potential for lay-offs, elimination of support programs, and reduction in hours and types of services provided to our patients.
- Meetings with vendors that currently support in-house pharmacy operations to ensure systems remain compliant following full implementation.
- Subscribe to and dedicate staff time to monitor, review and bring forward issues noted in regular updates from the Medi-Cal Rx Subscription Service
- Secure Provider Portal access and enroll approximately 250 prescribing providers into the provider portal, necessitating hundreds of hours of administrative staff time.

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- Review all medication and pharmacy related policies and protocols across the organization to align with new systems and ensure compliance.
- Educate providers about the transition from the MCO formulary to using drugs on the FFS formulary.
- Educate providers on the new Prior Authorization (PA) systems as drugs prescribed that are therapeutic substitutions for more commonly prescribed drugs not found on the CDL, including any step therapy or pre-requisite therapies.
- Educate clinic directors, billing staff and other administrative personnel as to the new systems, how to use them and how to trouble shoot difficulties for patients and providers.
- Review how FHCSD payor mix will change given the pharmacy transition and evaluate whether it's beneficial for FHCSD and our patients to maintain current contract pharmacy relationships or cancel them.

10. The state and local governments still expect FHCSD to maintain the same quality of care and to serve more patients in more ways while implementing Medi-Cal Rx, which will squeeze FHCSD's resources at precisely the wrong time. Without the 100 percent reimbursement rate guaranteed by federal Medicaid law and the 340B savings FHCSD relies on, we simply will not be able to provide the same level of care for the patients we have worked tirelessly to serve. I fear that the healthcare workers and

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patients who have suffered the most throughout the COVID-19 emergency will also bear the burden of the Medi-Cal Rx initiative's consequences.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 20th day of January, 2021, at San Diego, California.

[redacted]

FRAN BUTLER-COHEN

Exhibit I
to letter dated 4/16/2021

Medi-Cal Rx Monthly Bulletin

April 1, 2021

The monthly bulletin consists of alerts, bulletins and notices posted to the Medi-Cal Rx Web Portal within the previous month.

Contents

1. Changes to the Contract Drugs List Effective April 1, 2021

The below changes have been made to the Contract Drugs List effective April 1, 2021.

For more information, see the Contract Drugs List on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Asenapine	FDA-approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Cabotegravir/Rilpivirine	Added to CDL with a restriction.	April 1, 2021
Exenatide	Extended release injectable suspension vial obsolete. Removed from CDL.	April 1, 2021
Leuprolide Acetate	Injection and powder for injection removed from CDL. Labeler restriction updated to 00074 only.	April 1, 2021

Drug Name	Description	Effective Date
Lurasidone Hydrochloride	FDA approved indication specific to beneficiaries residing in nursing home removed.	April 1, 2021
Morphine Sulfate/Naltrexone	Drug obsolete. Removed from CDL.	April 1, 2021
Nevirapine	Labeler restriction (00597) added to liquid only.	April 1, 2021
Propranolol	Additional liquid strength (1.28 mg/ml) added to CDL with a restriction.	April 1, 2021
Relugolix	Added to CDL with a restriction.	April 1, 2021
Sodium Zirconium Cyclosilicate	Added to CDL with labeler code restriction.	April 1, 2021

2. Updates to the List of Covered Enteral Nutrition Products

Effective for dates of service on or after March 1, 2021, the List of Covered Enteral Nutrition Products has been updated on the Medi-Cal Rx Web Portal. Effective for dates of service on or after April 1, 2021, products deleted from the List of Covered Enteral Nutrition Products will no longer be reimbursable, even with an approved prior authorization. The Maximum Acquisition Cost (MAC) for these products is no longer guaranteed.

3. Medi-Cal Provider Training Schedule

The transition of all administrative services related to Medi-Cal pharmacy benefits billed on pharmacy claims from the existing intermediaries, Medi-Cal Fee-for-Service (FFS) or Managed Care Plan (MCP) providers, will transition to the new Medi-Cal Rx vendor, Magellan Medicaid Administration, Inc. (MMA).

This article serves as a guide to outline the trainings planned for March 2021 until the Medi-Cal Rx implementation that will assist pharmacy providers, prescribers, and their staff as they transition to Medi-Cal Rx.

User Administration Console Training

All Medi-Cal Rx pharmacy providers, prescribers, and their staff will need to complete registration in order to access the secure areas of the Medi-Cal Rx Web Portal. Access to the secured Medi-Cal Rx Provider Portal starts with registration via the User Administration Console (UAC) application.

Training Information:

To assist pharmacy providers, prescribers, and their staff with UAC registration, there are job aids and computer-based trainings (CBTs) available to walk users through the registration process. Those materials are as follows:

- UAC Quick Start Guide
- UAC Tutorial #1: Start Registration Process
- UAC Tutorial #1 Supplement: Alternate Address Instructions
- UAC Tutorial #2: Complete Registration
- UAC Tutorial #4: Granting Access for Yourself and Staff

If you run into any issues or have any questions about the UAC registration process, feel free to attend an office hours session with one of our Pharmacy Representatives (PSRs) who can assist with the process.

To register for a UAC office hours session, please email the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of Office Hours session

As of April 1, 2021 UAC Office Hours Sessions will be offered on an as-needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Saba LMS Training

Saba is the one-stop shop for Education and Outreach information for Medi-Cal Rx pharmacy providers and prescribers. Topics to be covered during the Saba training sessions include how to view the Education and Outreach events calendar, how to register to attend an event or take an online course, and how to complete evaluations of training effectiveness.

Training Information:

Training for Saba includes a job aid with step-by-step instructions:

Medi-Cal Rx Saba℠ Provider Job Aid

In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via Hewlett Packard Enterprise (HPE) MyRoom™. To register to attend a live webinar, please email Medi-Cal Rx Education and Outreach at MediCalRxEducationOutreach@MagellanHealth.com and provide the following information in your email:

- Name of individual
- Provider name
- National Provider Identifier (NPI)
- Phone #
- Email address
- Preferred date and time of training session

Before enrolling in a Saba training session, providers will need to confirm in their email if they have completed the following tasks:

- Registered successfully for UAC
- Received a PIN letter and completed UAC registration
- Registered as the Delegated Administrator or have been created as a user by the Delegated Administrator
- Have added or been granted access to the Saba application

As of April 1, 2021, Saba Training Sessions will be offered on an as needed basis. Please contact the Medi-Cal Rx Education and Outreach Team at MediCalRxEducationOutreach@MagellanHealth.com to schedule a session.

Medi-Cal Rx Transition and Resources and Web Portal Training

This training is intended to give pharmacy providers and prescribers an overview of the Medi-Cal Rx Transition and the resources that are available on the Medi-Cal Rx Web Portal. Topics that will be covered in this training include the following:

- Medi-Cal Rx background and high-level changes affecting pharmacy providers and prescribers
- Point-of-Sale (POS) Technical and Operational Readiness
- Web Claims Submission and overview of the Finance Portal

Training Information:

Training will be available via job aids and live webinars coming April 2021.

Training sessions for Medi Cal Rx Transition and Resources and Web Portal will be offered via a series of videos and job aids with step-by-step instructions. In addition, the Medi-Cal Rx Education and Outreach Team will offer live webinar sessions via HPE MyRoom™. To register to attend a live webinar, please refer to the Saba Training Calendar for specific dates and times.

Pharmacy providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to the Saba application.

Medi-Cal Rx Transition and Resources and Web Portal Training Sessions (April 2021)	
Dates	**Times**
April 2021	Please refer to the Saba Training Calendar for specific dates and times.

Prior Authorization Training

A Prior Authorization (PA), previously known as a Treatment Authorization Request (TAR), requires providers to obtain approval before rendering certain services such as prescriptions.

This training will be intended for pharmacy providers and prescribers that plan to use the new Medi-Cal Rx Secured Portal to submit PAs.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available, live webinar training will be available via Saba. Providers and prescribers that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and PA applications.

Web Claims Submission Training

This training will give providers an overview of the new Medi-Cal Rx Web Claims Submission system. Providers currently using a POS system to process prescription claims can still continue to submit web claims via this channel.

Training Information:

Training will be available via job aid and live webinars 30 days prior to Medi-Cal Rx go-live.

When available live webinar trainings will be available via Saba. Pharmacy providers and prescribers and their staff that need to take this training will first need to make sure they have successfully registered for UAC and have been granted access to both the Saba and Medi-Cal Rx Web Claims Submission applications.

4. Prescriber Phone Campaign

Pharmacy Service Representatives (PSRs) will begin reaching out by phone to introduce the new Medi-Cal Rx Web Portal and available resources and functionality. This outreach to prescribers will accomplish the following:

- Provide guidance on how to start registration for the Secured Provider Portal.
- Inform prescribers of currently available training and resources for Medi-Cal Rx.

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure Web Portal registration in order to access Education and Outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba, and providers will have the ability to enroll in web-based, instructor-led, or computer-based training.

To access Saba, providers need to utilize the User Administration Console (UAC) application. Click the **Medi-Cal Rx Training** hyperlink on the Education & Outreach page of the Medi-Cal Rx Web Portal or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration.

To register for an Office Hours session, please email MediCalRxEducationOutreach@magellanhealth.com and include the following information:

1. Name of Individual
2. Provider Name
3. National Provider Identifier (NPI)
4. Phone Number
5. Email Address
6. Preferred Date and Time of Office Hours Session

5. Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey

How do you and your peers currently conduct business for Medi-Cal pharmacy services? We'd love to hear from you! The results of the Medi-Cal Rx Pharmacy Provider and Prescriber Readiness Survey will be used to tailor training offerings for Medi-Cal Rx to ensure you are prepared for the upcoming transition. The information you provide is confidential and will be used only for future training.

6. Pharmacy Provider Self-Attestation Period Begins April 2021

Although currently delayed, Medi-Cal pharmacy benefits will eventually be transitioned to and thereafter administered through the Fee-for-Service (FFS) delivery system for all Medi-Cal beneficiaries (generally referred to as "Medi-Cal Rx"). The Department of Health Care Services (DHCS) has partnered with Magellan Medicaid Administration, Inc. (MMA) to provide a wide variety of administrative services and support for Medi-Cal Rx.

MMA has contracted with Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to administer the annual pharmacy provider self-attestation survey for professional dispensing fee reimbursement. The objective of the next self-attestation survey is to assign professional dispensing fee rates for Medi-Cal-enrolled pharmacies beginning July 1, 2021 and ending June 30, 2022.

DHCS, through Mercer, will be initiating the provider self-attestation process in April 2021 for the 2020 calendar year reporting period for those pharmacy providers seeking the higher of two professional dispensing fee rates determined by annual prescription volume. Key changes to the self-attestation process include the following:

- The provider self-attestation period for the calendar year 2020 reporting period will run from April 1 through April 30, 2021 (in previous years, the survey period was January 15 through the end of February).
- Mercer, on behalf of MMA and DHCS, will administer the provider self-attestation survey with options for online submission or an email submission of a Microsoft® Excel®-formatted template.
- In addition to the standard online submission, pharmacies will have an additional survey submission option that will allow a bulk submission for multiple locations. The new template will allow a corporate office for chain-affiliated stores under common ownership to submit multiple stores in one self-attestation survey file.

As in previous years, newly approved FFS pharmacy providers that are notified of their Medi-Cal enrollment approval after the attestation period closes will automatically receive the higher dispensing fee. However, those same providers will have to attest for subsequent reporting periods in order to continue to be eligible for the higher dispensing fee in subsequent fiscal years.

Pharmacy providers may refer to the updated Pharmacy Provider Self-Attestation FAQs for more information.

DHCS reminds the Medi-Cal pharmacy FFS provider community to closely monitor upcoming Medi-Cal pharmacy bulletins for additional information regarding future updates by signing up via the Medi-Cal Rx Subscription Service.

For updates on Medi-Cal Rx, please visit the Medi-Cal Rx Web Portal and the DHCS Medi-Cal Rx Transition website. In addition, DHCS encourages stakeholders to review the Medi-Cal Rx Frequently Asked Questions (FAQ) document, which continues to be updated as the project advances.

7. Portal Registration

What is Medi-Cal Rx and When Does it Happen?

Medi-Cal Rx is the name the Department of Health Care Services (DHCS) has given to the collective pharmacy benefits and services that will be administered through the Fee-for-Service (FFS) delivery system by its contracted vendor, Magellan Medicaid Administration, Inc. (MMA). Medi-Cal Rx will include all pharmacy services billed as a pharmacy claim, including but not limited to outpatient drugs (prescription and over the counter), Physician-Administered Drugs, enteral nutrition products, and medical supplies.

DHCS is delaying the planned Go-Live date of April 1, 2021, for Medi-Cal Rx. For more information, please see the Important Update on Medi-Cal Rx alert dated February 17, 2021.

What Should I Do Now?

Start by visiting the new Medi-Cal Rx Web Portal to review general information about the transition and to access registration and training for the Web Portal. This website serves as a platform to educate and communicate on Medi-Cal Rx resources, tools, and information. To stay informed, sign up for the Medi-Cal Rx Subscription Service (MCRxSS). Similarly, closely monitor Medi-Cal Rx news and bulletins for additional information regarding any future updates.

Next, register for the secure Medi-Cal Rx Provider Portal. Providers will need to complete registration for the User Administration Console (UAC) application. UAC is a registration tool that controls and manages a user's access to the secure section of the Medi-Cal Rx Web Portal and associated applications.

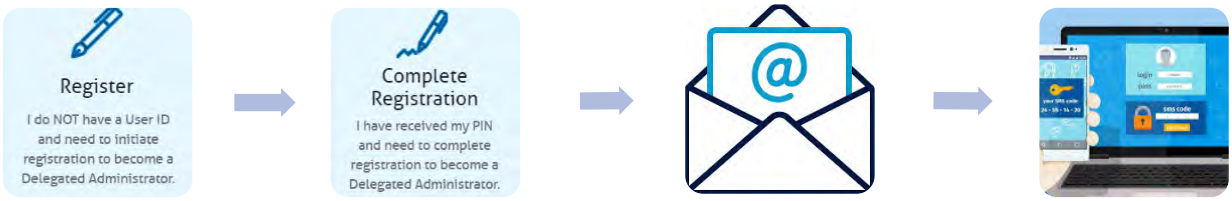
The following systems are available in the secured section on the Medi-Cal Rx Provider Portal:

- Prior Authorization System
- Secure Chat and Messaging Features
- Beneficiary Eligibility Lookup
- Web and Batch Claims Submission
- Education & Outreach Calendar and Training Registration

Refer to the UAC Quick Start Guide (PDF) and the information below for assistance with registering for UAC.

UAC Registration

All Medi-Cal Rx providers, including pharmacies, prescribers, and their staff, will need to complete secure web portal registration in order to access education and outreach training calendars, training course enrollment, and resources located in the Medi-Cal Rx Learning Management System (LMS), Saba. All Education and Outreach events will be posted in a calendar on Saba and providers will have the ability to enroll in web-based, instructor-led, or computer-based training. To access Saba, providers need to utilize the UAC application. Click the hyperlink under **Medi-Cal Rx Training** on the Education & Outreach page of the Medi-Cal Rx Web Portal, or go directly to the UAC website. UAC office hours are available to assist providers in successfully completing UAC registration. To register for an Office Hours session, please email MediCalRxEducationOutreach@MagellanHealth.com and include the following information in your email: name of individual, provider name, National Provider Identifier (NPI), phone number, email address, and preferred date and time of Office Hours session.



To register, visit https://uac.magellanrx.com.

- Click **Register**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering as many IDs as necessary
- Click **Submit**

You will receive a letter with a PIN number.

- Return to the UAC website
- Click **Complete Registration**
- Complete required fields (*)
- Click **Validate Org**
- Continue entering and validating all necessary IDs
- Click **Submit**

You will receive an email with an activation link (check spam or junk folder).

- Click activation link
- Confirmation screen appears indicating *You Have Been Successfully Added*
- Click on link in confirmation screen directing you to UAC application
- Here you can assign access and create accounts

Assign access/privileges and organizations.

- The first time you log into UAC, set up multifactor authentication
- Continue with sections 2.0, 3.0, and 4.0 in the Medi-Cal Rx UAC Quick Start Guide located at https://medi-calrx.dhcs.ca.gov/home/education

Christopher M. House

From: UPS <pkginfo@ups.com>
Sent: Monday, April 19, 2021 7:22 AM
To: Christopher M. House
Subject: [EXTERNAL] UPS Delivery Notification, Tracking Number 1ZA47F260198305886

Hello, your package has been delivered.

Delivery Date: Monday, 04/19/2021
Delivery Time: 10:20 AM
Left At: DOCK
Signed by: ANDRE

HANSON BRIDGETT LLP

Tracking Number:	1ZA47F260198305886
Ship To:	CENTER FOR MEDICAID & CHIP SERVICES 7500 SECURITY BOULEVARD, MAIL STOP S2-25-26 BALTIMORE, MD 212441850 US
Number of Packages:	1
UPS Service:	UPS Next Day Air®
Package Weight:	2.0 LBS
Reference Number:	37366.3
Reference Number:	FHCSD / CHCAPA
Reference Number:	KATHRYN DOI

Download the UPS mobile app

Nurse-Family Partnership
Helping First-Time Parents Succeed®

May 6, 2021

Director Will Lightbourne
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

RE: CalAIM Section 1115 demonstration application

Submitted electronically via CalAIMWaiver@dhcs.ca.gov

Dear Director Lightbourne:

On behalf of the Nurse-Family Partnership® National Service Office (NFP NSO), thank you for the opportunity to comment on DHCS' CalAIM Section 1115 demonstration application. Nurse-Family Partnership (NFP) is a national, evidence-based, maternal-infant health community nursing program that partners highly skilled registered nurses with first-time[1] expectant mothers (adolescents and adults) to improve pregnancy outcomes, improve child health and development, reduce instances of child maltreatment and neglect, and increase families' economic self-sufficiency.

We are writing in support of key provisions of the 1115 waiver renewal, to collaborate with DHCS to refine other provisions, and to partner in prioritizing maternal and child health when identifying and managing Medi-Cal members' risks and needs through whole-person care approaches that address social determinants of health.

NFP draws on more than 40 years of research and implementation experience to demonstrate effectiveness in successful replication of the program. Under normal circumstances, NFP's weekly-to-biweekly, 60- to 75-minute encounters occur in the home (or other location preferred by the client). Participants enroll during pregnancy and receive visits from their personal nurse through their children's second birthday. During the pandemic, NFP nursing has been delivered continuously through the use of telehealth. In this time of health inequities laid bare by COVID, strategic integration of proven, evidence-based programs like NFP can be crucial tools to manage Medi-Cal members' needs by addressing social determinations of health.

NFP currently has capacity to serve 5,500 mothers in 22 counties[2] through partnerships with county health departments, a school district, and a health system. More than 90% of NFP participants are Medi-Cal members (both fee-for-service and managed care plan members). We are excited about opportunities described in the 1115 waiver renewal to partner with the State to offer NFP nursing services to more Medi-Cal members given our shared goal of ensuring optimal outcomes for California's most vulnerable families, including:

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[1] Los Angeles and San Francisco counties have secured authorization to enroll expectant mothers who already have children into their NFP programs – a variance from the traditional delivery model of first-time expectant mothers - as part of a formative study to learn how best to deliver NFP to multiparous mothers (and are 2 of just 31 sites authorized in 12 states to do so). We encourage DHCS to leverage this adaptation in a targeted way to support expectant and new mothers who are Medi-Cal members who are navigating multiple social and structural determinants of health and who are managing complex behavioral and physical health needs.
[2] Alameda, Contra Costa, Fresno, Humboldt, Kern, Los Angeles, Monterey, Orange, Riverside, Sacramento, San Diego, San Francisco, San Luis Obispo, San Mateo, Santa Clara, Santa Cruz, Shasta, Solano, Sonoma, Stanislaus, Ventura and Tulare.

a) reducing disparities in maternal and infant health outcomes,
b) mitigating the effects of perinatal or postpartum mood and anxiety disorders (PMAD) or perinatal substance misuse,
c) connecting children with early intervention services, and
d) increasing children's immunization rates.

Within the first 12 months that expectant and new mothers participate in the program, ***NFP reduces health care costs by reducing preterm births by 15% and cutting pregnancy-induced hypertension by 32%***. ***The program also reduces costs associated with emergency room utilization through a projected 33% cut in ER visits or hospitalizations for childhood injuries for infants through age 2.*** NFP also improves infant health by, among other outcomes, increasing immunizations by a projected 13% for children through age 2.[3] Moreover, an independent analysis projects that **for every California mom and baby who receive NFP nursing services, government programs save $28,137 - 60% of which accrues to Medicaid.[4]**

NFP NSO support's DHCS's commitment to Identifying and managing members' risks and needs through whole-person care approaches that address social determinants of health

As a national service provider, NFP NSO can support DHCS in integrating evidence-based maternal, infant and early childhood community nursing services that address social determinants of health. NFP:

- Uses specially trained nurses who enroll participants early enough in pregnancy to improve maternal health outcomes during pregnancy and after their children's birth, as determined by the U.S. Administration for Children & Families Home Visiting Evidence of Effectiveness clearinghouse.[5]
- Uses validated nursing assessments, clinically recognized developmental and mental health screening tools (PHQ-9, GAD-7, ASQ3 and others), and continuous electronic data collection to identify and document physical health, behavioral health, and social risks that inform client-centered care plans to address those needs.[6]
- Uses client-centered care plans to deliver care coordination, case management, health education, screenings, assessments, parenting education and anticipatory guidance for both mom and infant through a strengths-based, two-generational, whole-person approach.
- Provides enhanced training, skills and nursing practices to address opioids/substance misuse, disparities in maternal mortality and severe maternal morbidity, and maternal mental health – issues prioritized by the State around which to strengthen integrated support across the human services and behavioral and physical health systems.[7]

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[3] "Nurse-Family Partnership: Outcomes, Costs and Return on Investment in California," 2019, Nurse-Family Partnership National Service Office, Accessed May 2021 at https://www.nursefamilypartnership.org/wp-content/uploads/2019/04/NFP-Multidomain-Impact_CA_20190221.pdf. This fact sheet relies on a state-specific return on investment calculator derived by Dr. Ted Miller from published national estimates to project state-specific outcomes and associated return on investment. The calculator is revised periodically to reflect major research updates (latest revision: 12/22/2018).

[4] "Cost Savings of Nurse-Family Partnership in California" fact sheet produced by Ted R Miller, PhD, Pacific Institute for Research & Evaluation, funded in part by NIDA grant 1-R01 DA021624. Accessed May 2021 at https://www.nursefamilypartnership.org/wp-content/uploads/2019/04/NFP-Govt-Savings-CA_2019.pdf.

[5] "Home Visiting Evidence of Effectiveness Outcomes: Maternal Health," U.S. Department of Health & Human Services Administration for Children & Families, accessed Nov. 30, 2020, at https://homvee.acf.hhs.gov/outcomes/maternal%20health/In%20Brief

[6] See addendum: Physical Health, Behavioral Health & Social Risk Factors Assessed and Managed through NFP Nursing Services

[7] NFP has developed enhanced training for NFP nurses regarding opioid use disorder and neonatal abstinence syndrome for nurses' use with clients experiencing perinatal opioid/substance addiction. Standard NFP nursing

- Monitors many of the same quality and outcome measures prioritized by the State, such as prenatal and post-partum care; screenings for adverse childhood and community experiences, intimate partner violence, anxiety and depression, childhood developmental delays, and lead exposure; well-child visits in the first 15 months of life; and childhood immunization status.
- Is one of the evidence-based maternal, infant and early childhood home visiting programs authorized by CDPH and CDSS to be delivered by counties.

Moreover, standard NFP nursing practice also includes consistent data collection and reporting using a Web-based platform toward measurable impacts, including:

- Preterm births;
- Child injuries and hospitalizations/emergency department utilization;
- Birth spacing between 1st and 2nd child;
- Developmental screenings; and
- Adherence with immunization, well-child, and postpartum care guidelines.

While NFP NSO appreciates clarifications and amendments to CalAIM since the original proposal was released, we seek to partner with DHCS to clarify or further refine the following provisions:

1. Population Health Management

We support DHCS' proposal to require managed care plans to develop population health management plans, inclusion of community-based providers to meet members' needs, and requiring MCPs to coordinate population heath management strategies with counties' public and behavioral health departments. ***However, we believe DHCS missed an opportunity to achieve the goals outlined on pages 25-26 of the CalAIM proposal for women and children by omitting inclusion of evidence-based maternal, infant and early childhood home visiting programs like NFP that the State has invested in to improve maternal and child health.***

Evidence-based home visiting is recognized as both primary and secondary prevention strategies that can reduce or prevent the effects of adverse experiences for very young children, and can improve long-term health outcomes throughout the entire family – having a two-generation effect on health and welfare. Specially trained individuals are paired with families to provide support services in the home or other non-institutional settings that create trust between the family and the home visitor. Through the range of home visiting models authorized for delivery in the state, home visitors come from a variety of backgrounds, including nursing, social work, and community health workers. All models are found to improve maternal and child health, prevent adverse childhood experiences, encourage positive parenting, and promote early childhood development. Positive outcomes consistently delivered by NFP include reductions in: pre-term births, pregnancy complications, intimate partner violence, childhood injuries, and child abuse and neglect ;and increases in: mothers' attempts to breastfeed, tobacco cessation, children's completion of high school with honors, and mothers' increased educational attainment and employment.

We appreciate DHCS' intent to provide technical assistance to MCPs to identify and incorporate best practices in how to use population health management programs to support specific populations of

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practice includes baseline assessment for anxiety and depression during prenatal program enrollment, again before delivery, upon delivery, and regularly during the postpartum period and the duration of program participation up to two years after delivery. In addition, the program has developed a mental health integration recognized by the U.S. Health Resources and Services Administration as meeting standards for certain referred mental health services. Because of NFP nurses' trusted relationship with expectant mothers, they are able to monitor clinical indicators of high-risk pregnancy and birth complications that contribute to disparities in maternal mortality and severe maternal morbidity.

interest, such as children and pregnant women, in ways that align with other DHCS initiatives. ***Given guidance jointly issued by the U.S. Centers for Medicare and Medicaid Services and Health Resources and Services Administration to states encouraging the integration of home visiting services as a strategy to improve outcomes for Medicaid members[8], we encourage DHCS to explicitly include in the CalAIM proposal reference to evidence-based maternal, infant and early childhood home visiting services that meet federal standards for evidence-based home visiting[9], are recognized as well-supported in the Title IV-E Prevention Services clearinghouse[10], and have been authorized by CDPH[11] and CDSS[12] to be delivered by counties***.

2. Continuance of Local Governmental Agency Targeted Case Management Pending CMS Approval

Although we appreciate DHCS confirmation that LGA TCM will continue pending CMS approval, ***it is still unclear how counties will be made whole for provision of NFP nursing services that currently are reimbursed through the TCM benefit when individuals become "newly" ECM-eligible.*** DHCS has not confirmed that the scope of activities and services that NFP nurses deliver to Medi-Cal members in the home or other non-clinical setting qualify for Medicaid reimbursement through an alternative benefit.

It also remains unclear whether the populations described as ECM-eligible would be excluded from the targeted populations authorized to received TCM services under SPAs 20-0027-0031, or whether DHCS considers ECM-eligible populations a "sub-population" of TCM-eligible populations. ***We are further concerned that leaving it to each MCP whose catchment areas include TCM-providing counties could result in inconsistent determinations about TCM or ECM allowances for MCP members.***

These are issues of particular concern to NFP because of the profile of Medi-Cal members typically served by the program. California NFP client demographic data shows moms are likely to have experienced, or be at risk of experiencing:

- addiction or substance misuse
- developmental delays
- high-risk pregnancy
- homelessness or housing instability
- intimate partner violence
- involvement with child welfare or the criminal justice systems
- lower levels of educational attainment
- mental or behavioral health needs
- teen pregnancy
- trafficking

We have similar concerns with DHCS' proposed trailer bill language dealing with TCM, in particular, subsection (e) of 14184.205:

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[8] "Joint Informational Bulletin: Coverage of Maternal, Infant, and Early Childhood Home Visiting Services," March 2016, Accessed May 2021 at https://www.medicaid.gov/federal-policy-guidance/downloads/cib-03-02-16.pdf
[9] Home Visiting Evidence of Effectiveness, U.S. Administration for Children & Families, Accessed May 2021 at https://homvee.acf.hhs.gov/
[10] Maintained by the U.S. Administration for Children & Families, Accessed May 2021 at https://preventionservices.abtsites.com/
[11] See https://www.cdph.ca.gov/Programs/CFH/DMCAH/CHVP/Pages/default.aspx
[12] See https://www.cdss.ca.gov/inforesources/calworkshomevisitinginitiative

(e) Notwithstanding any other law, for any time period in which a Medi-Cal beneficiary who is eligible to receive ECM services through enrollment in their Medi-Cal managed care plan, the beneficiary shall not receive duplicative targeted case management services as described in Section 14132.44 or otherwise authorized in the Medi-Cal State plan, as determined by the department.

For managed care plan members who are pregnant or parenting, if they are also in a group eligible to receive ECM services, we want to ensure that NFP's standing services that are reimbursed through TCM to counties by our home visiting nurses are kept whole.

Given the opportunity to comment on extension of the 1115 waiver, we wanted to highlight our desire to partner with the State to better integrate NFP nursing services as the provisions of CalAIM are implemented. Should you have questions about this response, please contact me directly at toni.panetta@nursefamilypartnership.org or NFP NSO's Sacramento-based legislative advocate, Vanessa Cajina, at vcajina@ka-pow.com.

Sincerely,

Toni Panetta
Southwest Regional Government Affairs Manager
Nurse-Family Partnership National Service Office

Addendum: Physical Health, Behavioral Health & Social Risk Factors Assessed and Managed through NFP Nursing Services

Domain of NFP Nursing Practice	Factors Assessed
Personal health	• substance use • pregnancy complications and/or chronic illness • developmental and intellectual disability • depression, anxiety, and behavioral health issues
Maternal role	• caregiving attitudes and behaviors • child health and development • childcare
Life course development	• maternal education and work • pregnancy planning • English literacy limitations • criminal justice/involvement in the legal or child welfare system
Family and friends	• loneliness and social isolation • intimate partner violence • unsafe family or friend network
Environmental health	• economic adversity • homelessness or residential instability • environmental health • home safety
Health and human services system	• health services utilization • well-child care • use of other community services

May 6, 2021

Will Lightbourne, Director
California Department of Health Care Services
1501 Capitol Avenue, MS 4000
Sacramento, CA 95899-7413

Jacey Cooper, Chief Deputy Director, Health Care Programs, and State Medicaid Director
California Department of Health Care Services
1501 Capitol Avenue, MS 4000
Sacramento, CA 95899-7413

Subject: CBHDA Comments – CalAIM Section 1115 & 1915(b) Waivers

Dear Mr. Lightbourne and Ms. Cooper:

Thank you for the opportunity to comment on the Section 1115 and 1915(b) waiver proposals that the state will use to enact key components of the California Advancing and Innovating in Medi-Cal (CalAIM) initiative. The County Behavioral Health Directors Association (CBHDA) represents the county behavioral health executives who administer Medi-Cal and safety net services for serious mental health (MH) conditions and substance use disorders (SUDs) in all 58 counties in California. County behavioral health plans believe the reforms included in CalAIM are critical steps toward large-scale system transformation within Medi-Cal. In several cases, these changes promise to address longstanding inefficiencies in the way counties are required to operate public behavioral health systems. If successfully implemented, the CalAIM initiatives will remove administrative barriers and enable meaningful improvements in access and quality of behavioral health (BH) care for some of our state's most vulnerable populations. We commend the Department of Health Care Services (DHCS) for its work on CalAIM to date, and its close collaboration with county behavioral plans and other stakeholders.

In this letter, we offer detailed comments on those waiver proposals that are most relevant for BH plans. We reiterate priority policy recommendations and highlight new concerns and nuances that have emerged during our engagement with DHCS on these proposals. In summary:

- **The state must maximize opportunities to address health equity goals via CalAIM.** We believe that every CalAIM proposal, including the waiver components discussed in this letter, should be developed and implemented with a health equity lens. Analysis of health disparities must be taken into account during planning and policy development, and delivery system reforms should be put into practice in a manner that will address longstanding health challenges for the communities of color that make up the largest proportion of Medi-Cal beneficiaries, along with other marginalized populations, including individuals with serious mental illness (SMI) and SUDs.

- **CBHDA strongly supports the CalAIM proposals for behavioral health payment reform, medical necessity changes, administrative integration of mental health and substance use disorder services, and the Drug Medi-Cal Organized Delivery System (DMC-ODS) renewal.** These proposed reforms will be challenging but worthwhile to implement, with many key policy decisions yet to be addressed. The changes related to "medical necessity," or coverage and payment criteria for specialty behavioral health services, are intended to reduce barriers to access and enable more appropriate reimbursement for BH plans while supporting client-centered care. If the state hopes to realize these goals, DHCS must also enact comprehensive reforms to documentation and audit practices that align requirements for specialty BH programs with requirements for other Medi-Cal Delivery systems. For effective payment reform, we hope the state will continue to collaborate closely with counties to establish appropriate reimbursement for all behavioral health services, and to allow for system reinvestment and increased fiscal stability.
- **County BH plans are essential partners in initiatives that impact the broader Medi-Cal delivery system, including Enhanced Care Management, In Lieu of Services, Population Health Management Programs, and services for justice-involved populations.** County BH plans are responsible for serving high-risk populations with SMI and SUDs who are disproportionately impacted by many social determinants of health and experience significant health disparities. BH plans have extensive expertise in meeting the complex needs of the populations we serve. We employ a unique biopsychosocial model of care to support recovery and resilience for our clients. County BH plans are both payers and providers, and consistently leverage innovative partnerships with local law enforcement, schools, social services providers, and other entities to offer care that extends beyond the four walls of a clinic and the limits of Medi-Cal coverage. We are eager to use our population data, local infrastructure, and clinical expertise to collaborate with Managed Care Plans (MCPs) to drive improvements in outcomes for shared beneficiaries, and we have offered specific recommendations that we believe will support and enhance this collaboration.

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I. HEALTH EQUITY & CALAIM

Over the past year, COVID-19 brought disproportionate suffering to communities of color that continue to live with overincarceration, police violence and many other harms that stem from racism and discrimination. These same communities have long faced health disparities, including disparities in access, use, and quality of mental health services.[1] LGBTQ people, individuals with disabilities, and other marginalized groups also face persistent health and behavioral health inequities, including disproportionately high rates of suicide and harmful substance use for members of the LGBTQ community.[2]

Historically, the Medi-Cal program has suffered from a lack of timely and meaningful data on health outcomes (distinct from measures of utilization or process measures) that can be used to illuminate disparities for California's diverse low-income populations. Medi-Cal policy decisions have not always been informed by clear health equity goals or even analyses of how new programs or policy initiatives would improve – or worsen – existing health disparities. **CalAIM presents a far-reaching and significant opportunity to prioritize equity in all policy and implementation decisions. We urge the state to partner actively with stakeholders, including members of communities that face identified health disparities, to ensure that equity goals, particularly**

[1] McGuire, T. G., & Miranda, J. (2008). New evidence regarding racial and ethnic disparities in mental health: policy implications. *Health affairs (Project Hope)*, *27*(2), 393–403. https://doi.org/10.1377/hlthaff.27.2.393

[2] U.S. Department of Health and Human Services, "Lesbian, Gay, Bisexual and Transgender Health", https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health#top, accessed March 2021.

racial equity and behavioral health equity, are carefully identified and advanced as CalAIM is implemented.

We commend DHCS for naming the reduction of disparities and inequities as one of the Guiding Principles for CalAIM. We share the following recommendations with the acknowledgement that they barely begin to scratch the surface of the health equity discussion that must take place for Medi-Cal. We are eager to collaborate with the Legislature, Administration, and other health care stakeholders to make tangible, and overdue, progress on these issues in the immediate future and over time.

- **Apply a health equity lens to all CalAIM policies, including behavioral health proposals.** As described above, the policy and implementation decisions that we are making now in CalAIM can retrench health disparities, or begin to unravel them. At minimum, every CalAIM proposal should be assessed in terms of impacts to diverse communities. If a proposal does not advance equity, we must ask how it could be modified and improved to further concrete disparities reduction and equity outcome goals.

- **Develop statewide health equity goals and prioritize corresponding strategies in CalAIM population health management plans.** DHCS has rightly called out the need to focus on identifying and addressing disparities in certain CalAIM policy initiatives, including the new process for population health management planning that will be required of Medi-Cal Managed Care Plans (MCPs). We agree that population health management planning cannot be separated from analysis of health disparities and the development of new strategies to support equity. We know, for example, that MCPs currently overserve white beneficiaries with the Mild-to-Moderate Medi-Cal mental health benefit, and that both MCPs and MHPs underserve Latino and Asian and Pacific Islander beneficiaries. We hope DHCS will consider identifying statewide equity goals that cut across Medi-Cal delivery systems to identify disparities, including areas of disproportionality. Medi-Cal leaders could then incentivize MCPs, county behavioral health plans, and other key programs to work together to meet targets for reductions in disparities. This approach should be undertaken *in addition to* the more localized goals and strategies that DHCS has said will be identified by each Medi-Cal Managed Care plan.

- **Medi-Cal Managed Care Plans should be required to collaborate with county BH plans to identify population health strategies specific to behavioral health.** We know that individuals with serious mental illness and substance use disorders face disparate rates of mortality and other poor outcomes. People with behavioral health conditions must be prioritized in any population health management or quality improvement frameworks developed by health plans or by DHCS, consistent with recommendation put forward by the National Association of State Mental Health Program Directors that states should "Prioritize the public health problem of morbidity and mortality and designate the population with SMI as a priority health disparities population." County BH plans have specific expertise in quality improvement for behavioral health services, and in developing culturally relevant programs informed by community engagement which, to a large degree, are core investments made possible through the Mental Health Services Act. Ultimately, according to a recent health spending analysis of both government and commercially insured populations, approximately 60% of healthcare spend is attributable to the roughly 23% of the population diagnosed with behavioral health conditions.[3] County BH plans have data on our SMI and SUD populations that can be leveraged through collaborative analysis and planning with MCPs to address not only early mortality driven by a lack of access to primary care, but also higher overall medical need and cost drivers within Medi-Cal. Finally, we note that there is also

[3] Erica Hutchins Coe and Kana Enomoto, "Returning to resilience: The impact of COVID-19 on mental health and substance use," April 2, 2020, McKinsey.com., available at: https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/returning-to-resilience-the-impact-of-covid-19-on-behavioral-health.

valuable expertise and "lessons learned" available through the California Reducing Disparities Project, a statewide policy initiative focused on identifying solutions for behavioral health disparities experienced by underserved populations.

- **Explore new options for Medi-Cal to cover community defined practices and culturally specific providers.** CBHDA strongly supports the Department's goal of improving health equity by ensuring that all Californians can receive culturally inclusive services. For example, as part of the CalAIM DMC-ODS renewal, DHCS has proposed coverage for traditional healers employed by American Indian Health Care Providers. Ideally, a broader array of Medi-Cal services could be provided to beneficiaries by members of their own communities. In the short term, we ask the state to prioritize expansion and/or clarification of Medi-Cal benefits to include community-defined behavioral health practices. We believe more of these community defined practices should be covered through expanded benefit definitions and clarified state guidance to prevent audit disallowances, in order to ensure that effective community defined practices are sustainably integrated and supported for under Medi-Cal. DHCS could also consider adding culturally specific provider types that represent other racial, ethnic, or cultural groups as another way to expand access to community defined practices.

- **New requirements for BH screening, assessment, treatment planning, and progress notes should be developed with a focus on improving health equity.** Existing requirements for documentation and reimbursement of behavioral health services create barriers to client-centered care. BH providers report that the current process for client intake and establishment of medical necessity can be particularly onerous for some ethnic or cultural groups that already face health disparities or disparities in access to care. DHCS should incorporate direct feedback from diverse community and client voices to ensure that new procedures or treatment tools do not reinforce existing inequities, from initial screening through to assessment and treatment planning, in coordination with county behavioral health plans.

II. CHANGES TO SPECIALTY BEHAVIORAL HEALTH COVERAGE AND PAYMENT CRITERIA AND RELATED REFORMS

CBHDA supports the concepts DHCS has put forward to clarify coverage and payment criteria for the Specialty Mental Health (SMH) and Drug Medi-Cal Organized Delivery Systems (DMC-ODS); revise documentation requirements and audit practices; increase flexibility for BH plans to cover services during the assessment period; utilize standardized screening and transition of care tools to improve coordination between county BH and Medi-Cal Managed Care Plans; and clarify that there is "No Wrong Door" for Medi-Cal clients seeking behavioral health services.

We emphasize that there are many key policy decisions related to these proposals that are still outstanding. These details will ultimately determine whether these reforms succeed in improving access to client-centered care and ensuring appropriate reimbursement to county BH plans. CBHDA hopes to engage in ongoing dialogue with DHCS to address the concerns and recommendations summarized below.

A. Waiver proposals: Clarify criteria to access the SMHS delivery system, align medical necessity with federal definition, clarify documentation requirements, and allow treatment during the assessment period, prior to diagnosis.

- **DHCS audit practices must reflect updates to coverage and payment criteria, particularly for the EPSDT population.** Historically, both children and adults have been required to meet criteria for included diagnoses in order to access specialty BH services, and DHCS has disallowed payments for SMH and DMC-ODS services when diagnostic requirements are not met. DHCS' proposed revisions to coverage and payment criteria for SMH services would eliminate included diagnosis as a prerequisite for SMH services. In addition, DHCS proposes that children with a history of trauma, homelessness, or involvement in the child welfare be considered automatically eligible for clinically appropriate SMH services. Finally, proposed updates to the DMC-ODS specify that youth under 21 who engage in risky

substance use are entitled to early intervention services as part of the federal EPSDT mandate, and adults may receive reimbursable SUD services during the assessment period even if they ultimately do not meet eligibility criteria.

CBHDA strongly supports these significant policy changes. We also emphasize that if these updates to coverage criteria are approved by CMS, it will be essential for DHCS to update audit protocols and engage in careful training of program auditors to ensure that services are not retrospectively disallowed. This is particularly important in cases when a child did not have a diagnosis and/or did not demonstrate a high level of acuity or functional impairment. Mental health conditions present differently in children than adults, and it is not appropriate to require either a diagnosis or a certain level of acuity or severity before a child may access medically necessary services. If a child's condition is consistent with the definition of medical necessity included in the federal EPSDT statute, and a specialty service is clinically appropriate to treat the child's condition, the child is entitled to that service and the BH plan is entitled to reimbursement. We thank DHCS in advance for working to adjust audit practices to reflect these important policy revisions and expand the scope of Medi-Cal reimbursable specialty behavioral health services.

- **New billing mechanisms and guidance are needed to ensure county BH plans can cover, and receive reimbursement for, medically necessary EPSDT services that are not included in the state plan.** DHCS has affirmed that the state, and counties in their roles as managed care plans, are obligated to cover medically necessary services for the EPSDT population even when those services are not included in California's Medi-Cal state plan.[4] At present, this policy cannot be easily operationalized by BH plans because there are no mechanisms to bill for services not included in the state plan.[5] BH plans regularly pay for services for children without federal Medi-Cal reimbursement, but have also advocated that the state develop solutions so BH plans may claim FFP in cases where services should be reimbursable under EPSDT. In addition to adjusting audit practices as described above, CBHDA requests that DHCS identify new billing mechanisms and issue corresponding guidance to enable county BH plans to claim Medi-Cal reimbursement for all EPSDT services. New guidance should address whether/how BH plans are expected to use provisional diagnostic codes for SMH and DMC-ODS services rendered prior to completion of assessment or diagnosis. DHCS should also clarify expectations for EPSDT claims for children who need early intervention services but may not meet diagnostic criteria for an SUD or MH disorder.
- **Coverage and payment criteria for inpatient psychiatric services should also be updated at this time.** DHCS' 1915(b) waiver overview proposal does not include revisions to existing coverage and payment criteria for inpatient psychiatric services. These criteria are currently outlined in CCR Title 9, Section 1820.205, and reiterated in the existing 1915(b) waiver.[6] DHCS may not need waiver authority to update criteria that apply specifically to inpatient psychiatric levels of care. Nonetheless, CBHDA suggests that now is the time for DHCS to revise criteria for inpatient services and promptly issue secondary guidance that describes how hospitals and mental health plans are expected to document the need for an inpatient level of care. CBHDA has provided DHCS with detailed recommendations for revisions to existing Title 9 payment criteria and for documentation of inpatient services, and we look forward to discussing DHCS' response to our proposals.
- **Additional guidance is needed to clarify responsibility for non-psychiatric services for Medi-Cal beneficiaries that have physical or neurological conditions as well as serious mental illness.** While we recognize that this recommendation is outside the scope of the waiver proposal, we would like to

[4] Social Security Act §1905(r)(5)
[5] We are aware of one exception: In 2016, DHCS issued Information Notice 16-063 on "Substance Use Disorder Treatment Services for Youth in California." This Notice describes how county Drug Medi-Cal programs may claim for youth residential treatment services, even though those services are not explicitly included in the DMC benefits package outlined in SPA 13-038.
[6] California Section 1915(b) Waiver, 2015-2020, Version June 10, 2015, Section A: Program Description, Part 1: Program overview, p. 21. Available at: https://www.dhcs.ca.gov/services/MH/Documents/1915-b-SMHS-Waiver.pdf

highlight an existing challenge within Medi-Cal that is closely related to coverage and payment criteria for specialty mental health services. Due to a lack of delivery system capacity within Medi-Cal managed care, particularly for long-term services and supports, county BH plans are often expected to pay for services that fall outside the scope of the psychiatric or mental health benefits covered by the county. This occurs frequently with beneficiaries who have co-occurring physical or neurological diagnoses as well as mental health needs. County BH plans can only cover, and receive reimbursement for, covered specialty services when those services are appropriate to treat mental health conditions. BH plans cannot receive reimbursement for non-psychiatric services that individuals may need to treat their other health needs. Counties should not be expected to pay for these other types of services, nor should they be expected to offer psychiatric care when in fact a different type of intervention is needed. However, these distinctions are not well understood by providers, consumers, or other stakeholders. Too often it falls to BH plans to solve for systemic gaps within other Medi-Cal delivery systems without commensurate associated funding.

CBHDA seeks updated guidance from DHCS to clarify that while county BH plans are obligated to provide clinically appropriate, covered specialty mental health services to address the mental health needs of Medi-Cal beneficiaries, BH plans are not responsible for covering all costs for all health services for people with serious mental illness. Namely, coverage for interventions needed to treat physical or neurological conditions is typically the responsibility of Medi-Cal Managed Care Plans. Some supportive services for individuals with development disabilities may also be accessed through Regional Centers. Critically, mental health facilities should not stand in for long term care. For example, people with a history of SMI may later develop dementia, and dementia may produce symptoms and functional impairment that cannot be resolved through psychiatric treatment. These clients may need long-term care placements or other services and supports so they can live safely at home. Often these services and supports are not readily available within Medi-Cal, sometimes because long-term care providers refuse to accept clients with a history of SMI. Consequently, these individuals remain in MH facilities (often IMDs, where costs are covered completely by county BH plans in the absence of federal reimbursement), even though they do not need the intensive level of mental health care provided in those specialized facilities. A similar gap in coverage or services can occur for people with traumatic brain injuries, who need ongoing interventions to address their neurological symptoms. These interventions are distinct from covered SMH benefits. MH services can help address co-occurring mental health needs but cannot in fact ameliorate traumatic brain injury or other neurological conditions.

These access and coverage challenges for people with conditions like TBI and dementia in Medi-Cal managed care delivery systems present a complex financing and coordination challenge for county behavioral health plans. We also note that related, but distinct, challenges exist for people with conditions like autism and eating disorders. CBHDA members are available to provide DHCS with additional feedback on these challenges. County BH plans urge DHCS to begin to assess the needs of these populations; identify gaps in capacity within managed care plan networks; and work with the legislature and other stakeholders, including CBHDA, to propose solutions.

B. Waiver proposals: No Wrong Door, documentation requirements, audits, and statewide screening and transition tools

- **Successful implementation of "No Wrong Door" depends on successful reforms to documentation and audit practices.** County BH plans strongly support DHCS' proposals to cover clinically appropriate mental health and SUD services during the assessment period, even if the client does not ultimately meet coverage criteria for SMH or DMC-ODS services. We also thank DHCS for including language in the waiver proposal to clarify that beneficiaries may receive non-duplicative behavioral health services in multiple delivery systems, and to affirm that co-occurring substance use disorder does not preclude access to covered and medically necessary SMH services. These changes can help improve access to care over time, but only if documentation and audit requirements for specialty BH plans are successfully revised.

For example, BH plans will need updated billing guidance that specifies acceptable diagnostic codes and any other specific instructions for claiming services provided during the assessment period, particularly if assessment and diagnosis are never completed or the client ultimately does not meet coverage criteria for ongoing specialty care. Further, discussion of SUD during a MH service or discussion of MH needs during an SUD service, and documentation of these dual areas of focus in a clinician's progress note, should never lead to recoupment. DHCS claims adjudication and audit practices must be adjusted as soon as possible to reflect these changes, or BH plans and providers will remain unable to "open the door" and meet clients where they are.

- **Documentation and audit standards for SMH and DMC/DMC-ODS must be revised to align with standards for other Medi-Cal delivery systems.** Compared to requirements for other Medi-Cal delivery systems, existing documentation standards for SMH and DMC-ODS are uniquely complex and prescriptive. This complexity is almost entirely the result of state-level policy decisions. DHCS standards for clinical and fiscal audits/reviews of BH plans are highly punitive and rely heavily on fiscal disallowances for an array of minor documentation errors that are unrelated to clinical quality. While these disparate regulatory and enforcement practices for behavioral health services may not technically constitute a violation of parity laws, we suggest that they have significant, unintended consequences for access. These requirements can stigmatize and segregate specialty behavioral health in comparison to other kinds of health care. They also add undue administrative burden to county BH plans and contracted behavioral health providers.

  We believe the state can conduct appropriate oversight of program integrity for specialty BH services without subjecting clients or providers to excessive administrative burden and unnecessary fiscal risk. We emphasize that DHCS already does this successfully for other Medi-Cal programs. In the future, assurance of clinical quality should be decoupled entirely from fiscal penalties. Fiscal disallowances should be reserved for cases of fraud, waste, or abuse. To detect actual wrongdoing, DHCS should identify data sources and analytic strategies beyond chart sampling. Conversely, minor documentation errors that surface in chart reviews can be readily addressed through quality improvement strategies carried out at the BH plan level. BH plans are already required to maintain quality improvement plans and to monitor quality and compliance for their subcontractors. DHCS can also leverage annual EQRO reviews and other contractual quality improvement strategies to address quality issues that may emerge at the plan level but do not rise to the level of abuse or misconduct.

  Attempting minor or incremental revisions to existing documentation requirements will not produce the transformation that is needed. Instead, DHCS should work with county BH plans and other subject matter experts to redesign clinical documentation standards entirely. New standards should meet minimum requirements for federal Medicaid reimbursement while aligning more closely with those used elsewhere in Medi-Cal. Enacting these reforms will require revisions to multiple authorities, including Title 9 and Title 22 regulations and possible amendments to the SMH and DMC state plans. This process may take time and a significant investment of resources, but these changes are essential and should be prioritized.

  CBHDA recommendations for changes to existing documentation standards and audit practices include, but are not limited to, the following:

  - **Assessment:** County BH plans support the adoption of standardized assessment domains developed in consultation with county BH plans and other subject matter experts. We would like to see assessment requirements streamlined and simplified to the greatest extent possible.
  - **Client plan vs. problem list:** We recommend that DHCS substantially revise or eliminate requirements for overly prescriptive, point-in-time "client plans," that include pre-planned treatment goals and interventions, as described in the Medicaid state plan for SMH and DMC. A flexible problem list approach, like that often used for primary care services, would enable clinicians to be more responsive to client needs and tailor the clinical interaction to the client in a way that can help address cultural barriers and improve health equity. Clinically appropriate BH

interventions should be made available to clients and covered even if they are not pre-planned in a client plan or linked to client plan goals. Requirements for client signatures on treatment plans should be replaced with more meaningful strategies for shared decision-making.

- **Progress notes:** Clinical notes should accurately reflect services delivered. The integrity and usefulness of these notes are compromised when they are structured strictly to avoid disallowances by repeatedly referencing coverage/impairment criteria (referred to as "medical necessity") and pre-identified treatment plan goals. These requirements prohibit a strengths-based focus in clinical notes because clinicians must formulaically reiterate the problem and purpose of the interventions, rather than focusing on accurate clinical impressions. Requirements to re-establish medical necessity in each note and tie all interventions to treatment plan goals should be eliminated altogether.
- **Clinical audit protocols:** Clinical audit protocols should be revised and simplified significantly to reflect standards used elsewhere in Medi-Cal. As noted above, DHCS should reserve fiscal disallowances for patterns of fraud, waste or abuse. We also emphasize the need to provide effective, ongoing training for DHCS auditors to ensure audit findings reflect DHCS policy, and standards are applied consistently statewide. These reforms would help drive improvements in standardization across plans that DHCS seeks in CalAIM.

- **BH plans support statewide simplification and standardization but do not support a "ceiling" that restricts the information that BH plans may request from their subcontractors.** In discussions with stakeholders, DHCS has referenced the idea of restricting BH plans' ability to enact data or documentation standards for their subcontractors that exceed minimum statewide requirements. CBHDA understands that providers that contract with multiple BH plans seek to reduce variation in contract requirements. We support strategies that will increase standardization, such as the adoption of new domains for assessment and the use of statewide screening and transition of care tools. However, we also believe much of the existing variation between plans is a result of the overly complex documentation currently required for specialty BH services and inconsistencies in state audit and oversight practices. Simplifying documentation requirements as proposed in CalAIM is an essential first step that will help reduce much variation. However, CBHDA believes it is essential that a BH plan retains the ability to advance more rigorous documentation or reporting requirements with a contractor as a tool for innovation or quality improvement. Typically, this kind of flexibility and oversight is part of the role of a managed care plan. As mentioned elsewhere in this document, we hope DHCS will avoid imposing a disparate and more prescriptive standard on county BH plans, and seek alignment with standards for Medi-Cal Managed Care Plans wherever appropriate. Over the next five years, we suggest it is important to focus first on successfully enacting CalAIM documentation reforms, and managing the extensive policy changes that have been proposed. We also anticipate DHCS' own data reporting and quality improvement initiatives will change with the newly established Chief Quality Officer role at DHCS. When simplification and streamlining of specialty BH documentation has been achieved, the state can reevaluate whether additional standardization or a "ceiling" on plan-level documentation, data, or reporting requirements is needed.

III. DRUG MEDI-CAL ORGANIZED DELIVERY SYSTEM (DMC-ODS) UPDATES

CBHDA members look forward to continuing the vital work of improving access to an expanded array of SUD services through the DMC-ODS waiver. Continued capacity-building for publicly funded SUD services is critical in this moment, as the long-running U.S. overdose epidemic intersects with the COVID-19 pandemic. A recent analysis of U.S. Centers for Disease Control and California Department of Public Health data by California Health Policy Strategies found that fatal, drug-related overdoses in California increased by 50 percent between

2017 and 2020, a more significant increase than that in the United States as a whole.[7] Alarmingly, much of this increase is attributable to synthetic opioids like fentanyl, which are often mixed in other drugs such as cocaine and methamphetamine, acting as a hidden killer and increasing a trend of youth overdose deaths. The same analysis found that deaths linked to synthetic opioids rose 541 percent in the same three-year period. Counties have also begun to report rises in overdose rates during the COVID-19 pandemic. Turning the tide on these dangerous trends will require dedicated and sustained investments in SUD treatment, as well as continued attention to refining California's delivery system to improve access and quality of care.

CBHDA generally supports DHCS' proposals to update DMC-ODS waiver terms and conditions. The DMC-ODS is a demonstration program, and clarifying terms and conditions based on lessons learned during the initial demonstration period is necessary progress. We recently submitted detailed comments on several draft Behavioral Health Information Notices that outline DMC-ODS changes that will take effect in 2021, including important clarifications on recovery services and DMC-ODS coverage and payment criteria. In addition to that feedback, we emphasize the following:

- **Contingency management is an important addition to covered DMC-ODS benefits.** As DHCS points out, contingency management is a rare, evidence-based intervention to address stimulant use disorders. Data from the National Survey on Drug Use and Health show that rates of methamphetamine use in adults are growing significantly across the country and are relatively higher in California than in the U.S. as a whole. In 2018, California fell into the second-highest quintile when states are grouped based on rates of past-year meth use (neighbors Oregon and Nevada fall into the highest quintile).[8] We applaud DHCS' efforts to work with CMS to secure Medicaid reimbursement for contingency management and to devise innovative strategies to offer motivational incentives for clients through an approved electronic application or "app."

  We understand that the use of web-based applications is currently the most feasible way to manage motivational incentives given concerns about kick-backs and program integrity. Nonetheless, we would like to share some concerns about reliance on electronic apps. The COVID-19 pandemic has highlighted the digital divide that still exists for many low-income communities and communities of color in California, and we hope the state will work with counties to determine how contingency management may be made more accessible to all Californians. It will also be critical for the state to solicit stakeholder feedback to identify effective contingency management apps that are culturally accessible for diverse Medi-Cal clients. If need be, the state should secure funding to develop such apps. Historically, innovative technologies including direct-to-consumer mental health apps have been plagued by cultural biases that reflect the structural racism and other prejudices of the society that designed them. This is not a reason to abandon these tools, but it is a critical caution whenever we propose to rely on them more extensively. We look forward to partnering with DHCS to address these issues.

  Finally, it appears that contingency management as proposed by DHCS will be an optional component of outpatient treatment among counties that opt into the DMC-ODS. If this proposal is implemented as a pilot program and outcomes are positive, the state should consider investing in this important intervention as a State Plan benefit so it can be available in all counties. In the interim, we ask the Department to communicate clearly to behavioral health advocates that the state has chosen not to fund a universal contingency management benefit at this time, and will instead rely on individual counties to make this investment locally. Counties sincerely appreciate the opportunity to "opt in" and self-finance new Medi-Cal services. We also acknowledge concerns from advocates about the extent to which California relies

[7] California Health Policy Strategies, LLC, "Trends in California Overdose Deaths," (March 2021 Policy Brief), available at: https://secureservercdn.net/198.71.233.109/zb0.123.myftpupload.com/wp-content/uploads/2021/02/Policy-Brief-Overdose-Trends-3.2020.pdf

[8] "The National Survey on Drug Use and Health, 2018", presentation by Elinore McCance-Katz, U.S. Substance Abuse and Mental Health Services Administration, available at https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH. See also NSDUH State Result Reports, 2016-17: https://www.samhsa.gov/data/nsduh/state-reports-NSDUH-2016.

on local, discretionary funding to underwrite valuable behavioral health programs that, consequently, cannot be equally available in all counties. This approach drives unnecessary variation in the delivery of specialty behavioral health services across the state.

- **As described above, we commend DHCS' proposal to increase access to DMC-ODS for youth who are at high-risk for substance use disorders by adding ASAM 0.5 early intervention benefits for Medi-Cal clients under 21 years of age (the EPSDT population).** Research indicates that most adults with substance use disorders begin using drugs or alcohol in their teens. Providers and counties need tools and funding to reach youth *before* they meet diagnostic criteria for an SUD. In the past few years, DMC-ODS counties have worked hard to improve specialty SUD services for adolescents and transition-age youth, and to develop new strategies to engage youth in services. The ability to offer covered Medi-Cal services to a broader population of youth will enable counties to reinvest funds that are currently used for early intervention into areas like upstream prevention activities, recovery housing, and other services that cannot be reimbursed under Medi-Cal.

- **Residential length of stay should be based on clinical need; California must avoid arbitrary limits on reimbursement that will produce unintended consequences for clients**. CBHDA has long advocated that the state and DHCS eliminate the two-episode limitation on reimbursement for adult residential treatment services that was included in the original DMC-ODS demonstration. We thank the state for advancing this change, but caution that the two-episode rule should not be replaced with a similar, one-size-fits-all limit that prioritizes cost containment over clinically appropriate care. We recognize that CMS may ask California to demonstrate a 30-day average residential length of stay as a condition for continued participation in the demonstration waiver. In fact, current data indicates DMC-ODS counties may be able to attain that target. Nonetheless, we ask the state to advocate strongly on behalf of counties and Californians with SUDs. Reimbursement for residential treatment should not be arbitrarily limited. Instead, as DHCS has suggested, the state should evaluate lengths of stay in relation to positive treatment outcomes, and focus on quality improvement and ensuring appropriate transitions of care to other recovery-oriented services for all clients following residential treatment.

- **California should invest in expanding DMC-ODS benefits to all counties to ensure statewide access to the DMC-ODS Medi-Cal benefit.** To date, 37 counties have initiated DMC-ODS demonstrations. Although these counties account for more than 90 percent of the state's Medi-Cal beneficiaries, there are 21 counties that are not yet able to offer the more robust continuum of care covered under DMC-ODS. Most of these are rural counties where geography, small populations, workforce/provider shortages and lack of economies of scale make it more challenging to deliver all health care services. At the same time, many of these counties also have relatively high per capita rates of overdose deaths.

  California's rural counties understand the value of securing federal funding for expanded SUD services and adopting the managed care quality standards of the DMC-ODS. However, they are not well-equipped to take on additional fiscal risk and lack new resources for SUD-specific workforce development or innovative solutions for the unique challenges of rural health care delivery. The option for several counties to enter the DMC-ODS as a multi-county model, potentially in collaboration with a health plan or other 3rd party administrator, is one strategy for building administrative capacity. But this is unlikely to resolve questions around financial risk or network adequacy and workforce development. If the state wishes to prioritize expansion of Medi-Cal SUD services statewide, it must consider allocating dedicated, ongoing funding to help support capacity building and the full array of DMC-ODS benefits. California's opioid epidemic makes expanded access to drug treatment an urgent public health matter.

IV. FACILITATED REFERRAL AND LINKAGE FROM CRIMINAL JUSTICE TO BEHAVIORAL HEALTH AND MEDI-CAL SERVICES 30 DAYS PRIOR TO RELEASE

CBHDA supports the CalAIM proposal to facilitate more consistent referral and linkage from criminal justice settings to community-based behavioral health services. We also applaud the state's proposal to cover select benefits for highly vulnerable populations, including people with behavioral health conditions, for 30 days prior to release from prison or jail through the 1115 demonstration opportunity authorized under the SUPPORT Act. Justice-involved individuals frequently have mental health or substance use conditions and are uniquely vulnerable to overdose and other negative consequences during transitions from incarceration to the community.[9] County behavioral health plans actively partner with Sheriffs, probation, local law enforcement, and the California Department of Corrections and Rehabilitation (CDCR) to coordinate care and referrals for justice-involved individuals. Statewide strategies are also needed to ensure incarcerated people with SMI and SUD are reliably enrolled in Medi-Cal and connected with necessary health and behavioral health services at the time they re-enter their communities.

CBHDA looks forward to participating in stakeholder planning efforts related to these proposals. At present, we offer the following comments and recommendations:

A. Waiver proposal: Facilitated referral and linkage from criminal justice to behavioral health upon release from jail

- **Data and communication solutions will be essential to facilitate effective transitions to community-based BH services.** County BH plans consistently report that one of the biggest barriers to improving timely access to care for justice-involved individuals upon release is simply that county BH plans are not given any timely notification of who these individuals are. This means BH plans have little or no opportunity to assist with care coordination or connection to services. Client referrals are often just that: contact information for the county or a provider is given directly to the individual, who may or may not successfully reach out to request behavioral health services and consequently may "fall through the cracks." Some counties have begun to develop more reliable methods for regular notification and even data exchange, and we would expect DHCS will seek to learn from these success stories to inform solutions that can be scaled. CDCR has also begun to invest in a system for sharing client data and health information with county behavioral health plans or community-based providers. There may strategies that can be adapted from these efforts as well. Ultimately, we would expect that successful warm hand-offs will require some combination of new workflows for jail health services and pre-release coordinators, implementation of "in-reach ECM" as described below, and investments in data solutions.
- **To the extent county BH plans are expected to implement new processes or programs specific to the criminal justice population, the state must provide funding pursuant to Proposition 30/the California Constitution.** County behavioral health plans currently serve numerous justice-involved individuals. These clients are linked to care through a variety of pathways, including 24-hour access call lines, walk-in appointments, direct-to-provider referrals, and specialized programs that focus on criminal justice populations. To implement "facilitated referral and linkage to services," will DHCS require county BH plans to establish new referral processes or coordination programs specific to individuals transitioning from jail? If the state expects county BH to make significant changes to current operations, add staff, invest in new data systems, or otherwise incur new costs, the state must help cover the cost increase as specified in Article 13 Section 36 of the California Constitution.
- **The state should invest in capacity building and workforce development to help Medi-Cal delivery systems better meet the complex needs of justice-involved individuals.** DHCS has already proposed

[9] In the first two weeks after being released from prison, former inmates are 40 times more likely to die from an overdose than the general population. Individuals with heroin use disorders were 74 times more likely to overdose than the general population. See: Shabbar I. Ranapurwala, Meghan E. Shanahan, Apostolos A. Alexandridis, Scott K. Proescholdbell, Rebecca B. Naumann, Daniel Edwards Jr, and Stephen W. Marshall, 2018: Opioid Overdose Mortality Among Former North Carolina Inmates: 2000–2015, *American Journal of Public Health 108,* 1207_1213, https://doi.org/10.2105/AJPH.2018.304514.

PATH supports and incentive payments to help wind down Whole Person Care Pilots and the Health Homes programs, and implement Enhanced Care Management and In Lieu of Services. Successful implementation of ECM and ILOS will benefit justice-involved individuals, who are included in the populations of focus for these programs. We want to highlight a different, but related, need: Currently, counties face shortages of public behavioral health providers that have the ideal skill set and programming to work with justice-involved individuals with complex behavioral health needs and criminogenic risk factors. It is important to note that mental illness and criminogenic risk present providers with distinct training, competency, and capacity needs. In other words, forensic behavioral health could be considered a subspecialty within behavioral health. As the state increases its desire for individuals with justice involvement to be served locally, communities must develop additional, specialized capacity to serve this population. As it stands today, county BH plans frequently face challenges identifying providers that can offer competent care for individuals with criminogenic risk factors, or programs willing to serve individuals with a history of violent offenses, sex offenses, arson, and other justice-involvement. There are excellent models that do exist for these high-needs individuals, but if the state wants to prioritize better care for this population over the long term, California should make targeted investments in workforce training and other capacity building options to strengthen the delivery system for this population.

B. Waiver proposal: Medi-Cal services 30 days prior to release

- **County behavioral health plans will be critical partners for Managed Care Plans as MCPs administer "in-reach ECM" services for incarcerated individuals with SMI and SED and work to connect beneficiaries with appropriate behavioral health services upon re-entry.** DHCS' proposal to cover Enhanced Care Management services for 30 days prior to release from jail, prison, or juvenile detention facilities promises to help improve coordinated transitions to community-based services for individuals with serious mental illness and substance use disorder. As with Enhanced Care Management more broadly, this focus on the SMI and SUD populations means that Medi-Cal Managed Care Plans must engage county BH plans as partners in implementing the benefit and ensuring care coordination. MCPs should also consider offering ECM contracts to county BH plans that are inclusive of the pre-release SMI/SUD population, if the county believes it has capacity to take on jail in-reach.

V. BEHAVIORAL HEALTH PAYMENT REFORM

The current CalAIM proposal would transition counties from cost-based reimbursement to standard fee-for-service (FFS) reimbursement supported by intergovernmental transfers (IGT). County BH plans thank DHCS for the work on these proposals to date, and affirm that payment reform for Medi-Cal behavioral health services is essential. At present, federal reimbursement to county behavioral health plans is strictly limited to the costs to provide each Medi-Cal service. To obtain federal reimbursement, both counties and the state must engage in onerous, labor-intensive tracking and reporting processes. Counties self-finance the non-federal share of Medi-Cal payments for BH services using dedicated revenue sources (1991 and 2011 Realignment and MHSA), and it can take as many as six to ten years to fully audit and reconcile federal reimbursement for each fiscal year. Consequently, counties carry significant financial risk from year to year. But unlike other Medi-Cal managed care plans, behavioral health plans receive no underwriting gain (the increment above cost that is built into capitated rates to accommodate a health plan's ongoing management of fiscal risk). These stringent limitations on federal reimbursement, combined with the risk resulting from self-financing, virtually eliminate opportunities for BH plans to reinvest in delivery system improvements, expand services, or offer value-based payments to their subcontracted BH providers. Necessary non-Medi-Cal reimbursable costs for serving this population, including IMD services which may be required for Medi-Cal beneficiaries, further constrain the availability of additional resources for capacity building investments.

Counties view the FFS/IGT transition as an incremental step to adopting capitated rates. Ultimately, capitation can support maximum flexibility for effective benefits administration and innovative payment arrangements with

BH providers. A transition to capitation raises complex questions about risk management for a population that is, by definition, seriously ill and high-cost. At this point in time, the FFS/IGT model is a viable short-term option to increase BH plan efficiency, maximize federal reimbursement and improve fiscal stability, and eventually enable value-based payment of behavioral health services.

To ensure our specialty delivery systems can capitalize on the potential benefits of payment reform, CBHDA recommends the following:

- **Establish cost-plus FFS reimbursement rates that fully cover the costs of each service for each county within a "peer group," and enable system reinvestment**. CBHDA appreciates DHCS' commitment to collaboration with counties on rate development, as well as other key components of payment reform. CBHDA has emphasized that historical cost data for many counties and service types will not fully capture future costs. CalAIM policy changes are likely to significantly change patterns of utilization by increasing the population that is eligible for specialty BH services. In some cases CalAIM will also enable reimbursement for new services, like peer-based supports and contingency management for SUD. CBHDA and DHCS have discussed gaps or shortcomings in available cost report data, such as the minimal data available on relatively new DMC-ODS services in many counties, the lack of data on services represented by specific CPT codes which are more granular/specific than the HCPCS codes that were previously used, and inconsistencies in the way costs are allocated by counties and then re-allocated by DHCS auditors. Given this complexity, CBHDA strongly recommends that DHCS continue to collaborate closely with counties and outside subject matter experts to develop a "cost, plus" rate-setting methodology that begins with historical cost data, then uses supplemental data sources to make appropriate adjustments for trends, policy changes, and market factors and identify a reasonable level of reimbursement above cost. Once a framework for rate development has been identified, the data analysis conducted to inform rate-setting can help identify the number and composition of county peer groups. CBHDA looks forward to providing additional recommendations on rate development in the near future.

- **Create mechanisms to review rates and adjust if needed.** CBHDA has requested that at least initially, DHCS should conduct annual reviews of FFS rates for specialty behavioral health services to determine whether adjustments are needed. Individual county BH plans should also be permitted to request a review of their peer group/rates. Mechanisms should be considered to allow for emergency review or rate exceptions where access to medically necessary services might be compromised, particularly in the first few years of this transition.

- **Offer timely and accurate IGT payments to county BH plans to mitigate risk to counties.** As noted, counties have experienced longstanding challenges managing financial risk that results from delayed reconciliation of federal reimbursement. Because IGTs require counties to make prospective payments to the state in order to draw down federal dollars, payment reform will introduce a new kind of risk. The IGT process will strain cash flow in counties if payments processed by the state are not unfailingly regular and reliable. Counties have endorsed DHCS' proposal to administer federal reimbursement using monthly IGT transfers with counties (at least for an initial period). We believe this method can work if DHCS is fully prepared to process timely IGT payments to counties in order to stabilize cash flow, and to focus on improving accuracy in claims processing so that reconciliation can occur efficiently.

- **Provide regular updates on payment reform policy and implementation decisions to counties, BH providers, and other stakeholders, and engage in ongoing TA with county BH plans, specifically.** CBHDA appreciates DHCS' plans to engage CBHDA members and the CalAIM Behavioral Health Payment Reform workgroup throughout the payment reform implementation process. We also suggest that a more inclusive forum for stakeholder updates may be helpful, and additional TA for county BH plans will be critical. Thousands of staff members that work for both county BH plans and subcontracted providers across the state must play a role in implementing payment reform changes like the CPT code transition. DHCS can support these efforts by providing frequent and clear communication about policy

decisions, and creating forums to address FAQs from stakeholders. CBHDA also recommends that DHCS establish a learning collaborative or regular Training and Technical Assistance series specifically for county BH plans.

VI. BEHAVIORAL HEALTH REGIONAL CONTRACTING

County behavioral health plans value the flexibility that is currently available in state statute and under the DMC-ODS waiver to execute their Medi-Cal responsibilities jointly as a group of counties. CBHDA members recognize that administering BH services collectively can improve standardization of policies and care delivery, create efficiencies, and optimize scarce fiscal and workforce resources. Potential approaches to regional contracting range from a Joint Powers Authority of two or more counties (like that currently used by Sutter and Yuba counties to administer MH and SUD services) to a multi-county collaborative led by a single administrative entity, such as the DMC-ODS model led by Partnership Health Plan. In fact, California's 58 counties have invested in a statewide Joint Powers Authority, CalMHSA, which offers additional promise for intra-county collaboration and coordination.

Counties are currently exploring options to jointly administer specific managed care functions or contracts, such as joint procurement and implementation of a shared, "semi-statewide" electronic health record and multi-county provider contracts to help address behavioral health access and workforce shortages. Counties will also consider options for forming multi-county behavioral health plans or networks, akin to the Partnership Health Plan DMC-ODS model. However, we note that implementation of these models requires significant technical expertise, financial investment, and time. Regional models are not quick fixes for existing resource gaps. In pursuing any strategies for administrative efficiency or integration, CBHDA members will continue to prioritize quality of care and outcomes for behavioral health clients.

VII. ADMINISTRATIVE INTEGRATION OF MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES

CBHDA members strongly support DHCS' proposal to integrate Medi-Cal Specialty Mental Health (SMH) and Drug Medi-Cal/Drug Medi-Cal Organized Delivery System (DMC/DMC-ODS) services under a single managed care contract with county behavioral health departments. This proposal will improve administrative efficiency for the state and for counties. Critically, it should be implemented in a manner that prioritizes clinical integration alongside administrative integration.

California's SMH and DMC/DMC-ODS programs are distinct benefits packages that, for the most part, are delivered through distinct delivery systems and provider networks even though both are administered by county behavioral health plans. Until 2014, these programs were also regulated by separate state agencies. They continue to be governed by distinct state plan amendments, regulations, waiver programs, and oversight practices. For the most part these differences are not codified in state statute but have been enacted through disparate regulations and layers of policy guidance contained in DHCS Information Notices, waiver terms, and contract provisions.

The need to comply with two extensive sets of programmatic and fiscal requirements (even though the contracting entity is the same) discourages BH providers from participating in both programs. The bifurcated benefit structure also disincentivizes co-located or team-based treatment for co-occurring mental health and substance use conditions. At present, to offer MH and SUD services at the same clinic site, an operator must obtain multiple licensure types and/or site and program certifications. Client assessments and treatment plans must be completed according to two different sets of standards. Claiming and coding rules are different, and medical charts and other records are subject to separate audits and reviews. Providers must report similar or overlapping SMH and DMC/DMC-ODS encounter data through two different data systems. The list goes on.

Per SAMHSA's National Survey on Drug Use and Health, roughly 1 in 4 adults with SMI also has an SUD. The rates of cooccurring SED and SUDs are even higher among youth. **If California hopes to improve treatment**

outcomes for people with co-occurring behavioral health conditions, we must advance delivery system reforms that align specialty behavioral health program requirements.

- **In addition to pursuing combined contracts and oversight procedures at the state/county level, DHCS should work with stakeholders to identify and resolve differences in existing regulatory and programmatic requirements for SMH and DMC/DMC-ODS that discourage BH providers from participating in both programs or offering more integrated care.** Changing this landscape of disparate requirements that has evolved for two separate programs over many decades will take time and resources. We urge DHCS to prioritize this work over the next five years so that the contract change proposed for 2027 can also support improvements in patient care.
- **Where possible, enable counties to move ahead with integration of specific functions ahead of 2027.** Advancing integrated MH and SUD services is a longstanding priority for county BH plans. We hope DHCS will examine lessons learned from those counties that are at the forefront of clinical and programmatic integration for MH and SUDs, and seek to identify state administrative and contract functions that can be aligned, and requirements that can be reformed, in advance of the new contract structure in 2027.

VIII. BENEFITS STANDARDIZATION: SACRAMENTO AND SOLANO KAISER BENEFICIARIES

DHCS' updated CalAIM proposal outlines the state's intention to implement a carve-out of Specialty Mental Health Services for Medi-Cal beneficiaries enrolled in Kaiser managed care plans in Solano and Sacramento counties beginning January 1, 2022. Historically, in Sacramento and Solano, Kaiser has covered inpatient and outpatient specialty mental health benefits for its serious mentally ill enrollees. Beneficiaries served by other managed care plans have received SMH benefits administered by the county behavioral health plan.

CBHDA must oppose the current proposal to implement this significant change in eight months' time with no additional funding or coordination planning to support the transition and continuity of care for these beneficiaries. This approach leaves the two counties without adequate time or resources to prepare to serve significant numbers of new beneficiaries. Sacramento County estimates that, under the state's proposal, 11,000 new SMI beneficiaries will transition into a program currently structured to serve approximately 30,000 beneficiaries, with no new resources.

Without additional resources, the proposed transition threatens to harm an extremely vulnerable population of Medi-Cal clients with serious mental illness. We support DHCS' goal to align benefits coverage and care delivery statewide. However, we do not believe the state has proposed an appropriate timeline for this change, and we do not agree that the two counties should be asked to absorb a significant increase in their covered populations and somehow pay for all needed services within existing funds.

The following facts from Sacramento County illustrate the scope of this challenge: Sacramento County currently serves approximately 30,000 SMH clients a year. Kaiser has estimated that its SMI beneficiary population would add approximately 11,000 additional Medi-Cal beneficiaries with SMI to the county behavioral health plan. This would be a 36.67% increase in Sacramento County's SMH obligation. These Medi-Cal beneficiaries will require the county to expand its networks and purchase new, costly and scarce inpatient care. In fact, due to a lack of Medi-Cal reimbursable inpatient beds, the County would likely incur significant new IMD costs for those higher acuity individuals in need of inpatient levels of care. These new costs would strain already scarce resources available for other beneficiaries in need of IMD levels of care not fundable through Medi-Cal. Based on current per capita expenditures, Sacramento has estimated that it would cost the county approximately $130.8 million to build out their capacity by roughly a third to serve the new Kaiser beneficiaries. Beyond the immediate cost pressure and lack of dedicated resources for this transition, the state's proposal would not allow adequate time to

plan for continuity of care for tens of thousands of complex, vulnerable beneficiaries while the challenges of the COVID-19 pandemic persist.

- **DHCS should work with Sacramento and Solano counties and Kaiser to negotiate a fully funded transition of benefits that allows substantial time for planning and network procurement.** We do not understand the rationale for an unfunded, hastily planned transition which could put these beneficiaries at risk. We expect it would lead to disruptions in care for Kaiser beneficiaries, while forcing Sacramento and Solano counties to make painful and unnecessary decisions about how to reallocate resources that are currently being used to provide life-saving mental health services to other Medi-Cal beneficiaries. We urge the administration to significantly adjust this proposal and the timeline for enactment.

IX. BEHAVIORAL HEALTH PEER SUPPORT SPECIALIST SERVICES

CBHDA strongly supports the waiver necessary to allow the optional county implementation of peer support specialist certification and Medi-Cal reimbursable peer support services. CBHDA championed the option to implement peer support specialist certification at the county level as a response to various failed efforts to establish this program statewide.

Peer support is an evidence-based, cost-effective model of care proven to reduce costly hospitalizations and homelessness, increase participation in treatment, and improve service experience. Peer support specialists, people who self-identify as having lived experience of a mental health and or substance use condition, use their lived experience along with skills learned in formal training to assist others in their recovery from mental illness. Forty-eight states recognize their value and have a certification process in place or in development for mental health peer support specialists.

Peer support specialist certification is conducted at the state level in other states; however, in California integrating this critical workforce within Medi-Cal will be the responsibility of counties. In California, counties will have the option to include this valuable workforce to provide Medi-Cal reimbursable peer support services based on statewide standards that meet CMS requirements developed by DHCS. The DHCS comprehensive stakeholder process to develop the statewide standards has been a commendable example of partnership with an invested group of stakeholders, and CBHDA looks forward to continued partnership with DHCS and other behavioral health stakeholders to support effective implementation of peer support specialist services.

X. ENHANCED CARE MANAGEMENT AND IN LIEU OF SERVICES

DHCS' proposals for Enhanced Care Management (ECM) and In-Lieu-of-Services (ILOS) promise to improve health outcomes for Californians with SMI and/or SUDs, and county BH plans are committed to collaborating with DHCS and their local managed care plans to realize this potential. People with SMI and/or SUDs currently experience significant health disparities, most notably rates of premature mortality that reduce life expectancy by 7-24 years when compared with the general population.[10] Much of this excess mortality risk is attributable to poorly treated physical health conditions, including cardiovascular disease.[11] These poor outcomes are not unique to California or to Medicaid; they are reported across the United States and more broadly throughout the world. Health policy experts generally agree that improvements in care coordination across providers and service delivery systems, and enhanced attention to addressing social determinants of health like poverty and housing, are key interventions to reverse these trends. Care coordination can ensure that people undergoing treatment for MH

[10] Chesney, E., Goodwin, G. M., & Fazel, S. (2014). Risks of all-cause and suicide mortality in mental disorders: a meta-review. *World psychiatry : official journal of the World Psychiatric Association (WPA), 13*(2), 153–160. https://doi.org/10.1002/wps.20128

[11] Colton CW, Manderscheid RW. Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states. *Prev Chronic Dis [serial online]* 2006 Apr. Available from: URL: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm.

or SUD conditions also receive accessible and effective treatment for their physical health needs. By incorporating and reimbursing additional services meant to address social determinants of health, a model like ECM plus ILOS can offer holistic health supports and begin to reduce the disparities in mortality experienced by people with BH conditions.

County behavioral health (BH) plans are key partners in care management for Medi-Cal beneficiaries that the Department of Health Care Services (DHCS) hopes to serve with ECM and ILOS. Numerous individuals with behavioral health conditions will become eligible for ECM within DHCS' proposed populations of focus. Many of these beneficiaries currently rely on county behavioral health plans as their primary providers of health care services and primary points of contact within Medi-Cal. At present, county BH plans use both Medi-Cal and other funding sources like the Mental Health Services Act (MHSA) to underwrite specialized case management and an array of supportive services for people with SMI and SUD. Services offered by county BH may include transition planning, family and caregiver supports, coordination of physical health and social services, and housing navigation. These services are in-person, field-based, and similar to activities that DHCS proposes to cover through ECM or as ILOS. CBHDA has consistently expressed concerns that if ECM and ILOS are implemented without sufficient coordination between MCPs and county BH plans, duplication of services or payment could occur, along with missed opportunities to augment available services and address social determinants of health for high-risk beneficiaries with behavioral health conditions.

County BH plans hope to partner with MCPs to implement a coordinated ECM program that supplements and complements county BH services and does not duplicate or replace them. Ideally, ECM could open up new opportunities for federal reimbursement for services that county behavioral health may currently pay for using other, non-Medicaid funding sources (e.g., unmatched Mental Health Services Act dollars). This would enable county BH plans to reinvest dedicated BH funds in areas where Medi-Cal reimbursement remains unavailable, such as housing subsidies or "upstream" prevention services like early psychosis programs. Investments in behavioral health services can in turn help improve physical health outcomes for individuals with SMI and SUD, and reduce reliance on hospital, emergency, and long term care services. In other words, all Medi-Cal delivery systems can benefit from effective implementation of ECM and ILOS.

Ongoing dialogue between DHCS, county BH plans, and MCPs will be needed to achieve these goals. CBHDA has provided DHCS with detailed comments and recommendations in response to DHCS' draft guidance, including the ECM Model of Care template. Please see our letter dated March 12, 2021, and subsequent recommendations shared with representatives from Manatt Health Strategies. We continue to emphasize the following key recommendations:

- **ECM/ILOS should be data driven and informed by data exchange and collaborative analysis between MCPs and county BH plans.** Plan-to-plan data exchange and related strategies could be formalized as part of the CalAIM population health management planning requirements for MCPs that DHCS plans to implement in 2023. Data analysis undertaken as part of ECM implementation and CalAIM population health management planning offers unprecedented opportunities for DHCS to work with MCPs and county BH plans to measure and address health disparities faced by individuals with SMI and SUDs, as well as disparities linked to race, ethnicity, gender, and other factors.

- **ECM target populations and eligibility criteria should be refined to prioritize individuals with SMI and SUDs who are at high risk for premature mortality or poor health outcomes due to the acuity of their MH or SUD.** We recommend DHCS eliminate the proposed requirement that individuals with SMI/SED/SUD also have chronic physical health conditions. ECM can be a valuable tool to support BH clients in identifying and addressing physical health needs *before* those physical needs become chronic and costly. It is well documented that individuals with SMI and SUD often lack connections to primary care. As a result, these beneficiaries are at highest risk for undiagnosed or untreated underlying physical health conditions and may not be known to their MCP. ECM benefits should not be limited to

beneficiaries who are already "high cost" or "high utilizers," but rather target known high-risk populations, including county BH plan clients.

- **County behavioral health plans and MCPs should use statewide eligibility criteria published by DHCS to identify individuals who can benefit from ECM. MCPs should accept ECM referrals from county behavioral health plans and authorize ECM for an initial period until reassessment.** This would be similar to the way DHCS has proposed to automatically authorize ECM for beneficiaries who were previously served in Whole Person Care pilots and Health Homes programs and who already meet defined eligibility criteria.

- **DHCS should require MCPs to engage in ECM/ILOS transition planning with county BH and to pursue contracts with county BH plans to administer ECM for beneficiaries with SMI/SED/SUDs, unless specified exception criteria apply** (e.g., the BH plan declines to contract). While not all county BH plans will ultimately contract to provide ECM services, all should be engaged in collaborative planning. Consistent with the policies DHCS has proposed for Whole Person Care and Health Homes entities and Local Government Agency Targeted Case Management programs, MCPs should report to DHCS on the policies and procedures they will implement to avoid duplication of services with BH plans and maximize Medi-Cal reimbursement.

XI. PATH SUPPORTS AND INCENTIVE PAYMENTS

CBHDA applauds DHCS' acknowledgment that the system transformations envisioned in CalAIM will require new resources for health plans, counties, and Medi-Cal providers. We support the proposal for expenditure authority for Providing Access and Transforming Health (PATH) supports. We also support the state's plan to offer incentive payments through Medi-Cal managed care plans to develop the infrastructure needed to expand Enhanced Care Management and In Lieu of Services.

- **CBHDA would like to work with the state to identify options to fund ongoing joint planning and improvements in data exchange between MCPs and county BH plans.** We have consistently recommended that Medi-Cal Managed Care Plans actively partner with county behavioral health plans to assess risk for shared beneficiaries, plan new programs and interventions, and administer Medi-Cal services and supports in a coordinated fashion. Specifically, we have asked the state to require this joint planning as part of the CalAIM Population Health Management Program proposal, and for ECM and ILOS implementation. If DHCS seeks to reduce health disparities experienced by people with SMI and SUDs, it is imperative that the state support MCPs and county BH plans in identifying shared population health goals specific to high-risk individuals with BH conditions and improving plan-to-plan coordination. One key strategy to drive better coordination is reliable plan-to-plan data exchange, which has long posed challenges for both MCPs and county BH plans. Dedicated funding for joint population health planning would help advance these efforts. We recognize that DHCS' proposals already include opportunities for MCPs to share incentive payments with ECM and ILOS contractors, but emphasize that joint planning functions are distinct from the functions a BH plan may perform if they contract with the MCP as an ECM or ILOS provider. We ask DHCS to consider incorporating milestones related to plan-to-plan data-sharing and joint population health management planning in proposals for incentive payments to MCPs. Funds could then be used to build capacity for county BH plans to partner with their MCPs in these ways. We are also interested in exploring options for incentive payments administered directly through county BH plans following BH payment reform.

* * *

CalAIM promises to create real, positive, and long-lasting improvements in the ability of Medi-Cal beneficiaries to receive accessible, timely, culturally, and linguistically appropriate behavioral health services. The behavioral

health proposals represent a sweeping and ambitious overhaul of our state's specialty behavioral health system for Medi-Cal beneficiaries. This evolution of the public behavioral health safety net comes at a time when behavioral health services are more important than ever, and we applaud the administration for its significant investment in the needs of Medi-Cal beneficiaries with behavioral health conditions. We look forward to supporting successful implementation of the CalAIM vision.

Thank you for your consideration of our comments and recommendations. Please contact our team directly at mcabrera@cbhda.org or pwilhelm@cbhda.org if we can answer any questions or provide any additional information to clarify our comments in this letter.

Sincerely,

Paula Wilhelm
Director of Policy

Cc: Lindy Harrington, DHCS
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NEMS
NORTH
EAST
MEDICAL
SERVICES

東 北 醫 療 中 心

May 5, 2021

Will Lightbourne, Director
California Department of Health Care Services
1500 Capitol Avenue
Sacramento, CA 95814

Via Electronic Submission through CalAIMWaiver@dhcs.ca.gov

RE: Public Comments on California 1115 & 1915(b) Waiver Proposal

Dear Director Lightbourne,

North East Medical Services (NEMS) appreciates the opportunity to comment on the proposed CalAIM Section 1115 and Section 1915(b) Waiver Amendment and Renewal Applications. NEMS is one of the largest community health centers in the United States targeting the medically underserved Asian population. Based in the San Francisco Bay Area with clinics in San Francisco, Daly City, and San Jose, we offer comprehensive health care services to over 65,000 patients, a majority of whom are uninsured or low-income. As most of our patients prefer to be served in a language other than English, NEMS prioritizes providing linguistically competent and culturally sensitive health care services to some of [redacted] unities.

NEMS 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:

- Remove the implementation of Medi-Cal Rx as part of the CalAIM proposal 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.
- DHCS must ensure community providers, including community health centers and clinics, 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 should remove the implementation of Medi-Cal as part of the CalAIM proposal 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***.

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Providing pharmacy benefits and services in the context of Medi-Cal managed care enables FQHCs like NEMS to effectively leverage discount drug pricing available through the 340B Drug Pricing Program. The savings available through participation in the 340B program allow us to provide vital services to more patients, such as behavioral health services, subsidized prescriptions, and expanded health programs and services that are not covered by any other funding source. Additionally, integrating pharmacy and medical services in managed care allows us to better serve patients by allowing us to assist patients in following their treatment plan, including pharmacy.

NEMS has many monolingual, Chinese-speaking and non-English-speaking patients, so it is even more crucial that our doctors can directly coordinate with our pharmacy care team to oversee our patients' care. Our health care and pharmacy team work together to monitor our patients' medication compliance and provide follow-up care in a language that our patients can understand. Our multilingual pharmacy care team provides consults and answers questions about medications in a culturally and linguistically competent manner – especially for specialty medications, which can require a lot of detailed instructions. To avoid patients missing doses or risk having the medication spoil by delivering specialty medicines through a mailing service, NEMS offers hand-delivery of specialty medicines to our patients' homes, which is something unique to our health center. These services are made possible in part by 340B savings, which supports our ability to deliver the best [redacted]atients.

Medi-Cal Rx, however, 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. There is not a more inappropriate and inopportune time to create a challenge for FQHCs in California, especially those who serve people of color, as we face the double pandemic of COVID-19 and the proliferation of hate crimes against Asians and systemic racism in general. 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. DHCS needs 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, which will not be achieved through the CalAIM 1915b waiver.

2. ***DHCS must ensure community providers, including health centers, are eligible for support under Providing Access and Transforming Health (PATH).***

The "Providing Access and Transforming Health (PATH) Supports" is a new, time-limited initiative under the new proposed Medicaid 1115 waiver. Pending CMS approval of this new initiative, PATH funding will be used to support capacity building, infrastructure, and IT systems for community-based ECM and ILOS providers. NEMS 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

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these elements, it is important that community-based organizations, including health centers, have the tools and resources needed to work together. Therefore, we respectfully ask DHCS to ensure ample resources and support available to ECM and ILOS providers.

3. ***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. As we support the Administration in the COVID-19 effort by vaccinating over 41,000 patients and vulnerable community members to date, the January 1, 2022 implementation date is ambitious and requires careful planning to ensure successful implementation while avoiding disruption to current operation.

NEMS appreciates this opportunity to submit comments on the waiver proposal. We look forward to working with you to implement these major changes.

Sincerely,

[redacted]

Eddie Chan, PharmD
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