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January 28, 2022

Ms. Jacey Cooper  
Chief Deputy Director  
State of California, Health Care Programs  
1501 Capitol Avenue, MS 0000  
P.O. Box 997413  
Sacramento, CA 95899-7413

Dear Ms. Jacey Cooper:

California submitted a Managed Care Risk Mitigation COVID-19 Public Health Emergency (PHE) section 1115 demonstration application on December 29, 2021. This letter serves as time-limited approval of the request included in the state's Managed Care Risk Mitigation COVID-19 PHE section 1115 demonstration application, which will be approved as an amendment under the "California Advancing and Innovating Medi-Cal" (CalAIM) section 1115(a) demonstration (Project Number 11-W-00193-9).

On March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act) as amended (42 U.S.C. 1320b-5). On March 13, 2020, pursuant to section 1135(b) of the Act, the Secretary of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences of the COVID-19 pandemic, to the extent necessary, as determined by the Centers for Medicare & Medicaid Services (CMS), to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the respective programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of such requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect on March 15, 2020, with a retroactive effective date of March 1, 2020. We note that the emergency period will terminate upon termination of the public health emergency (PHE), including any extensions.

In response to the section 1115(a) demonstration opportunity announced to states on March 22, 2020 in State Medicaid Director Letter (SMDL) #20-002,<sup>1</sup> on December 29, 2021, California submitted an 1115 COVID-19 demonstration application to address the COVID-19 PHE. CMS has determined that the state's application is complete, consistent with the exemptions and

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<sup>1</sup> See SMDL #20-002, "COVID-19 Public Health Emergency Section 1115(a) Opportunity for States," available at <https://www.medicare.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20002-1115template.docx>.

flexibilities outlined in 42 CFR § 431.416(e)(2) and 431.416(g).<sup>2</sup> CMS expects that states will offer, in good faith and in a prudent manner, a post-submission public notice process, including tribal consultation as applicable, to the extent circumstances permit.

This amendment would test whether, in the context of the current COVID-19 PHE, an exemption from the regulatory prohibition in 42 CFR § 438.6(b)(1) promotes the objectives of Medicaid. To that end, the expenditure authority is expected to support states with making appropriate, equitable payments during the PHE to help maintain beneficiary access to care. This exemption allows states to enter into or modify a risk mitigation arrangement with a Medicaid managed care plan after the applicable rating period has begun.

CMS has determined that this amendment – including the expenditure authority detailed below – promotes the objectives of Medicaid because it is necessary to ensure appropriate, equitable payment for services during the PHE, and it assists the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE. To that end, the demonstration amendment is expected to help the state furnish medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by the COVID-19 PHE. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation but before the start of the rating period.

As part of ongoing managed care oversight, CMS will investigate how providing this authority results in either increased or decreased payments to plans, given the significant fluctuations in utilization that may occur during a pandemic. In addition, CMS's managed care oversight efforts will include an assessment of whether and how payments under the retroactive risk mitigation arrangements, which must be developed in accordance with all other applicable requirements in 42 CFR § 438, including §§ 438.4 and 438.5, and generally accepted actuarial principles and practices, are sufficient to cover costs under the managed care contract. Finally, CMS will ascertain how the implementation of risk mitigation after the start of the rating period, which may not truly address the uncertainty inherent in setting capitation rates prospectively, compares to not allowing retroactive risk sharing during a PHE, which may lead to substantially inaccurate or inequitable payments given the severe disruption in utilization. As with all section 1115 demonstrations, CMS will take into account the experience of the state and managed care plans in this demonstration, gathering more information about the efficacy of such a demonstration during a PHE.

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<sup>2</sup> Pursuant to 42 CFR 431.416(g), CMS has determined that the existence of unforeseen circumstances resulting from the COVID-19 PHE warrants an exception to the normal state and federal public notice procedures to expedite a decision on a proposed COVID-19 section 1115 demonstration. States applying for a COVID-19 section 1115 demonstration are not required to conduct a public notice and input process. CMS is also exercising its discretionary authority to expedite its normal review and approval processes to render timely decisions on state applications for COVID-19 section 1115 demonstrations. CMS will post all section 1115 demonstrations approved under this COVID-19 demonstration opportunity on the Medicaid.gov website.

### **Expenditure Authority**

CMS is approving expenditure authority for the state to add or modify a risk sharing arrangement after the start of the rating period to maintain capacity during the emergency. This expenditure authority applies only to contracts and rating periods that begin or end during the COVID-19 PHE. This expenditure authority allows the state to add or modify the risk sharing mechanism(s) after the start of the rating period as specified in the state's contracts with its Medicaid managed care plans. The authority would exempt, as necessary, the state from compliance with the current requirements in section 438.6(b)(1), until the end of the PHE. The authority would allow one or more retroactive risk mitigation arrangements to remain in place even if the state and the managed care plan had agreed to these arrangements after the requirements in section 438.6(b)(1) became effective. This authority is effective regardless of whether the state substantially complied with the regulation by, for example, submitting unsigned contracts and rate certification documents for CMS review either before or after the effective date of the new regulation, but before the start of the rating period.

If the contract and rating period begins or ends during the COVID-19 PHE and the contract was signed prior to the last day of the PHE, CMS is hereby granting expenditure authority to permit the state to retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period *ended* on or after March 1, 2020 and ended prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. If the rating period *began* after March 1, 2020, and prior to the last day of the PHE, the state can retroactively implement one or more risk sharing arrangements for the full duration of the rating period. A state can only retroactively implement risk sharing arrangements under this demonstration for multiple rating periods if the contract signature criteria as well as the rating period beginning and/or ending criteria are met for each rating period.

### **Monitoring and Evaluation Requirements**

Consistent with CMS requirements for monitoring and evaluation of section 1115 demonstrations, the state will be required to develop an Evaluation Design and a Final Report, that will consolidate the demonstration's monitoring and evaluation requirements. The draft Evaluation Design will be due to CMS no later than 180 calendar days after approval of the demonstration. The draft Final Report will be due to CMS 18 months after either the expiration of the demonstration approval period or the end of the latest rating period covered under the state's approved expenditure authority, whichever comes later.

CMS will provide guidance to help the state fulfill the monitoring and evaluation requirements, including assistance in developing the Evaluation Design. Given the unique circumstances and time-limited nature of the demonstration, CMS expects California to undertake data collection or analyses that are meaningful but not unduly burdensome for the state. Specifically, the state should focus on qualitative methods and descriptive statistics to address evaluation questions that will support understanding the successes, challenges, and lessons learned in implementing the demonstration. The state is also expected to review 42 CFR § 431.428 to ensure that the Final Report captures all applicable requirements stipulated for an annual report (e.g., incidence and results of any audits, investigations or lawsuits, or any state legislative developments that may

impact the demonstration). The Evaluation Design and the Final Report will cover all risk sharing arrangements and rating periods under the scope of the demonstration.

Once approved, per 42 CFR § 431.424(e), the state is required to post the Evaluation Design to its Medicaid agency website within 30 calendar days of CMS approval. Likewise, per the standard Public Access requirement associated with section 1115 demonstration deliverables, the state will post the CMS-approved Final Report to its website within 30 calendar days of CMS approval.

Per 42 CFR § 431.420(f), the state must comply with any requests for data from CMS and/or its federal evaluation contractors.

In addition to the section 1115 monitoring and evaluation requirements outlined above, the state must separately comply with the applicable managed care reporting requirements per 42 CFR § 438.66 and section 1936(b) of the Social Security Act.

*Other Information*

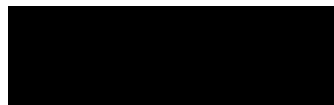
Approval of this expenditure authority is conditioned upon continued compliance with the previously approved STCs, which set forth in detail the nature, character and extent of anticipated federal involvement in the project.

In addition, the approval is subject to CMS receiving written acceptance of this award within 15 days of the date of this approval letter. Your project officer is Julian Taylor. Mr. Taylor is available to answer any questions concerning implementation of the state's section 1115(a) demonstration amendment and his contact information is as follows:

Centers for Medicare & Medicaid Services  
Center for Medicaid and CHIP Services  
Mail Stop S2-25-26  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850  
Email: [Julian.Taylor@cms.hhs.gov](mailto:Julian.Taylor@cms.hhs.gov)

We appreciate your state's commitment to addressing the significant challenges posed by the COVID-19 pandemic, and we look forward to our continued partnership on the CalAIM section 1115(a) demonstration. If you have any questions regarding this approval, please contact Ms. Judith Cash, Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Sincerely,

A black rectangular redaction box covering the signature of Daniel Tsai.

Daniel Tsai  
Deputy Administrator and Director

cc: Cheryl Young, State Monitoring Lead, Medicaid and CHIP Operations Group