

January 14, 2022

Ms. Jacey Cooper
Chief Deputy Director, Health Care Programs
California Department of Health Care Services
1501 Capitol Avenue, 6th Floor, MS 0000
Sacramento, CA 95814

Dear Ms. Cooper:

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 as of 6:00 PM Eastern Standard Time 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.

For the reasons discussed below, CMS is approving an amendment to the Special Terms and Conditions (STC) for California's section 1115(a) demonstration titled, "Medi-Cal 2020" (Project No. 11-W-00193/9). The amendment provides expenditure authority for state payments to providers for the administration of a COVID-19 vaccine for the following state plan limited-benefit populations from December 14, 2020 through March 10, 2021:

1. Individuals eligible for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1);
2. Individuals eligible for the optional COVID-19 group, as described in section 1902(a)(10)(A)(ii)(XXIII); and

3. Individuals eligible for family planning benefits under the Family Planning Access, Care and Treatment (Family PACT) program, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii).

Starting March 11, 2021, section 1905(a)(4)(E) of the Act (as added by section 9811 of the American Rescue Plan Act of 2021 (ARP)), and corresponding amendments to sections 1902(a)(10), 1916, 1916A, and 1937 of the Act, require states to cover COVID-19 vaccines and their administration, without cost-sharing, for nearly all Medicaid beneficiaries, including most groups receiving limited-benefit packages under the state plan or a section 1115 demonstration. This coverage is required beginning March 11, 2021, and (generally) ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. Under the ARP's amendments, individuals in the specific limited-benefit eligibility groups listed above are eligible for coverage of a COVID-19 vaccine and its administration under the state plan beginning March 11, 2021. This demonstration amendment provides expenditure authority for vaccine administration coverage provided to these limited-benefit populations during the period prior to the effective date of the ARP coverage requirements, when they did not receive COVID-19 vaccination coverage under the state plan. Currently, and during the effective period of this amendment, COVID-19 vaccines are federally purchased; therefore the only expenditure authority necessary for this amendment is for payments for the administration of a COVID-19 vaccine.

CMS has determined that the state's application is complete, consistent with the exemptions and flexibilities outlined in 42 CFR 431.416(e)(2) and 431.416(g).¹ CMS expects that states will offer, in good faith and in a prudent manner, a post-award public notice process, including tribal consultation as applicable, to the extent circumstances permit.

CMS has determined that California's COVID-19 Vaccine Administration PHE amendment to its section 1115(a) demonstration titled, "Medi-Cal 2020" is necessary to assist the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE. The demonstration is likely to assist in promoting the objectives of the Medicaid statute because it 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 COVID-19.

In addition, in light of the unprecedented emergency circumstances associated with the COVID-19 pandemic and consistent with the President's declaration detailed above – and because of the time-limited nature of this demonstration amendment – CMS did not require the state to submit budget neutrality calculations for this California COVID-19 Vaccine Administration PHE amendment. In general, CMS has determined that the costs to the federal government are likely

¹ 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 or amendment. States applying for a COVID-19 section 1115 demonstration or amendment are not required to conduct a public notice and input process prior to submission of the application to CMS. 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 or amendments. CMS will post all section 1115 demonstrations or amendments approved under the COVID-19 demonstration opportunity on the Medicaid.gov website.

to have been otherwise incurred and allowable. California will still be required to monitor and evaluate the expenditure authority that CMS approved, including tracking demonstration expenditures and assessing how such outlays would facilitate the state's response to the COVID-19 PHE. Due to the highly limited scope of the changes under the amendment, CMS is approving this expenditure authority, as described below and in Attachment RR, as an amendment to the STCs for California's "Medi-Cal 2020" Demonstration.

Vaccine Administration Payments. Expenditure authority for state payments to providers for the administration of a COVID-19 vaccine for the following state plan limited-benefit populations from December 14, 2020 through March 10, 2021:

1. Individuals eligible for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1);
2. Individuals eligible for the optional COVID-19 group, as described in section 1902(a)(10)(A)(ii)(XXIII); and
3. Individuals eligible for family planning benefits under the Family Planning Access, Care and Treatment (Family PACT) program, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii).

Monitoring and Evaluation Requirements

Given the unique circumstances and time-limited nature of this demonstration amendment, CMS expects California to undertake data collection and analyses that are meaningful but not unduly burdensome for the state, while also being consistent with the applicable provisions of 42 CFR §§ 431.424 and 431.428. It is still important to gather evidence regarding the operation and effectiveness of this amendment, but, recognizing the challenges associated with the COVID-19 PHE and the distinctly brief approval period for this demonstration amendment, CMS has simplified the monitoring and evaluation requirements for this amendment. The state's streamlined monitoring and evaluation activities for this amendment, including an outline of an Evaluation Design, will be encapsulated in a Final Report, the draft of which will be due to CMS no later than eighteen (18) months after the state's receipt of the approval of the amendment. The monitoring and evaluation requirements are reflected in Attachment RR of the approval letter for this amendment.

The Final Report should include a background description of the scope and objectives of the amendment and outline the evaluation questions, suggested ideas for which are provided in Attachment RR of the approval letter. The Final Report should also narrate how the state would leverage the simplified expectations for data collection and analyses for this amendment, in alignment with information outlined in Attachment RR, to support contextualizing and addressing the evaluation questions. Briefly, the Final Report should provide a discussion of the findings that will support understanding the successes, challenges, and lessons learned in implementing the amendment to help inform best practices for similar situations in the future. Additionally, the state should provide summary data on demonstration expenditures under this amendment, and describe briefly how these outlays were effective at achieving the objectives of the demonstration amendment. Finally, the Final Report should outline any challenges and limitations encountered in the planning and conduct of the

monitoring and evaluation activities. Per requirements described in Attachment RR, the state is required to post the CMS-approved Final Report to the state's Medicaid agency website within 30 days of CMS approval.

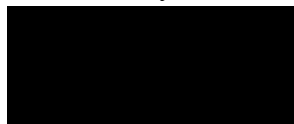
Approval of this demonstration amendment is subject to the limitations specified in this letter. The state may deviate from its Medicaid state plan requirements only to the extent that the requirements have been specifically identified as not applicable for the demonstration as specified in the list of approved authorities. This approval 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.

The award is subject to CMS receiving written acceptance of this award within 15 days of the date of this approval letter. Your project officer is Mr. Julian Taylor. Mr. Taylor is available to answer any questions concerning implementation of the state's section 1115(a) demonstration 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

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 California "Medi-Cal 2020" 1115 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,



Daniel Tsai
Deputy Administrator and Director

Enclosure

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

Attachment RR
**Time-limited Expenditure Authority and Associated Requirements for the COVID-19
Public Health Emergency (PHE) Demonstration Amendment**

Expenditure Authority

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act, shall, for the period from December 14, 2020 through March 10, 2021, be regarded as expenditures under the State's title XIX plan.

Vaccine Administration Payments. Expenditure authority for state payments to providers for the administration of a COVID-19 vaccine for the following state plan limited-benefit populations from December 14, 2020 through March 10, 2021:

1. Individuals eligible for tuberculosis-related benefits, as described in sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1);
2. Individuals eligible for the optional COVID-19 group, as described in section 1902(a)(10)(A)(ii)(XXIII); and
3. Individuals eligible for family planning benefits under the Family Planning Access, Care and Treatment (Family PACT) program, as described in sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii).

Monitoring and Evaluation Requirements

Evaluation Design and Final Report. Given the unique circumstances and the time-limited nature of this demonstration amendment, CMS has streamlined the monitoring and evaluation requirements for this amendment. While it is important to gather evidence regarding the operation and effectiveness of this amendment, CMS understands the unusual situation of the COVID-19 PHE and the challenges it presents to data collection and analyses required to comply with the systemic monitoring and robust evaluation requirements for more traditional section 1115 demonstrations, including the other aspects of the Medi-Cal 2020 demonstration. Therefore, the requirements for data collection and analyses for this amendment are structured to be meaningful and productive, and importantly, consistent with the applicable provisions of 42 CFR §§ 431.424 and 431.428, but not unduly burdensome for the state in light of the distinctly short approval period for this amendment.

Specifically, the state will be required to develop a Final Report, which will consolidate the amendment's monitoring and evaluation requirements. To address the requirements in 42 CFR § 431.424(c), the Final Report will include a section clearly outlining the state's underlying Evaluation Design for the evaluation of the expenditure authority approved in this amendment. The draft Final Report will be due to CMS no later than eighteen (18) months after the state's receipt of the approval of the amendment. CMS's section 1115 demonstration evaluation guidance "Preparing the Evaluation Report"² provides pertinent instructions that would be helpful in preparing the consolidated Final Report. The state should customize the content of the Final Report to align with the specific scope of the demonstration amendment.

² Available at <https://www.medicaid.gov/medicaid/downloads/preparing-the-evaluation-report.pdf>.

The state should include in the Final Report a background description of the scope and objectives of the demonstration amendment's expenditure authority. The Final Report should be structured such that the section describing the Evaluation Design of this amendment outlines the evaluation questions the state will examine as part of its evaluation, a description of the data sources the state will leverage to both contextualize and respond to these questions, and the methodologies and approaches used in the evaluation.

For this demonstration amendment, the state will test whether and how the approved expenditure authority facilitated the state's response to the COVID-19 PHE, and helped promote the objectives of Medicaid. To that end, the evaluation for this amendment will address thoughtful evaluation questions that support understanding the successes and challenges in implementing the expenditure authority. The state may use evaluation questions that will provide insight into: the populations affected by the expenditure authority under this amendment; specific policies and procedures that reduced barriers to care (e.g., the steps taken to ensure access to COVID-19 vaccines); challenges associated with implementing the amendment and engaging with beneficiaries, as well as how the state overcame these challenges, as applicable; and principal lessons learned for any future PHEs. Additionally, the state should track demonstration expenditures under this amendment, including—as appropriate—administrative and program costs and health services expenditures under the amendment, and assess how these outlays were effective at achieving the objective of the demonstration amendment. The Final Report should also outline any challenges and limitations encountered in the planning and conduct of the monitoring and evaluation activities.

To address the evaluation questions as well as for providing contextual information to better understand the extent of the challenges presented by the COVID-19 PHE, and any unresolved or ongoing challenges the state continues to face, the state should identify and use suitable qualitative and quantitative data. The state may also use publicly available benchmark data from other federal agencies, such as the Centers for Disease Control and Prevention (CDC), on rates of COVID-19 cases and associated vaccinations, hospitalizations and deaths.³ Overall, the Final Report should provide an understanding of the successes, challenges, and lessons learned in implementing the demonstration amendment.

The state is required to post the CMS-approved Final Report to the state's Medicaid agency website within 30 days of CMS approval, per 42 CFR § 431.428(b)(2). In addition, per 42 CFR § 431.420(f), the state must comply with any requests for data from CMS and/or its federal evaluation contractors.

³ For example, see <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>, https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm, and https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.