DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850

State Demonstrations Group

May 23, 2024

Tyler Sadwith
State Medicaid Director
California Department of Health Care Services
1501 Capitol Avenue, 6th Floor, MS 0000
Sacramento, California 95814

Dear Director Sadwith:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Final Report for the COVID-19 Public Health Emergency Vaccine Administration amendment to the section 1115 demonstration entitled, "Medi-Cal 2020" (Project No: 11-W-00193/9). This report covers the demonstration period from December 14, 2020 through March 10, 2021. CMS determined that the Final Report, submitted on March 12, 2024, is in alignment with the requirements set forth in Attachment RR of the Special Terms and Conditions (STCs), and therefore, approves the state's Final Report.

In accordance with Attachment RR, the approved Final Report may now be posted to the state's Medicaid website within 30 days. CMS will also post the approved Final Report on Medicaid.gov.

We sincerely appreciate the state's commitment to evaluating the COVID-19 PHE Vaccine Administration amendment under these extraordinary circumstances. We look forward to continuing our partnership on the CalAIM section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S

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Date: 2024.05.21 08:05:23 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

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

CALIFORNIA'S COVID-19 SECTION 1115 DEMONSTRATION VACCINE ADMINISTRATION REIMBURSEMENT

Final Evaluation Report
March 13, 2024

DHCS
CALIFORNIA DEPARTMENT OF
HEALTH CARE SERVICES

TABLE OF CONTENTS

Executive Summary

The California Department of Health Care Services (DHCS) obtained approval from the Centers for Medicare and Medicaid Services (CMS) for an amendment under the Special Terms and Conditions (STCs) for California's section 1115(a) demonstration titled, "Medi-Cal 2020" (Project No. 11-W-00193/9) related to the vaccine administration reimbursement of Coronavirus Disease 2019 (COVID-19). Given the unprecedented nature of the COVID-19 Public Health Emergency (PHE), DHCS sought authority for the flexibility, described in more detail below, to prevent gaps in coverage and to help ensure equitable and efficient access to the COVID-19 vaccines for individuals covered under California's Medicaid program, Medi-Cal.

Pursuant to CMS' demonstration opportunity communicated in the November 2, 2020, Interim Final Rule entitled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 Fed. Reg. 71142, 71150), DHCS sought federal approval to extend coverage of the COVID-19 vaccines and its administration to the following limited-scope benefit populations in Medi-Cal 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 testing group, as described in Section 1902(a)(10)(A)(ii)(XXIII).
3) Non-citizen individuals eligible for only restricted scope emergency services, as described in Section 1903(v)(2).

The final report provides general background information; explains, in detail, DHCS' demonstration objectives; evaluation questions; methodology; methodological limitations; and DHCS' policy implications and interactions with other state initiatives.

General Background Information

On January 31, 2020, the United States Secretary of Health and Human Services declared a public health emergency due to an outbreak of COVID-19. The President of the United States declared a national emergency due to COVID-19 on March 13, 2020. Pursuant to section 1135(b) of the Act, the Secretary of Health and Human Services modified certain requirements of titles XVIII, XIX, and XXI of the Act because of the consequences of the COVID-19 pandemic, as determined by CMS, to ensure that sufficient health care items and services were available to meet the needs of individuals enrolled in the respective programs. Additionally, health care providers that furnish such items and services in good faith but are unable to comply with one or more of such requirements because of the COVID-19 pandemic, may be reimbursed for such items and services. On March 15, 2020, this authority took effect with a retroactive effective date of March 1, 2020.

On January 14, 2022, CMS approved DHCS' 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 approved amendment issued permission for state payments to providers for the administration of a COVID-19 vaccine(s) 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).

Beginning March 11, 2021, the American Rescue Plan Act of 2021 required states to cover COVID-19 vaccines and administration, without cost-sharing, for nearly all Medicaid members, including most groups receiving limited-benefit packages under the state plan or section 1115 demonstration. DHCS' demonstration amendment provided expenditure authority for vaccine administration coverage to the above 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. Since vaccines are federally purchased and is no cost to states, the only expenditure authority approved was payments for the administration of a COVID-19 vaccine(s).

Evaluation Objectives and Questions

Demonstration Objectives

On January 14, 2022, CMS approved DHCS' amendment to receive vaccine administration coverage for the three limited-benefit populations: 1) Individuals eligible for tuberculosis-related benefits; 2) individuals eligible for the optional COVID-19 group; and 3) individuals eligible for family planning benefits under the Family PACT, to prevent gaps in coverage and help ensure equitable and efficient access to the COVID-19 vaccines.

Evaluation Questions

The evaluation of the vaccine administration coverage for the three limited-benefit populations during December 14, 2020, through March 10, 2021, tracked demonstration amendment expenditures and evaluated the connection between those expenditures and DHCS' response to the COVID-19 PHE. The evaluation questions used to guide this final report were:

1. What were the principal challenges associated with engagement with Medicaid members during the timeframe of December 14, 2020, through March 10, 2021?
2. What strategies did DHCS pursue to address those challenges?
3. What policies and procedures were most helpful to DHCS and providers in leveraging flexibilities to reduce barriers and ensure access to care, including accessing medical supplies and equipment?
4. What were some successes noted related to the approval of the amendment of payments for the administration of a COVID-19 vaccine during December 14, 2020, through March 10, 2021?

Evaluation Methodology

The Evaluation Design was a hybrid approach using various quantitative elements to support qualitative elements. On October 29, 2020, the Centers for Disease Control and Prevention (CDC) released a playbook titled, "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations," outlining guidance for states. This playbook aided DHCS' implementation of policy instructions for providers regarding vaccine coverage, distribution, storage, handling, and administering during the timeframe of this report. The COVID-19 pandemic was unprecedented, and DHCS adjusted quickly to the guidelines set forth from the CDC. In addition, the California Department of Public Health (CDPH), the state's public health department, played a significant role during this timeframe. CDPH provided reliable and accurate information on public health recommendations and guidance related to COVID-19 based on scientific evidence and epidemiological data for the state to follow.

The data for this evaluation includes:

- Medi-Cal members enrollment data from December 2020 and March 2021.
- Total number of distinct Medi-Cal members, claims, and Medi-Cal vaccine reimbursement for the three limited-benefit groups: 1) Individuals eligible for tuberculosis-related benefits, 2) individuals eligible for the optional COVID-19 group, and 3) individuals eligible for family planning benefits under Family PACT.

DHCS gathered Medi-Cal member enrollment data from December 2020 and March 2021, of all affected limited-benefit populations described in this report. Table 1, below, describes the total eligible members enrolled in each limited-benefit group in the December 2020 month of eligibility (beginning of the waiver period) and the total eligible members enrolled in March 2021 (end of the waiver period). For the Tuberculosis coverage group, there was no change in eligible members enrolled. For the Family PACT group, there was a decrease of approximately 50,000 eligible members enrolled in comparison to December 2020. However, for the Optional COVID-19 Group, there were approximately 50,000 more eligible members enrolled since December 2020.

Table 1: Total Medi-Cal Members by Month of Eligibility and Coverage Group

Month of Eligibility	Tuberculosis Group	Family PACT Group	Optional COVID-19 Group
December 2020	38	493,236	79,120
March 2021	38	441,578	129,679

Through the course of the waiver, California tracked demonstration amendment expenditures and evaluated the connection between those expenditures and DHCS' response to the COVID-19 PHE. The expenditure data used in this evaluation was drawn from various eligibility and claims data sources.

The demonstration expenditure data from December 14, 2020, through March 10, 2021, is described in Table 2, below. In the pharmacy setting, the number of claims from the Tuberculosis coverage group was zero. For the Family PACT and Optional COVID-19 group, the number of individuals who received the COVID-19 vaccine under these programs were also very low compared to the number of eligible members enrolled in both groups during this timeframe. In the clinic setting, the number of claims for Optional COVID-19 was significantly higher than in the pharmacy setting.

Table 2: Demonstration Expenditure Data

Location	Name of Group	Number of Distinct Individuals	Number of Claims	Total Medi-Cal Reimbursement
Pharmacy	Tuberculosis	0	0	$0
	Family PACT	148	166	$3,327.24
	Optional COVID-19	67	82	$1,617.91
Clinic	Family PACT	25	25	$423.50
	Optional COVID-19	4,808	5,458	$290,757.79
	Total	**5,048**	**5,731**	**$296,126.44**

Methodological Limitations

Given the unique circumstances and time-limited nature of this demonstration amendment, there is limited availability of data, and the findings would not be conclusive due to the short evaluation timeline.

Evolving Federal Guidance

The COVID-19 pandemic was an unprecedented public health emergency. DHCS sought flexibilities throughout the COVID-19 pandemic, responding, and at times pivoting to updated CMS guidance as directed in the federal Medicaid Vaccine Toolkit. Since the initial vaccines were federally purchased, CMS's Medicaid Vaccine Toolkit was designed to assist the States and providers to primarily focus on coverage of vaccine administration.

Limited Communication Modalities with Medi-Cal Members to Share Vaccine Information

DHCS only had the ability to communicate directly with providers in a quick, robust manner through newsflashes, provider bulletins, etc. DHCS did not have quick means to communicate directly with Medi-Cal members since most member communication is through the county social services agencies or Medi-Cal managed care plans. DHCS did not have available modalities such as text messaging, phone calls, mail, to do outbound campaigns since these correspondences are generally through county social services agencies or Medi-Cal managed care plans. During the beginning of the pandemic, it was imperative to inform members of the availability of the COVID-19 vaccine(s), that members understood where they could receive a COVID-19 vaccine(s), the number of required and available doses and spacing between doses (if a multi-dose vaccine was used), and how to obtain additional information. Therefore, due to DHCS' limited communication modalities during the time of this evaluation, it inhibited DHCS from informing its members about the vaccines across the three-limited benefit coverage groups.

Limitations with Vaccine Storage

At the start of the pandemic, many facilities and clinics were not equipped to administer the COVID-19 vaccines. Per CMS, providers were to administer the vaccines in accordance with the CDC Committee on Immunization Practices and storage requirements. COVID-19 vaccine products were temperature-sensitive and had to be

stored and handled correctly to ensure efficacy and maximize shelf-life. Proper storage and handling practices were critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. For the three limited-benefit groups, many clinics did not have the proper refrigeration storage or supplies to store the COVID-19 vaccines.

Requirements to Administer COVID-19 Vaccines

Since there were certain requirements for qualified persons authorized to administer COVID-19 vaccines, this created a barrier of access for the three limited-benefit groups during the waiver period. On March 10, 2020, the United States Health and Human Services (HHS) Secretary issued a Public Readiness and Emergency Preparedness (PREP) Act declaration, effective February 4, 2020, to provide liability protections for activities related to medical countermeasures against COVID-19. Pharmacists, pharmacy interns, and pharmacy technicians are covered persons under the PREP Act when they administer certain covered countermeasures, including certain COVID-19 tests, routine childhood vaccinations, and COVID-19 vaccinations, provided that the conditions in the PREP Act and the HHS COVID-19 PREP Act declaration and authorizations have been satisfied. As mentioned above, the list of guidance and updated information from CMS was ever changing. There were several amendments and corrections to the HHS COVID-19 PREP Act declaration, including:

- The Fifth Amendment, effective February 2, 2021, added categories of qualified persons authorized to administer COVID-19 vaccines.

- The Sixth Amendment, effective February 16, 2021, added another category of qualified persons (i.e., certain federal workers) authorized to administer COVID-19 vaccines.

- On February 22, 2021, HHS issued technical corrections to the Fifth and Sixth Amendments (effective retroactively to the effective dates of the Fifth and Sixth Amendments, as applicable), including clarification that members of a uniformed service are included in the list of federal workers authorized to administer COVID-19 vaccines.

Limited Dose Distribution of COVID-19 Vaccines

Since this report specifies the waiver period of December 14, 2020, through March 10, 2021, it is also valuable to mention that the dose distribution was limited and the original COVID mRNA vaccines from both Pfizer, Moderna, and Janssen were the only

three vaccines available. In addition, the allocation of doses had to focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The populations of focus for initial COVID-19 vaccination included:

- Healthcare personnel (paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials);
- Non-healthcare essential workers;
- Adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness; and,
- People 65 years of age and older (including those living in long-term care facilities)

The vaccinations were specific to the groups listed above; however, Family PACT and the COVID-19 Optional group may not fall under the critical populations, which explains the possible low utilization in the three limited-benefit coverage groups in this report.

Conclusion

The evaluation was conducted internally by DHCS. The final report was organized based on the structure outlined in CMS' section 1115 demonstration evaluation guidance "Preparing the Evaluation Report." Per CMS guidance, the state must include in the Final Report a discussion of the findings that support understanding the successes, challenges, and lessons learned in implementing the amendment to help inform best practices for similar situations in the future.

The demonstration amendment was instrumental for members and providers during the timeframe of December 14, 2020, through March 10, 2021. Without coverage for these groups, these members would not have had the necessary vaccination for their health and safety. As there were challenges and barriers experienced during the timeframe of this report, such as anticipated low utilization in the three-limited benefit coverage groups, DHCS learned principal lessons for any future PHEs. For example, DHCS learned how to provide quicker notifications to members, obtain proper storage equipment and supplies, and a much clearer view of Medi-Cal vaccination rates.

Interpretations, and Policy Implications and Interactions with Other State Initiatives

The approval of the waiver amendment paved the way for California's COVID-19 vaccination rates. California recognizes the disproportionate impact of COVID-19 on disadvantaged communities, including many communities of color, which account for a large share of the Medi-Cal member population. Until recently, California's knowledge of the extent of COVID-19 vaccination among the Medi-Cal population was limited to what was gathered from claims data. Now, with new linkages to immunization registry data from CDPH, California has a much clearer view of Medi-Cal vaccination rates compared to statewide rates, stratified by county and by health plan. While Medi-Cal COVID-19 vaccination rates are gradually improving across the state, the percentage of Medi-Cal members with at least one dose lags the population-at-large rate, sometimes by as much as 30 percent.

California is strengthening its efforts to work with managed care plans, local public health departments, agencies and stakeholders serving our homebound populations, as well as providers, health systems and community-based organizations to improve vaccination rates and help ensure that our members are protected against infection from current and emerging strains. To support and empower our partners with data and transparency, California updates and publishes this data periodically to support monitoring of progress and to guide further interventions.