

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



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## State Demonstrations Group

February 01, 2022

Jami Snyder  
Director  
Arizona Health Care Cost Containment System  
801 East Jefferson Street  
Phoenix, Arizona 85034

Dear Ms. Snyder:

The Centers for Medicare & Medicaid Services (CMS) approved the Evaluation Design required in the Special Terms and Conditions (STCs) for the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE) amendment to Arizona's section 1115 demonstration titled, "Arizona Health Care Cost Containment System (AHCCCS)" (Project No. 11-W-00275/09). We sincerely appreciate the state's commitment to efficiently meeting the requirement of an Evaluation Design for the COVID-19 PHE demonstration amendment, as stated in the STCs, especially under these extraordinary circumstances.

The approved Evaluation Design may now be posted to the state's Medicaid website within thirty days, per 42 CFR § 431.424(e). CMS will also post the approved Evaluation Design on Medicaid.gov.

The COVID-19 PHE demonstration amendment is effective through the date that is sixty calendar days after the PHE expires. In accordance with the STCs, a Final Report, consistent with the approved Evaluation Design, is due to CMS one year after the end of the COVID-19 section 1115 demonstration authority.

We look forward to our continued partnership with you and your staff on Arizona's AHCCCS section 1115 demonstration. If you have any questions, please contact your CMS project officer, Ms. Kelsey Smyth, who may be reached by email at [Kelsey.Smyth@cms.hhs.gov](mailto:Kelsey.Smyth@cms.hhs.gov).

Sincerely,

**Danielle  
Daly -S** Digitally signed by  
Danielle Daly -S  
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13:51:09 -05'00'

Danielle Daly  
Director  
Division of Demonstration  
Monitoring and Evaluation

cc: Brian Zolynas, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

Arizona Health Care Cost Containment System



# Arizona's Section 1115 Medicaid Waiver – COVID-19 Amendment

*Evaluation Design Plan*

*November 2020*



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## 1. Background

The Centers for Medicare & Medicaid Services (CMS) gave approval for the coronavirus disease 2019 (COVID-19) public health emergency (PHE) (11-W-00275/9) amendment to the Arizona Health Care Cost Containment System (AHCCCS) Section 1115 demonstration on January 19, 2021. The demonstration amendment is retroactive from March 1, 2020, through 60 days after the end of the PHE (including any renewal of the PHE). The determination that a PHE still exists was last renewed effective October 18, 2021.<sup>1-1</sup> This waiver allows Arizona to cover Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) dental services authorized prior to a beneficiary turning age 21 for those beneficiaries who turned 21 on or after March 1, 2020, and through 60 days after the termination of the COVID-19 PHE and who remain Medicaid eligible.

The COVID-19 pandemic has profoundly altered the environment for delivering Medicaid-funded dental services, as many dental offices in Arizona have been either closed or operating at limited capacity during the pandemic. Beneficiaries are eligible for EPSDT dental services up until their 21st birthday. However, when the pandemic began, this population of beneficiaries may have forgone routine dental care or dental care authorized prior to turning 21 due to pandemic mitigation strategies (e.g., stay-at-home orders, quarantine mandates.), and subsequently aged out (turned 21) on or after March 1, 2020. As a result, they would no longer remain eligible for EPSDT services absent the waiver. As AHCCCS does not provide adult comprehensive dental benefits, it was important for these members aging out of EPSDT services to complete their dental coverage, both preventive services as well as any treatment plans. As such, CMS has granted the current expenditure authority, which will enable such beneficiaries to receive this foregone dental care. This demonstration will assist the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE, as well as support the key objective of furnishing medical assistance in a manner that is intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals and providers who may be affected by COVID-19.

As requested in the demonstration approval letter, AHCCCS is required to track demonstration expenditures and to evaluate the connection between those expenditures, the State's response to the PHE, as well as the cost-effectiveness of those expenditures. AHCCCS is required to submit a final report, which will consolidate the monitoring and evaluation reporting requirements associated with the expenditure authority. The Evaluation Design Plan identifies research questions developed by AHCCCS that pertain to the approved expenditure authority and outline how the state will test whether and how the approved waiver and expenditure authorities have affected the State's response to the PHE.

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<sup>1-1</sup> U.S. Department of Health & Human Services. Renewal of Determination That A Public Health Emergency Exists. Oct 15, 2021. Available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVIDI-15Oct21.aspx> Accessed on: Nov 2, 2021.

## 2. Evaluation Questions and Hypotheses

The evaluation of the waiver demonstration will test whether and how the waiver and expenditure authorities mitigated any potential negative impacts of the coronavirus disease 2019 (COVID-19) public health emergency (PHE). Evaluation hypotheses are tailored to this core objective, and will be assessed via the following research questions:

### **Hypothesis 1: The PHE waiver will provide cost-effective care for qualifying beneficiaries.**

- **Research Question 1.1:** Is the cost of Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) care for qualifying beneficiaries less than or equal to care among beneficiaries turning 19 during the same time-period?

### **Hypothesis 2: The PHE waiver will give qualifying beneficiaries equal access to EPSDT services as beneficiaries turning 19 during the same time-period.**

- **Research Question 2.1:** Did beneficiaries who would otherwise have been ineligible to receive services after their 21st birthday know about the waiver?
  - Key informant interviews: Did most members know they would be ineligible upon turning 21 in the first place? Was any outreach/education provided among members to inform them about the waiver?
- **Research Question 2.2:** What were the principal challenges associated with engagement with Medicaid beneficiaries during this public health emergency?
  - **Sub Research Question 2.2a:** What strategies did the State pursue to address those challenges?
- **Research Question 2.3:** What were the unresolved or ongoing challenges related to the implementation of the demonstration flexibilities?
- **Research Question 2.4:** Was the rate of EPSDT services among qualifying beneficiaries equal to that of beneficiaries turning 19 during the same time period?
- **Research Question 2.5:** Is there evidence of pent-up demand in the months following the gradual opening up of the state and resuming routine care throughout 2020 and 2021?
  - **Sub Research Question 2.5a:** If so, does the volume of services appear to account for a decline in services during the peak impact of COVID on the health care system, even though PHE is still in effect?

### 3. Methodology

To assess the impact of the program, a comparison of outcomes between the intervention group and a valid counterfactual – the intervention group had they not been exposed to the intervention – must be made. The gold standard for experimental design is a randomized controlled trial which would be implemented by first identifying an intervention population, and then randomly assigning individuals to the intervention and the rest to a comparison group, which would serve as the counterfactual. However, random assignment is rarely feasible or desirable in practice, particularly as it relates to health care policies.

As such, a variety of quasi-experimental or observational methodologies have been developed for evaluating the effect of policies on outcomes. The research questions presented in the previous section will be addressed through at least one of these methodologies. The selected methodology depends on data availability factors relating to: (1) data to measure the outcomes; (2) data for a valid comparison group; and (3) data during the time periods of interest—typically defined as the year prior to implementation and annually thereafter. Table 3-1 illustrates a sampling of standard analytic approaches and whether the approach requires data gathered at the baseline (i.e., pre-implementation), requires a comparison group, or allows for causal inference to be drawn. It also notes key requirements unique to a particular approach.

**Table 3-1—Sampling of Analytic Approaches**

Analytic Approach	Baseline Data	Comparison Group	Allows Causal Inference	Notes
Randomized Controlled Trial		✓	✓	Requires full randomization of intervention and comparison group.
Difference-in-Differences	✓	✓	✓	Trends in outcomes should be similar between comparison and intervention groups at baseline.
Panel Data Analysis	✓		✓	Requires sufficient data points both prior to and after implementation.
Regression Discontinuity		✓	✓	Program eligibility must be determined by a threshold
Interrupted Time Series	✓		✓	Requires sufficient data points prior to and after implementation.
Pre-test/post-test	✓			Assesses whether a change was observed after implementation without a comparison group.
Cross-Sectional Analysis		✓		Assesses differences between groups after implementation. Does not account for pre-existing differences.

## Evaluation Period

This evaluation will cover the period from March 1, 2020, through 60 days after the end of the public health emergency (PHE) or September 30, 2022<sup>3-1</sup>, whichever is earlier. The September 30, 2022, date is chosen as it is the end of the Arizona Health Care Cost Containment System (AHCCCS) Section 1115 waiver demonstration period and is expected to be a sufficient amount of time to determine any impacts of the waiver demonstration as it overlaps with the height of the pandemic.

## Intervention and Comparison Populations

In accordance with the Centers for Medicare & Medicaid Services (CMS) guidance for coronavirus disease 2019 (COVID-19) Section 1115(a) demonstrations, the State proposes comparing utilization and cost patterns among Medicaid beneficiaries turning 21 on or after March 1, 2020, through 60-days following the end of the PHE or September 30, 2022, whichever is earlier (i.e., “demonstration beneficiaries”) to Medicaid beneficiaries turning 19 on or after March 1, 2020, through 60-days following the end of the PHE or September 30, 2022, whichever is earlier (i.e., “comparison beneficiaries”). This age threshold for the comparison group ensures that no one in the comparison group falls into the demonstration eligible population during the study period. This choice in comparison group is motivated by the concept behind a regression discontinuity design (RDD), which is often used for impact evaluation of programs that have a continuous eligibility index with a clearly defined cutoff score to determine eligibility. The RDD method exploits the discontinuity around the “cutoff score” for program eligibility (in this case, age) to estimate the counterfactual. For this evaluation, the comparison group is chosen to represent a group of beneficiaries who are similar in age and thus theoretically have similar characteristics and health care utilization patterns as the intervention group. In other words, beneficiaries who did not receive any Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services as part of the PHE waiver during the study period but are as close as possible in age to the cutoff will be used as a comparison group to estimate the counterfactual.

## Analytic Methods

### *Cross-Sectional Analysis*

To evaluate whether the PHE waiver is providing cost-effective care to qualifying beneficiaries (Research Question 1.1), the independent evaluation will estimate costs associated with EPSDT services among the demonstration beneficiaries in contrast to the comparison beneficiaries using a t-test. A t-test allows for comparison between two groups that have a continuous outcome, such as costs, to determine if there is a significant difference between the means of the two groups.

### *Difference-in-Differences*

A difference-in-differences (DiD) analysis will be performed on all measures for which baseline and evaluation period data are available for both the intervention and comparison groups. Because this is the preferred analytic approach, the DiD will be utilized to evaluate the rate of EPSDT services among demonstration beneficiaries

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<sup>3-1</sup> CMS approved a one-year extension of the AHCCCS section 1115 demonstration until September 30, 2022. Centers for Medicare & Medicaid Services. Letter of Temporary Extension of Section 1115 Demonstration. Sept 30, 2021. Available at: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/az-hccc-ca.pdf>. Accessed on: Nov 4, 2021.



compared to that of comparison beneficiaries during the same time-period. This analysis will compare the changes in the rates of dental services between the baseline period and the evaluation period. This allows for expected rates for the intervention group to be calculated by considering expected changes in outcomes had the PHE waiver not been implemented. This is done by subtracting the average change in the comparison group from the average change in the intervention group, thus removing biases from the evaluation period comparisons due to permanent differences between the two groups. In other words, any changes in the outcomes caused by factors external to the policy would apply to both groups equally and the DiD methodology will remove the potential bias. The result is a clearer picture of the actual effect of the program on the evaluated outcomes.

The generic DiD model is:

$$Y_{it} = \beta_0 + \beta_1 X_i + \beta_2 R_t + \beta_3 (R_t * X_i) + \gamma \mathbf{D}'_{it} + u_{it}$$

Where  $Y$  is the proportion for group  $i$  in year  $t$ ,  $X$  is a binary indicator for the intervention group (i.e., beneficiaries turning 21 on or after March 1, 2020, through 60 days following the end of the PHE or September 30, 2022, whichever is earlier),  $R$  is a binary indicator for the follow-up period, and  $u$  is an error term. The vector  $\mathbf{D}'$  will include observable covariates, where available, to ensure comparability of the groups for any measure-specific subgrouping (e.g., to address non-response bias) and  $\gamma$  is the related coefficient vector. The coefficient,  $\beta_1$ , identifies the average difference between the groups prior to the effective date of the PHE waiver. The time period dummy coefficient,  $\beta_2$ , captures the change in the outcome between baseline and evaluation time periods. The coefficient of interest,  $\beta_3$ , is the coefficient for the interaction term,  $R_t * X$ , which is the same as the dummy variable equal to one for those observations in the intervention group in the remeasurement period. This represents the estimated effect of the PHE waiver on the intervention group, conditional on the included observable covariates.

The generic DiD calculation is:

$$\delta = (\bar{y}_{T,R} - \bar{y}_{T,B}) - (\bar{y}_{C,R} - \bar{y}_{C,B}) | \mathbf{D}'$$

Assuming trends in the outcome between the comparison and intervention groups are approximately parallel during the baseline period, the estimate will provide the expected rates without intervention. As the goal of the PHE waiver amendment is that utilization and costs are maintained for the intervention group, a non-significant  $\beta_3$  coefficient would be consistent with a successful waiver amendment, and a significant negative  $\beta_3$  coefficient would be consistent with the intervention group not experiencing outcomes at the same level as the comparison group. In addition to assessing the degree of statistical significance for the result, as represented by the p-value associated with  $\beta_3$ , the results will be interpreted in a broader context of clinical and practical significance.<sup>3-2</sup>

For the DiD analysis, the baseline period for the intervention and comparison populations will be March 1, 2019, to February 29, 2020. The evaluation period will be specific to each beneficiary and will be defined as the period from their 21st birthday (or 19th birthday for the comparison population) until 60 days after the end of the PHE, or September 30, 2022, whichever is earlier. To be included in the analysis, all beneficiaries must be enrolled in Medicaid or the Children’s Health Insurance Program (CHIP) Medicaid Expansion programs for at least 90 continuous days during the baseline and/or evaluation periods.

<sup>1-2</sup> Results from statistical analyses will be presented and interpreted in a manner that is consistent with the spirit of recent guidance put forth in *The American Statistician*. Ronald L. Wasserstein, Allen L. Schirm & Nicole A. Lazar (2019) Moving to a World Beyond “ $p < 0.05$ ”, *The American Statistician*, 73:sup1, 1-19, DOI: 10.1080/00031305.2019.1583913.

To thoroughly evaluate Research Question 2.4, the independent evaluator will take two approaches to the DiD analysis (Table 3-2).

**Table 3-2—DiD models**

Model	Eligible Population	Numerator	Measure
<b>Model 1</b>	Intervention and comparison group beneficiaries who did not have a preventive dental visit between March 1, 2020 and their 21st (19th) birthday	Number of beneficiaries with preventive dental visits after their 21st birthday	CMS Child Core Set: PDENT
<b>Model 2</b>	Intervention and comparison group beneficiaries	Number of beneficiaries with non-preventive dental visits after their 21st birthday	Non-preventive EPSDT dental services (fillings, sealants, emergency procedures)

Model 1 will compare the rate of preventive dental visits between the intervention group and the comparison group. Beneficiaries who had a preventive dental visit between March 2020 and their 21st or 19th birthday will be excluded from this measure as we are only interested in the effect of the PHE waiver (i.e., dental services after the beneficiary’s 21st birthday that otherwise would not be covered without the PHE waiver). Model 1 will also include a control variable for the number of months enrolled between the beneficiary’s 21st or 19th birthday and September 30, 2022. Model 2 will examine the rate of non-preventive dental services between the intervention group and the comparison group.

### **Descriptive Time Series**

To answer Research Question 2.5 and determine if there is evidence of pent-up demand in the months following the gradual opening up of the State and resuming routine care throughout 2020 and 2021, a descriptive time series analysis will be conducted. Per member per month healthcare utilization trends for the intervention population will be studied to determine whether the PHE waiver may have mitigated some of the impact to beneficiaries who had forgone dental services due to the pandemic and have subsequently aged out.

### **Qualitative Synthesis**

To better understand the challenges presented by the COVID-19 PHE to the Medicaid program, how flexibilities of the PHE demonstration assisted in meeting those challenges, and any lessons learned for responding to similar PHEs in the future (Research Questions 2.1 – 2.3), a series of key informant interviews with AHCCCS and representatives from the health plans will be conducted. Key informant interviewees will be recruited from nominees identified by the health plans and AHCCCS. Interviews will invite input from health plan representatives and appropriate individuals identified by AHCCCS as having experience and subject matter expertise regarding the development and implementation of the PHE waiver.

The information obtained from these interviews will be synthesized with the results from other quantitative data analyses providing an in-depth discussion of each of the domains/objectives to be considered. As the key informant interviews are being conducted, the independent evaluator will perform ongoing and iterative review of the interview responses and notes to identify overall themes and common response patterns. Unique responses that are substantively interesting and informative will also be noted and may be used to develop probing questions for future interviews. The results of these preliminary analyses will be used to document the emergent and overarching themes related to this research question.

Following the completion of the key informant interviews, the interview notes and transcripts will be reviewed using standard qualitative analysis techniques. The data will first be examined through open coding to identify key concepts and themes that may not have been captured as emergent themes during previous analyses. After

identifying key concepts, axial coding techniques will be used to develop a more complete understanding of the relationships among categories identified by respondents in the data. The open and axial coding will be performed with a focus on identifying the dimensionality and breadth of responses to the research questions posed for the overall project.

## Measures

Table 3-3 details the proposed measures, populations, data sources and proposed analytic methods that will be used to evaluate the PHE waiver. While AHCCCS covers a preventive visit every six months, the modified annual CMS Child Core Set measure PDENT is appropriate for capturing whether the PHE waiver ensured members received services otherwise forgone, rather than the number of services received.

**Table 3-3—Evaluation Design Measures**

Research Question	Measure	Intervention Group	Comparison Group	Data Source	Analytic Approach
<b>Research Question 1.1:</b> Is the cost of EPSDT care for qualifying beneficiaries less than or equal to care among beneficiaries turning 19 during the same time-period?	Final paid claims encounter costs	All intervention group beneficiaries	All comparison group beneficiaries	Claims data	Cross-sectional analysis
<b>Research Question 2.1:</b> Did beneficiaries who would otherwise have been ineligible to receive services after their 21st birthday know about the waiver?	N/A	N/A	N/A	Key informant interviews	Qualitative synthesis
<b>Research Question 2.2:</b> What were the principal challenges associated with engagement with Medicaid beneficiaries during this public health emergency?	N/A	N/A	N/A	Key informant interviews	Qualitative synthesis
<b>Research Question 2.3:</b> What were the unresolved or ongoing challenges related to the implementation of the demonstration flexibilities?	N/A	N/A	N/A	Key informant interviews	Qualitative synthesis

Research Question	Measure	Intervention Group	Comparison Group	Data Source	Analytic Approach
<b>Research question 2.4:</b> <b>Was the rate of EPSDT services among qualifying beneficiaries equal to that of beneficiaries turning 19 during the same time-period?</b>	CMS Child Core Set: PDENT (modified)	Intervention group beneficiaries who did not have a preventive dental visit between March 1, 2020 and their 21st birthday	Comparison group beneficiaries who did not have a preventive dental visit between March 1, 2020 and their 19th birthday	Claims data	DiD
	Non-preventive EPSDT dental services (fillings, sealants, emergency procedures)	All intervention group beneficiaries	All comparison group beneficiaries	Claims data	DiD
<b>Research Question 2.5:</b> <b>Is there evidence of pent-up demand in the months following the gradual opening up of the state and resuming routine care throughout 2020 and 2021?</b>	Utilization of EPSDT dental services including exams, cleanings, X-rays, fluoride application, fillings, sealants, and emergency procedures	All intervention group beneficiaries	N/A	Claims data	Descriptive time series

## Data Sources

### Administrative Data

Administrative data extracted from the Pre-Paid Medical Management Information System (PMMIS) will be used to calculate most measures proposed in this evaluation design. These data include administrative claims/encounter data, beneficiary eligibility, enrollment, and demographic data. Provider data will also be utilized as necessary to identify provider type and beneficiary attribution where necessary.

Use of fee-for-service (FFS) claims and managed care encounters will be limited to final, paid status claims/encounters. Interim transaction and voided records will be excluded from all evaluations because these types of records introduce a level of uncertainty (from matching adjustments and third-party liabilities to the index claims) that can impact reported rates and cost calculations.

### Key Informant Interviews

Key informant interviews with AHCCCS staff and health plans will be conducted through semi-structured interview protocols and transcribed and imported into MAXQDA where the data will be coded to permit qualitative analysis. The transcripts, coding methodologies and coded data will be used to answer the appropriate research questions.

## 4. Methodology Limitations

The goal of the demonstration is to ensure that beneficiaries who turned age 21 during the period of March 1, 2020, until 60 days after the end of the public health emergency (PHE), and are no longer eligible for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, are able to receive any forgone routine dental services that were delayed due to the PHE. Despite the flexibilities offered by the PHE demonstration, the coronavirus disease 2019 (COVID-19) pandemic may have unpredictable impacts that alter the evaluation outcomes in an unknown direction (e.g., cancel out the mitigating flexibilities provided by the PHE demonstration), or there may be external factors that further confounds the outcomes of the evaluation.

Simultaneously with the PHE waiver demonstration, there are six other programs currently underway as a part of the Arizona Health Care Cost Containment System (AHCCCS) Section 1115 waiver demonstration project. As such, there is the potential for confounding effects from these other programs when evaluating the impact of the PHE demonstration. Confounding from these other waiver programs is expected to be minimal, as the PHE demonstration targets such a narrow age range and limited number of beneficiaries.

For measures that rely on t-tests between groups at only one point in time, or descriptive analyses that do not have a comparison group, causal statements regarding the impact of the PHE waiver cannot be made. Additionally, the difference-in-differences (DiD) method described above relies on the assumption that outcomes trends in both the intervention and comparison groups follow parallel trends during the pre-period. Visually inspection of pre-period trends will be undertaken, as violation of the parallel trends assumption may lead to biased estimation of the treatment effect.

## 5. Reporting

Results from this evaluation will be reported separately from the final summative report for the evaluation of the Arizona Health Care Cost Containment System's (AHCCCS') broader Section 1115 waiver demonstration approved from October 1, 2016, through September 31, 2022 (Project Number 11-W-00275/09).

## A. Timeline and Milestones

The following project timeline has been prepared for Arizona’s 1115 waiver demonstration evaluation outline in the preceding sections. This timeline should be considered preliminary and subject to change based upon approval of the Evaluation Design and implementations of the waiver amendment. Table A-1 outlines the proposed timeline for conducting the evaluation.

**Table A-1—Project Timeline**

Due Date	Milestone/Deliverable
<b>March 1, 2020</b>	Official start date of COVID-19 PHE waiver
<b>January 19, 2021</b>	CMS approval for COVID-19 PHE demonstration amendment to AHCCCS Section 1115 demonstration
<b>July 31, 2021</b>	COVID-19 PHE evaluation design due
<b>May–August 2022</b>	Conduct key informant interviews
<b>60-days after end of PHE</b>	Official end of COVID-19 PHE demonstration
<b>6–9 months after the end of the PHE demonstration</b>	Conduct analysis
<b>9–11 months after the end of the PHE demonstration</b>	Produce draft COVID-19 PHE demonstration report
<b>12 months after end of the PHE demonstration authority</b>	Final COVID-19 PHE demonstration report due
<b>September 30, 2022</b>	AHCCCS Section 1115 demonstration ends

AHCCCS: Arizona Health Care Cost Containment System; COVID-19: Coronavirus Disease 2019; PHE: Public Health Emergency