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 25, 2023

Sarah Fertig Medicaid Director Department of Health and Environment 900 SW Jackson Avenue, Suite 900 Topeka, KS 66612

Dear Ms. Fertig:

The Centers for Medicare & Medicaid Services (CMS) has approved the supplemental evaluation design for the state's amendment to the KanCare section 1115 demonstration (Project Number 11-W-00283/7) to address the COVID-19 public health emergency, effective through the date that is sixty calendar days after the public health emergency expires. We sincerely appreciate the state's commitment to efficiently meeting the requirement for an Evaluation Design stated in the demonstration's Special Terms and Conditions (STC), 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(c). CMS will also post the approved Evaluation Design on Medicaid.gov.

Please note that, in accordance with the State Medicaid Director Letter entitled "COVID-19 Public Health Emergency Section 1115(a) Opportunity for States" (SMDL #20-002), a final report, consistent with the approved evaluation design, is due to CMS no later than one year after the end of the COVID-19 section 1115 amendment authority. We look forward to our continued partnership with you and your staff on the "KanCare" demonstration. If you have any questions, please contact your CMS project officer, Kathleen OMalley, who may be reached by email at <u>Kathleen.OMalley@cms.hhs.gov.</u>

Sincerely,

Digitally signed by Danielle Danielle Daly -S Date: 2023.05.25 Daly -S 12:14:16 -04'00' Danielle Daly Director Division of Demonstration Monitoring and Evaluation

cc: Michala Walker, State Monitoring Lead, Medicaid and CHIP Operations Group

KanCare 2.0 COVID-19 PHE Amendment Evaluation Design

October 11, 2022

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A. General Background Information

KanCare, the Kansas statewide mandatory Medicaid managed care program, was implemented January 1, 2013, under authority of a waiver through Section 1115 of the Social Security Act. The Centers for Medicare and Medicaid Services (CMS) approved renewal of the KanCare demonstration (sometimes referred to as "KanCare 2.0") for the period of January 1, 2019, through December 31, 2023.¹ KanCare 2.0 operates concurrently with the State's Section 1915(c) Home and Community Based Services (HCBS) waivers. Together they provide the authority necessary for the State to require enrollment of almost all Medicaid beneficiaries (including the aged, people with disabilities, and some individuals who are dually eligible) and Children's Health Insurance Program (CHIP) beneficiaries.

CHIP provides health care coverage for low-income children living in families with incomes that exceed Medicaid limits. Unlike Medicaid, CHIP is not open-ended; states are awarded yearly allotments. Kansas provides low-cost health insurance coverage to children who are under the age of 19, do not qualify for Medicaid, have family incomes under 232% of the federal poverty level, and are not covered by private health insurance.²

On August 15, 2022, CMS approved KDHE's request for a KanCare demonstration amendment to address the COVID-19 Public Health Emergency (PHE). The amendment was authorized retroactively from March 1, 2020, through the end of the COVID-19 PHE unwinding period or until all redeterminations are conducted during the unwinding period as discussed in the State Health Official Letter (SHO) #22- 001.³ The COVID-19 PHE amendment provides for continuous coverage for CHIP enrollees who turn 19 during the public health emergency (and therefore lost eligibility for CHIP due to age) and who are otherwise ineligible for Medicaid. These enrollees will continue to receive the same benefits as they currently receive in KanCare.

In the approval letter, CMS stated the COVID-19 PHE amendment to the KanCare demonstration is "necessary to assist the state in delivering the most effective care to its beneficiaries in light of the COVID-19 PHE and to ensure renewals of eligibility and transitions between coverage programs occur in an orderly process that minimizes beneficiary burden and promotes continuity of coverage at the end of the COVID-19 PHE. The demonstration amendment 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 who may be affected by COVID-19. This approval allows the state to align its policies for young adults in Medicaid and CHIP, and prevent gaps in coverage during the PHE. Additionally, this amendment ensures that the state can mitigate churn for eligible beneficiaries and smoothly transition individuals between coverage programs during the COVID-19 PHE unwinding period."

COVID-19 PHE Amendment Goal

The COVID-19 PHE amendment extends eligibility for CHIP enrollees who turn 19 during the PHE, and are otherwise ineligible for Medicaid, with the goal of furnishing continued medical assistance in a manner intended to protect, to the greatest extent possible, the health, safety, and welfare of individuals who may be affected by COVID-19.

Hypothesis and Evaluation Questions

The focus of the evaluation is to examine whether the KanCare 2.0 demonstration COVID-19 PHE amendment achieved its goal, identifying successes, challenges, and lessons learned in implementing the demonstration amendment. Following is a general overview of the proposed evaluation questions.

¹ CMS approval letter. <u>https://www.kancare.ks.gov/docs/default-source/policies-and-reports/section-1115-waiver-comments/ks-kancare-2-0-approval-letter-final-to-ks.pdf?sfvrsn=9ed84c1b_2</u>

² About Medicaid & CHIP, Kansas Department of Health and Environment. <u>http://kdhe.ks.gov/250/About-Medicaid-CHIP</u>

³ See SHO #22-001, "Promoting Continuity of Coverage and Distributing Eligibility and Enrollment Workload in Medicaid, the Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Upon Conclusion of the COVID-19 Public Health Emergency," available at <u>https://www.medicaid.gov/federal-policy-guidance/downloads/sho22001.pdf</u>

Hypothesis

Extending eligibility for CHIP enrollees who turn 19 during the PHE, and are otherwise ineligible for Medicaid, will provide continued medical assistance to help protect their health, safety, and welfare during the COVID-19 PHE.

Evaluation Questions

- 1. What was the eligible members' service utilization during the period of extended coverage?
 - a. What types of services did eligible members access during the period of extended coverage compared to prior utilization?
 - b. What diagnoses were associated with services received by eligible members during the period of extended coverage compared to their prior diagnoses?
 - c. Did eligible members receive new diagnoses after turning age 19? If so, what diagnoses?
- 2. How was preventive, routine, chronic, and acute care impacted during the period of extended coverage?
 - a. Did treatment prior to age 19 for chronic conditions, including behavioral health issues, continue after members turned 19 years old during the COVID-19 PHE?
 - b. What were the patterns of preventive, routine, and acute health care during the period of extended coverage?
- 3. What was the cost of the extended period of coverage?
 - a. What was the cost of services provided to members who received the extended coverage, in total and by service type?
- 4. What were the key stakeholder perceptions and experiences regarding the extended coverage?
 - a. What were the members' perceptions of their extended coverage?
 - b. What were the MCOs' and State's experiences regarding implementation of the extended coverage?

B. Evaluation Design Methodology

The focus of the evaluation is to examine the achievement of the goal to furnish continued health care to help protect the health, safety, and welfare of individuals who may be affected by COVID-19. The evaluation will be completed through quantitative and qualitative analysis.

Quantitative Analysis

The quantitative analysis will focus on describing patterns in health and health care before and during the period of extended CHIP coverage. See Appendix A for a detailed discussion of data sources, and Appendix B for performance measure details.

Evaluation Period

Extended CHIP coverage was provided to CHIP members who turned age 19 between March 1, 2020, and the end of the PHE (date to be determined). Data will be analyzed by age, including age 18 for comparison purposes.

Study Population

The study population will be KanCare 2.0 CHIP members who turned age 19 during the COVID-19 PHE and had extended CHIP coverage.

Data Sources

All quantitative analysis will use the Kansas Modular Medicaid System (KMMS) databases for encounter, demographic, eligibility, and enrollment information. The Managed Care Organizations' member-level HEDIS data files may also be accessed for HEDIS measures. See Appendix 1 for detailed discussion of data sources.

Analytic Methods

Where possible, measures are developed according to technical specifications for recognized measures from sources

such as: Adult Core Set measures, including Healthcare Effectiveness Data and Information Set[®] (HEDIS) measures, stewarded by the National Committee for Quality Assurance (NCQA) and endorsed by the National Quality Forum (NQF). Descriptive statistics will be used for the evaluation, with comparisons across the consecutive years, by age. The following analytical methods will be used to assess the evaluation questions:

- Data obtained from various sources will be reviewed for missing values, inconsistent patterns, and outliers to ensure quality and appropriateness of the data for analyses required by the evaluation design.
- Descriptive statistics will examine member demographic characteristics.
- The descriptive statistics (e.g., numbers and percentages or rates) of the selected evaluation measures will be calculated and stratified by age. Note, the "Age 19" stratum of the measure Total Spending Per Member-Month, for example, would include claim payments for services for one year for each member, beginning with the member's nineteenth birthday. Since members with extended coverage did not turn 19 years old in the same year, the claim payments included in the measure would be for services from multiple calendar years.
- Appropriate statistical tests such as Fisher's exact and Pearson chi-square tests, with *p*<.05 indicating significance, will be used to compare percentages or rates between strata or to benchmarks, if available.

Table 1 outlines the evaluation questions and associated quantitative measures. See Appendix 2 for performance measure details.

Tak	ble 1. Quantitative Evaluation Quest	ions and Measures
Eva	luation Question	Measures
Que	stion 1: What was the eligible members'	service utilization during the period of extended coverage?
1.a.	What types of services did eligible members access during the period of extended coverage compared to prior utilization?	Summary of encounters by type of service: • Professional Visits • Pharmacy Fills • Outpatient Visits • Emergency Department Visits • Inpatient Stays • Dental Visits • Vision Visits • NEMT Trips
1.b.	What diagnoses were associated with services received by eligible members during the period of extended coverage compared to prior diagnoses?	Summary of diagnosis prevalence: • Primary diagnoses by ICD-10-CM chapter • Primary diagnoses by ICD-10-CM block or category Summary of inpatient stays by diagnosis: • CMS Major Diagnostic Category (MDC) • Medicare Severity Diagnosis Related Group (MS-DRG)
1.c.	Did eligible members receive new diagnoses after turning age 19? If so, what diagnoses?	Summary of diagnosis incidence: • Diagnoses by ICD-10-CM chapter • Diagnoses by ICD-10-CM block or category
Que	stion 2: How was preventive, routine	e, chronic and acute care impacted during the period of extended coverage?
2.a.	Did treatment prior to age 19 for chronic conditions, including behavioral health issues, continue after members turned 19 years old during the COVID-19 PHE?	 Service utilization by chronic condition: Asthma Diabetes Behavioral Health Others to be determined based on prevalent diagnoses (question 1.b) Prescription (pre-existing prescriptions) prevalence rates by generic therapeutic class

Evalu	ation Question	Measures
	tion 2: How was preventive, routi tinued)	ne, chronic and acute care impacted during the period of extended coverage?
2.b.	What were the patterns of preventir routine, and acute health care durin the period of extended coverage?	 ED visits, observation stays, or inpatient admissions for selected conditions: COVID-19 Acute respiratory infections Acute severe asthma Diabetic Ketoacidosis/ Hyperglycemia SUD Mental health issues External Causes of Morbidity Outpatient or professional claims for respiratory infections: Acute upper respiratory infections Influenza Pneumonia Other acute lower respiratory infections HEDIS measures (applicable age strata): Annual Dental Visit (ADV) Adults' Access to Preventive/ Ambulatory Health Services (AAP) Child and Adolescent Well-Care Visits (WCV) Emergency Department Utilization (EDU) – Observed Events, not risk adjusted Inpatient Utilization (IPU) – General Hospitalization/Acute Care, excluding maternity admissions.
Ques 3.a.	tion 3: What was the cost of the e What was the cost of services provid to members who received the	led Spending per member per month:
	extended coverage?	 Total by service type (see 1.a)

Qualitative Analysis

The focus of the qualitative analysis will be to describe member, MCO, and State perceptions regarding the extended CHIP coverage.

Evaluation Period

March 1, 2020, through the end of the PHE (date to be determined).

Study Population

The study population is KanCare 2.0 CHIP members who turned age 19 during the COVID-19 PHE and had extended CHIP coverage. Also, MCO and State staff involved in the implementation of the PHE amendment extended CHIP coverage will be identified.

Data Sources

An online member survey, using SurveyMonkey software, will be conducted at the conclusion of the PHE unwinding period. Letters will be mailed to members who received the extended CHIP coverage, with a link and QR code for web-based completion of the survey. MCO and State contacts will receive an email after the PHE unwinding period, with the link to an online stakeholder survey, using SurveyMonkey.

Analytic Methods

Qualitative data analysis techniques will be used to analyze data collected through the stakeholder surveys. The steps for qualitative data analysis will include: getting familiar with the data by looking for basic observations or patterns; revisiting evaluation questions that can be answered through the collected data; developing a framework (coding and

indexing) to identify broad ideas, concepts, behaviors, or phrases, and assign codes for structuring and labeling data; identifying themes, patterns, and connections to answer research questions; and summarization of the qualitative information to add to the overall evaluation results.

Table 2. Qualitative Evaluation Questions							
Question 4: What were	Question 4: What were the key stakeholder perceptions, and experiences regarding the extended coverage?						
Member perceptions • Were eligible CHIP enrollees aware of their extended coverage? • How did the extended coverage help the eligible enrollee during the COVID-19 PHE							
MCO and State perceptions	 What strategies did the MCOs use to engage members who turned 19 during the COVID-19 PHE. What were the principal challenges experienced with MCO engagement of CHIP beneficiaries turning age 19 during this public health emergency? What strategies did the MCOs pursue to address those challenges? 						

 Table 2 outlines the evaluation question and potential associated survey questions.

c. Methodological Limitations

The use of administrative claims and encounters data sources has limitations. These data sources are designed and collected for billing purposes but will be used in the evaluation to determine changes in access to services, quality of care, and health outcomes. However, most of the measures selected for assessment of the evaluation questions are validated and widely used for this purpose. While administrative data might be able to identify key cases and statistical trends, these are usually limited in providing detailed health and health behavior information, thus making it difficult to obtain information on possible covariates. Also, due to the use of population-level data, the effect size of measured differences represents true differences; however, this may or may not correspond to meaningful changes.

Data lag (the number of days from the date of service to the date the claims become available for analysis) may limit the amount of data available for the evaluation.

External administrative claims and encounters are not available, and it is not possible to answer the following key questions with KanCare encounter data.

- How did service utilization of the study group compare to utilization for non-CHIP persons aged 19–21-years during the PHE?
- In prior years, what services were utilized in the first two years after CHIP members lost eligibility on turning 19?

As evaluation is based on multiple years, the definitions and specifications of the evaluation measures, policies for data collection, and infrastructure of the data sources may change during the evaluation period, thus leading to unavailability of appropriate data for the analysis.

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Appendix A: Detailed Discussion of Data Sources Appendix B: Performance Measure Details

Appendix A: Detailed Discussion of Data Sources

Table A1. Detaile	Table A1. Detailed Discussion of Data Sources						
Data Source	Type of Data	Description of Data Source	Efforts for Cleaning/Validation of Data	Quality/Limitations of Data Source			
Kansas Modular Medicaid System (KMMS) Encounter database	Claims and Encounters	Encounter/claims data submitted to the State by MCOs used to support HEDIS® and other performance, service utilization, and cost metrics for all enrollees	 KMMS member demographics, enrollment, and encounter data obtained from the database will be reviewed for missing values, duplicate values, inconsistent patterns, and outliers to ensure quality and appropriateness of data for analyses of performance measures required by the evaluation design. Encounter data related pay-for-performance metrics are validated annually by KFMC as a part of their validation of all pay-for-performance metrics. For applying statistical procedures for analysis of performance measures, a final dataset with all required variables will be created by merging data variables obtained from the KMMS encounter database with other source data. 	 Encounters submitted to the State by MCOs are records of the billed claims MCOs receive from providers for service payment. Administrative claims and encounter data are routinely used in HEDIS and other performance measurement. These data sources will be used in the evaluation to determine changes in access to services, quality of care, and health outcomes. Most of the measures selected for assessment of the evaluation questions are validated and widely used for this purpose. Data are generally considered complete if one quarter is allowed for claims processing and encounter submission. There is known inconsistency in the population of the MCO claim status field for zero-dollar paid claims. Payment amounts by Medicare and commercial payors incomplete. 			
KMMS Eligibility and Enrollment database	Medicaid Eligibility and Enrollment data	Eligibility and enrollment detail for Medicaid members used to determine enrollee aid category and stratify data into subgroups	• Data variables obtained from KMMS eligibility and enrollment database will be merged with data from other data sources to create a final database for applying statistical procedures for analysis of performance measures.	 Quality is high. Enrollment records include beginning and end dates for eligibility periods. MCOs receive updated KMMS eligibility and enrollment data daily. 			
KMMS Demographics database	Medicaid member demographic data	Demographic data includes member's name, contact information, date of birth, date of death, gender, race, and ethnicity.	 Data variables obtained from KMMS demographics database will be merged with data from other data sources to create a final database for applying statistical procedures for analysis of performance measures. Contact information will be reviewed for missing and invalid entries prior to conducting member surveys. 	 Contact information is frequently not up to date. Email addresses are not available. Other demographics are considered high quality. Enrollment records include beginning and end dates for eligibility periods. MCOs receive updated KMMS demographic data daily. 			

Table A1. Detailed	Table A1. Detailed Discussion of Data Sources (Continued)						
Data Source	Type of Data	Description of Data Source	Efforts for Cleaning/Validation of Data	Quality/Limitations of Data Source			
HEDIS data from MCOs	Data for HEDIS performance measures	Member-level detail tables for HEDIS measures submitted by the MCOs that provide numerator and denominator values for stratified HEDIS results	 Comparison of numerator and denominator counts to NCQA-certified compliance audit results. The MCOs subcontract with HEDIS Certified Auditors to validate their HEDIS data for NCQA submission. KFMC subcontracts with a different HEDIS Certified Auditor to conduct validation of MCO HEDIS data; CMS validation protocols are followed. 	 Data Quality is closely monitored by the MCOs and EQRO. MCOs use NCQA Certified HEDIS software to calculate HEDIS measures and submit data to NCQA as part of their NCQA accreditation requirement. Data become available seven months after the measurement year. This can affect the availability of data for conducting the evaluation for the entire five-year period of the demonstration. 			
Online Surveys	Qualitative survey data	One online survey will collect qualitative information from members who received extended CHIP coverage during the COVID-19 PHE. One online survey will collect qualitative information from MCO and State staff involved in the implementation of the CHIP coverage extension (e.g., member benefits or customer service staff).	 Information from the online survey will be reviewed for completeness and clarity. Themes will be identified to understand successes and barriers in achieving its goal. Stratified response rates will be reviewed. 	 Few members may participate in the survey. Open-ended responses may not clearly communicate the respondent's intended message. 			

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Appendix B: Performance Measure Details

Performance Measure	Steward	Denominator	Numerator	Unit of Measure	Data Source
Annual Dental Visit (ADV) Percentage of members who had one or more dental visit with a dental practitioner during the measurement year	NCQA	CHIP members 18–20 years of age	Members 18–20 years of age who had one or more dental visit with a dental practitioner during the measurement year	Percentage	Kansas Modular Medicaid System (KMMS) databases; HEDIS data from MCOs
Adults' Access to Preventive/Ambulatory Health Services (AAP) Percentage of members who had an ambulatory or preventive care visit during the measurement year	NCQA	CHIP members 20–21 years of age	Members 20–21 years of age who had one or more ambulatory or preventive care visits during the measurement year	Percentage	Same as above.
Child and Adolescent Well-Care Visits (WCV) Percentage of members who had at least one comprehensive well-care visit with a PCP or an OB/GYN practitioner during the measurement year	NCQA	CHIP members 18–21 years of age	Members 18–21 years of age who had at least one comprehensive well- care visit with a PCP or an OB/GYN practitioner during the measurement year	Percentage	Same as above.
Inpatient Utilization—General Hospitalization/Acute Care Excluding maternity admissions	NCQA	Members, 18–21 years of age, enrolled in CHIP for at least one month (30 consecutive days) during the measurement period	Number of acute inpatient discharges (excluding discharges for maternity admissions) during the measurement period	Days per 1,000 member-months	Same as above.
Emergency Department Visits (EDU) Observed events, not risk adjusted	NCQA	Members, 18–21 years of age, enrolled in CHIP for at least one month (30 consecutive days) during the measurement period	Number of ED visits during the measurement period	Visits per 1,000 member- months	Same as above.

Table A2. Performance Measure Details (Continued)

Performance Measure	Steward	Denominator	Numerator	Unit of Measure	Data Source
ED Visits, Observation Stays, and Inpatient Admissions For the following conditions: • COVID-19 • Acute respiratory infections • Acute severe asthma • Diabetic ketoacidosis/hyperglycemia • Substance use disorder • Mental health issues • External Causes of Morbidity	N/A	Members, 18 years and older, enrolled in CHIP for at least one month (30 consecutive days) during the measurement period.	Number of claims for emergency department visits, observation stays, and inpatient admissions for COVID-19, acute respiratory infections, acute severe asthma, diabetic ketoacidosis/ hyperglycemia, substance use disorder, mental health issues, or external causes of morbidity— deduplicated to one service per member, per billing provider NPI, per last date of service	Services per 1,000 member- months	Same as above.
 Outpatient and Professional Services For following conditions: Acute upper respiratory infections Influenza Pneumonia Other acute lower respiratory infections 	N/A	Members, 18 years and older, enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Number of claims for outpatient or professional claims for diabetic retinopathy, influenza, pneumonia, or shingles— deduplicated to one service per member, per billing provider NPI, per last date of service	Services per 1,000 member- months	Same as above.

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Attachment 1: Independent Evaluator Attachment 2: Timeline and Major Milestones

Attachment 1: Independent Evaluator

KDHE has arranged to contract with the Kansas External Quality Review Organization (EQRO), KFMC Health Improvement Partners (KFMC), to conduct the evaluation of the KanCare 2.0 Demonstration COVID-19 PHE Amendment. They have agreed to conduct the demonstration evaluation in an independent manner. KFMC has over 50 years of demonstrated success in carrying out both Federal and State healthcare quality related contracts. They have provided healthcare quality improvement, program evaluation, review, and other related services including the following:

- Kansas Medicaid Managed Care EQRO since 1995 (over 27 years).
- CMS quality improvement organization (QIO) or QIO-Like entity since 1982 (40 years).
- Utilization Review/Independent Review Organization for the Kansas Insurance Department since 2000 (22 years) and for five other states.

KFMC is accredited as an Independent Review Organization (IRO) through URAC (formerly known as the Utilization Review Accreditation Commission). The URAC Accreditation process is a rigorous, independent evaluation, ensuring that organizations performing IRO services are free from conflicts of interest and have established qualifications for reviewers. KFMC considers ethics and compliance an integral part of all their business decisions and the services they provide. The KFMC Corporate Compliance Program supports the commitment of KFMC to conduct its business with integrity and to comply with all applicable Federal and State regulations, including those related to organizational and personal conflicts of interest. The KFMC compliance program ensures potential, apparent, and actual organizational and personal conflicts of interest (PCI) will be identified, resolved, avoided, neutralized, and/or mitigated.

Prior to entering into any contract, KFMC evaluates whether the identified entity or the work presents an actual, potential, or apparent organizational conflict of interest (OCI) with existing KFMC contracts. KFMC will not enter into contracts that are an OCI. If it is undetermined whether the new work could be a conflict of interest with their EQRO and independent evaluation responsibilities, KFMC will discuss the opportunity with KDHE, to determine whether a conflict would exist. In some cases, an approved mitigation strategy may be appropriate.

All Board members, managers, employees, consultants, and subcontractors receive education regarding conflicts of interest and complete a CMS developed PCI Disclosure Form. Disclosures include the following:

- Relationships with insurance organizations or subcontractor of insurance organizations
- Relationships with providers or suppliers furnishing health services under Medicare
- Financial interests in health care related entities
- Investments in medical companies, healthcare, or medical sector funds
- Governing body positions

Deliverable/Activity	Due Date
Initiate meeting with EQRO and State to finalize study measures.	January 15, 2023
Provide updates during routine quarterly EQRO/State/MCO meetings to review and discuss data sources, reports, and findings as applicable.	To be determined
Conduct online stakeholder surveys and analyze data.	1 to 6 months post PHE unwinding period.
Conduct final evaluation analysis, after the PHE unwinding period, allowing for data lag.	6–8 months post PHE unwinding period.
Draft evaluation report.	No later than one year after the end of the COVID-19 section 1115 demonstration authority.
Final evaluation report.	60 calendar days after receipt of CMS comments