DELAWARE HEALTH AND SOCIAL SERVICES

Division of Medicaid & Medical Assistance

Interim Evaluation of Delaware's Section 1115 Substance Use Disorder Demonstration for the Period August 1, 2019 to December 31, 2023

OCTOBER 31, 2022

HMA

HEALTH MANAGEMENT ASSOCIATES

Table of Contents

LISTING OF EXHIBITS

Number	Appears in	Exhibit Title
18	Section F	Concurrent Use of Opioids and Benzodiazepines
19	Section F	Summary of Findings for Measures Mapped to Milestone 4
20	Section F	Emergency Department Visits for SUD Per 1,000 Medicaid Beneficiaries
21	Section F	Inpatient Stays Per 1,000 Medicaid Beneficiaries
22	Section F	Follow-up After Emergency Department Visit for Alcohol or Other Drug Dependence
23	Section F	Summary of Findings for Measures Mapped to Milestone 5
24	Section F	Readmissions Among Beneficiaries with SUD
25	Section F	Case Management of SUD Clients
26	Section F	Transitions of Care for SUD Clients
27	Section F	Summary of Findings for Measures Mapped to Milestone 6
28	Section F	Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD
29	Section F	Summary of Findings for Other Measures Not Mapped to a Specific Milestone
30	Section F	Per Member Per Month Expenditures Among the SUD Population
31	Section G	Summary of Measures Examined by CMS Milestone

SECTION A: Executive Summary

Delaware's Diamond State Health Plan demonstration was approved for the period August 1, 2019 through December 31, 2023. This demonstration was originally approved in 1995. Prior to this most recent approval, the demonstration has been renewed five times.

Delaware's Section 1115 demonstration includes 12 goals. One of these goals is specific to substance use disorder (SUD):

> *Increase enrollee access and utilization of appropriate substance use disorder (SUD) treatment services; decrease use of medically inappropriate and avoidable high-cost emergency and hospital services; increase initiation of follow-up SUD treatment after emergency department discharge; and reduce SUD readmission rates.*

Delaware proposes to test whether it can enhance the effectiveness of the SUD treatment system in Medicaid by maintenance and expansion of SUD residential services as part of a coordinated and full continuum of care resulting in increased access and improved health outcomes for individuals with SUD.

Under the broader waiver demonstration goal stated above, as set forth in the SUD Implementation Plan, Delaware is aligning the six goals for the SUD waiver component with the milestones outlined by the Centers for Medicare and Medicaid Services (CMS) as follows:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

Delaware's Implementation Plan describes the planned activities in the waiver period organized by CMS milestone. Delaware identified its own milestones in its approved Implementation Plan which include:

1. Access to critical levels of care for opioid use disorder (OUD) and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care, including medication-assisted treatment (MAT);
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

Population Impacted by the Demonstration

Overall, Medicaid members with a SUD diagnosis represented 7.7 percent of the total Medicaid population in the fourth quarter of CY 2021. The evaluators used CMS's specifications for SUD Metric #3 (Medicaid Beneficiaries with SUD Diagnosis) to assess the trend in the Medicaid population most likely

to be impacted by the demonstration. Medicaid beneficiaries with a SUD diagnosis have remained steady during the three-year period examined, from 22,461 in Q1-2019 to 22,592 as of Q4-2021. The highest quarter reported was Q1-2020 with 23,483 beneficiaries with SUD.

Among the SUD beneficiaries in Q4-2021, only one percent of the population are adolescents and four percent are elderly. The remaining 95 percent are non-elderly adults. Dual eligibles represent 3.5 percent of the total SUD population. Pregnant women represent just 1.4 percent of the total SUD population. The mix between beneficiaries based on substances used is 40 percent with an opioid use disorder (OUD) and 60 percent some SUD.

Evaluation Questions and Hypotheses

Burns & Associates, a Division of Health Management Associates (HMA-Burns) is serving as the Independent Evaluator for this demonstration. HMA-Burns created a driver diagram with a focus on reducing opioid-related overdose deaths. HMA-Burns converted the primary and secondary drivers in the driver diagram into 11 hypotheses and five research questions. For each research question, measures were assigned as well as a targeted methodology.

At least one research question and one hypothesis is mapped to each of the CMS demonstration goals. As a means to answer the research questions posed, the results of 29 measures are reported on in this evaluation.

Methodology

HMA-Burns developed an Evaluation Design Plan for this demonstration which was approved by CMS on April 2, 2021. The full Evaluation Design Plan, which appears in Appendix A, reflects a range of data sources, measures and perspectives. It defines the most appropriate study population and sub-populations and describes the analytic methods included in the evaluation design which include (1) descriptive statistics; (2) statistical tests; (3) onsite reviews; (4) desk reviews; and (5) facilitated interviews.

Target Population

The target population is any Delaware Medicaid beneficiary with a diagnosis of SUD enrolled in the demonstration in the study period. HMA-Burns is using the CMS-defined specification for the individuals identified with an SUD. HMA-Burns has created flags to identify sub-populations within the demonstration population which include the following:

1. **Individuals with an OUD:** This flag was created to better understand the utilization and health outcomes of individuals with an OUD compared to other SUDs.
2. **Dual eligible**: Includes the population with an SUD who also meet criteria for being dually-eligible for both the Medicare and Medicaid population.
3. **Age Stratification**: Includes individuals with an SUD age 18 and younger, age 19 to 64, and age 65 and older.
4. **County stratification**: Includes the stratification of members with an SUD based on their home location in one of the three counties in Delaware: New Castle, Kent, or Sussex.
5. **MCO Stratification**: Includes the stratification of members with an SUD based on the MCO that they are enrolled with.

Evaluation Period

Metrics for the demonstration population and sub-populations are computed for a pre- and post-demonstration period. The pre-demonstration period is defined as January 1, 2016 through December 31, 2018. The demonstration period is defined as January 1, 2019 through December 31, 2023. To simplify the analytic plan, HMA-Burns is counting the first seven months of 2019 (for monthly measures) and CY 2019 data (for annual measures) prior to the approval of the current demonstration period as part of the demonstration period.

Data Sources

The primary data source used to compute measures in this evaluation is service utilization reported on encounters, member enrollment, and provider enrollment files from the Delaware Medicaid Enterprise System (DMES). Other data sources include primary data collected by HMA-Burns from the MCOs for focus studies; secondary data collected by DMMA from the state's Vital Statistics office and from the state's Prescription Drug Monitoring database; and qualitative feedback collected from facilitated interviews.

Results

In Section F of this report, each of the CMS milestones serves as a heading. Measures are reported for each milestone as they relate to the research questions posed in the Evaluation Design Plan. At the start of each subsection, there is a summary table that lists each measure reviewed that was mapped to a research question under the demonstration goal. The table shows the desired outcome for each measure, if the desired outcome is being met in the demonstration period thus far, and if the results were found to be statistically significant (when testing for significance was conducted). The test used for statistical significance is also shown, where applicable.

After the summary table, each of the individual measures examined appears on its own one-page dashboard report. Information about the research question posed, the measure and measure steward, and the data source used to analyze the measure are provided.

A summary of the results of all 29 measures, by CMS milestone, appears in Exhibit 1 at the end of this section. Among 29 measures reviewed, there were 15 where the desired outcome was met. Of these, eight measures had an outcome that was statistically significant in the desired direction. For the 14 measures where the desired outcome was not met, 11 measures had a statistically significant change in the wrong direction.

The DMMA was also successful in large part in the activities it set out to do in its SUD Implementation Plan. Among the eight activities identified, five were completed in full and the remainder are in progress.

Conclusions

Delaware did not meet all of the desired outcomes outright but still saw many positive impacts due to the demonstration. The PHE likely had a confounding effect in enabling Delaware to fully meet these aims during the demonstration period. When considering the CMS Milestones, Delaware saw success in each milestone with the exception of Milestone 6, Improved Access to Care for Physical Health Conditions Among Beneficiaries

1. **Increased rates of identification, initiation, and engagement in treatment.** Delaware did not see an increase in the initiation or engagement in treatment during the initial years of the demonstration when compared to the pre-demonstration period. There has been a significant ramp up in the use of the state's Prescription Drug Monitoring Program, both in number of clinicians using it and the number of inquiries.
2. **Increased adherence to and retention in treatment**. The percentage of beneficiaries with a SUD diagnosis who used SUD services each month increased 11.3 percent during the initial years of the demonstration (CY 2019, CY 2020, and CY 2021). But the continuity of pharmacotherapy for OUD decreased during this time period.
3. **Reduction in overdose deaths, particularly those due to opioids.** While overdose deaths did increase in CY 2020, there were positive trends observed in the use of opioids at high dosage in persons without cancer and the rate of concurrent use of opioids and benzodiazepines.
4. **Reduced utilization of emergency department and inpatient hospital settings**. The rate of ED visits for SUD on a per 1,000 Medicaid beneficiary basis for the total population and for members ages 18-64 both declined. There were also declines in inpatient stays per 1,000 Medicaid beneficiaries for the total population and for members ages 18-64. When assessing trends in follow-up from the ED for a visit related to alcohol or other drug dependence, results were mixed (improvement at the 30-day mark but not at the 7-day mark).
5. **Fewer readmissions to the same or higher level of care**. The rate of readmissions among beneficiaries with SUD decreased during the initial years of the demonstration. Also, among SUD beneficiaries with an inpatient stay, the percentage that used the ED in the 12 weeks after their discharge was lower than the 12 weeks prior to admission. Utilization of intensive outpatient services and medication assisted treatment increased in the 12 weeks post hospital discharge.
6. **Improved access to care for physical health conditions among beneficiaries.** For individuals with an SUD diagnosis, access to preventive or ambulatory care decreased between the pre-demonstration period and the initial years of the demonstration.
7. **Reduce the cost of the SUD population in the demonstration period**. The per member per month expenditures for all services among SUD beneficiaries remained steady during the demonstration period, but expenditures for SUD services increased 24.8 percent while non-SUD service expenditures decreased 20.6 percent during the same time period.

Assessment of Opportunities for Improvement

Delaware saw progress towards its aim to expand SUD-specific services to its Medicaid population through the initial phase of the SUD demonstration period. This occurred through the expansion of coverage for short-term stays in residential and hospital inpatient treatment settings that qualify as institutions for mental disease (IMDs), new services added across the ASAM continuum, and a concentrated effort to increase access to existing SUD. Opportunities for continued improvement remain. HMA-Burns has identified eight opportunities for the DMMA to consider as it continues to enhance service delivery and access. Recommendations focus on reimbursement strategies to encourage greater provider participation, education to providers on ASAM criteria and authorization requests, and strategies to incentivize the MCOs to improve initiation and engagement in treatment for SUD beneficiaries.

Exhibit 1
Summary of Measures Examined by CMS Milestone

CMS Milestone		Total Measures	Measures with Results Trending in the Intended Direction	Measures with Results Trending in the Wrong Direction	Total Measures Where Tests Were Run for Statistical Significance	Of these, the Total Where Trend in Intended Direction and Statistically Significant	Of these, the Total Where Trends in Wrong Direction and Statistically Significant	Of these, the Total Where There Was No Statistically Significant Change
ALL MEASURES		**29**	**15**	**14**	**22**	**8**	**11**	**3**
1	Increased rates of identification, initiation, and engagement in treatment	13	3	10	8	0	8	0
2	Increased adherence to and retention in treatment	2	1	1	2	1	1	0
3	Reductions in overdose deaths, particularly those due to opioids	3	2	1	3	2	1	0
4	Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	4	3	1	4	2	0	2
5	Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	3	3	0	1	1	0	0
6	Improved access to care for physical health conditions among beneficiaries	1	0	1	1	0	1	0
	Cost-related measures not tied to a specfic milestone	3	3	0	3	2	0	1

SECTION B: General Background Information

Description of the Demonstration's Policy Goals

Delaware's Section 1115 demonstration includes 12 goals. One of these goals is specific to substance use disorder (SUD):

- to increase enrollee access and utilization of appropriate SUD treatment services by decreasing the use of medically inappropriate and avoidable high-cost emergency and hospital services;
- to increase initiation of follow-up SUD treatment after emergency department discharge; and
- to reduce SUD readmission rates. [1]

Delaware proposes to test whether it can enhance the effectiveness of the SUD treatment system in Medicaid by maintenance and expansion of SUD residential services as part of a coordinated and full continuum of care resulting in increased access and improved health outcomes for individuals with SUD.

Under the broader waiver demonstration goal stated above, as set forth in the SUD Implementation Plan, Delaware is aligning the six goals for the SUD waiver component with the milestones outlined by the Centers for Medicare and Medicaid Services (CMS) as follows:[2]

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

Delaware's Implementation Plan describes the planned activities in the waiver period organized by CMS milestone. Delaware identified its own milestones in its approved Implementation Plan which include:

1. Access to critical levels of care for opioid use disorder (OUD) and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care, including medication-assisted treatment (MAT);
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

[1] Delaware Diamond State Health Plan 1115(a) Demonstration Special Terms and Conditions, accessed at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/de/de-dshp-ca.pdf

[2] State Medicaid Director Letter #17-003 Re: Strategies to Address the Opioid Epidemic, November 1, 2017, available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

Demonstration Name, Approval Date, and Time Period of Data Analyzed in the Assessment

Name: Delaware Diamond State Health Plan

Project Number: 11-W-00036/4

Approval Date: July 31, 2019, amended effective January 19, 2021

Time Period Covered by Evaluation: The demonstration covers the period from August 1, 2019 through December 31, 2023. This assessment covers the period with dates of service from August 1, 2019 through December 31, 2021.

Brief Description and History of Implementation

Delaware's Section 1115 Waiver Authority

Delaware's Diamond State Health Plan (DSHP) 1115 Demonstration Waiver was initially approved in 1995 and implemented beginning on January 1, 1996. The original goal of the demonstration was to improve the health status of low-income Delawareans by expanding access to healthcare to more individuals throughout the State; creating and maintaining a managed care delivery system with an emphasis on primary care; and controlling the growth of healthcare expenditures for the Medicaid population. The DSHP 1115 Demonstration was designed to mandatorily enroll eligible Medicaid recipients into managed care organizations (MCOs) and to create cost efficiencies in the Medicaid program that could be used to expand coverage.

Since the initial approval, the demonstration has been renewed six times. Key changes over the course of these renewals include the following:

- In 2012, creation of the Diamond State Health Plan Plus (DSHP-Plus), which is Delaware's managed long-term services and supports (MLTSS) program. This amendment requires additional state plan populations to receive services through MCOs.
- In 2013, extending benefits to the low-income adult demonstration population with incomes up to 100 percent of the FPL until December 31, 2013 upon which these members would become part of a new adult eligibility group authorized under the ACA.
- In 2014, authorizing coverage for enhanced behavioral health services and supports for targeted Medicaid beneficiaries through a voluntary program called PROMISE (Promoting Optimal Mental Health for Individuals Through Supports and Empowerment) starting in 2015. PROMISE enrollees include Medicaid beneficiaries who have a severe and persistent mental illness (SPMI) and/or a SUD and require HCBS to live and work in integrated settings.
- In 2021, adding adult dental services to the services administered by the state's managed care system.

Administration of Delaware's Medicaid Program

The Division of Medicaid and Medical Assistance (DMMA) of the Delaware Department of Health and Social Services (DHSS) has responsibility for the administration and oversight of Delaware's Medicaid program under the waiver and state plan authorities. At the end of Calendar Year (CY) 2021, total Medicaid enrollment in Delaware was 292,548, or 29 percent of the total state population (July 2021

Census). By the end of CY 2021, 88 percent of eligibles were enrolled in managed care. Total enrollment has grown by 17.8 percent since the start of the public health emergency (PHE) at the end of Q1-2020.

As of the fourth quarter of CY2021, 39 percent of Medicaid enrollees were children and adolescents, 54 percent were non-elderly adults, and seven percent were elderly. When viewed by enrollment category, just over half of the enrollees are TANF (Temporary Assistance for Needy Families) eligibles, or children with their parents. Another 28 percent of enrollees are childless adults that became eligible through the Affordable Care Act. Seven percent are in the aged, blind, and disabled category. Three percent of enrollees are dually eligible for both Medicare and Medicaid. The remaining ten percent of enrollees fall into various other small enrollment categories.

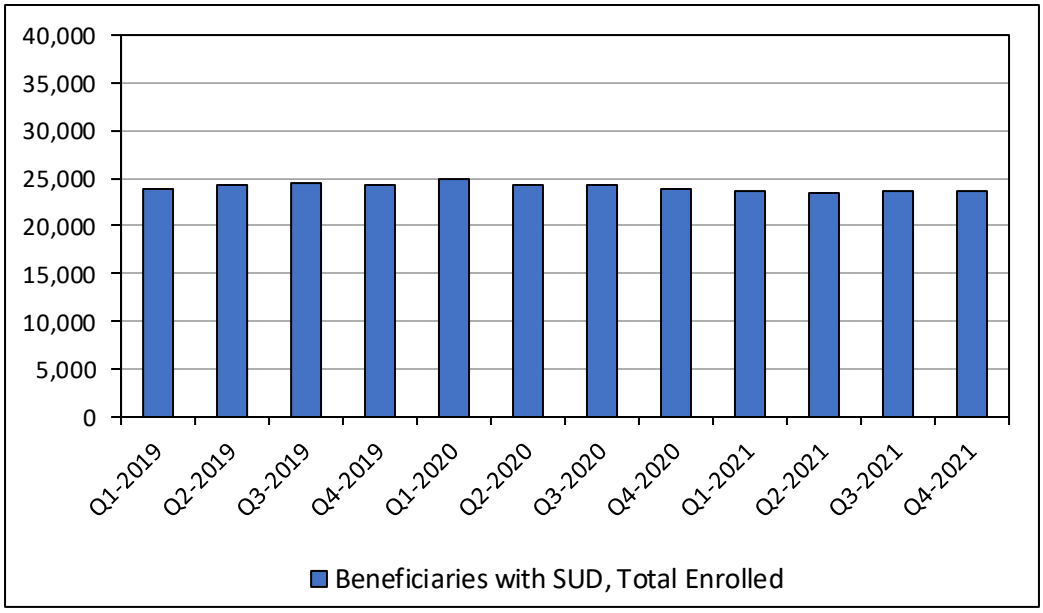
The MCOs under contract with DMMA currently are AmeriHealth Caritas Delaware and Highmark Health Options. The current DMMA contract with each MCO will expire December 31, 2022. The incumbent MCOs, with the addition of a new MCO (Delaware First Health), will enter into a new contract with DMMA effective January 1, 2023.

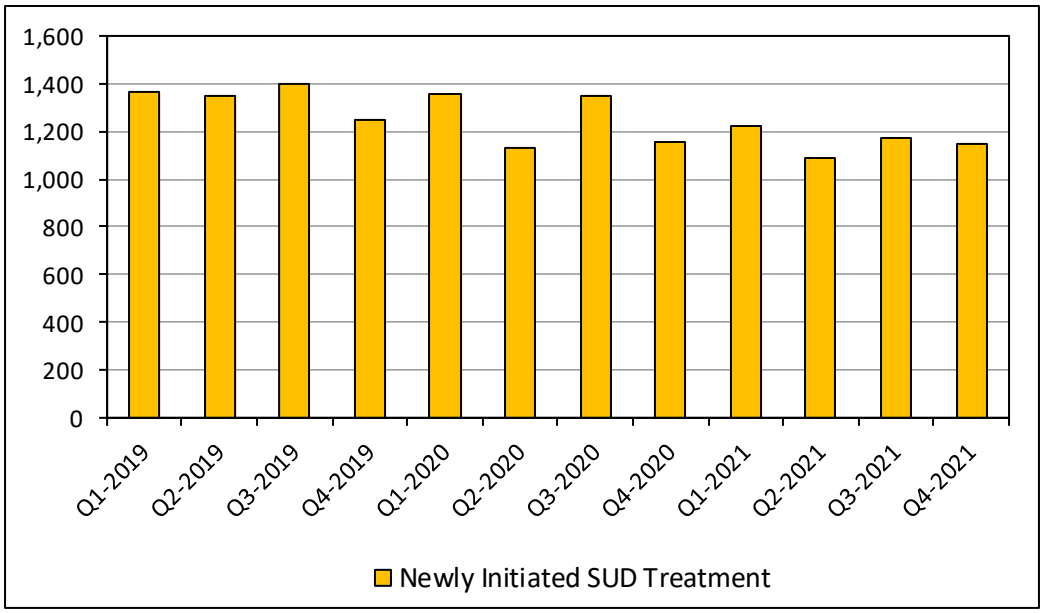
Population Groups Impacted by the Demonstration

The evaluators used CMS's specifications for SUD Metric #3 (Medicaid Beneficiaries with SUD Diagnosis) and Metric #2 (Medicaid Beneficiaries with Newly Initiated SUD Diagnosis) to assess the trend in the Medicaid population most likely to be impacted by the demonstration. Exhibit 2, which appears on the next page, shows the trend on both of these measures on a quarterly basis from Q1-2019 to Q4-2021.

Medicaid beneficiaries with a SUD diagnosis have remained steady during the three-year period examined, from 22,461 in Q1-2019 to 22,592 as of Q4-2021. The highest quarter reported was Q1-2020 with 23,483 beneficiaries with SUD. Since CMS's Metric #3 is dependent on utilization (claims) to count beneficiaries, the low fluctuation in the count of beneficiaries with SUD may be due to reduced utilization of SUD services at the start of the public health emergency (PHE). Individuals with a newly initiated SUD diagnosis has actually gone down since the start of the demonstration, again likely due to suppressed utilization in the early period of the PHE. The range for individuals with a newly initiated SUD diagnosis on average each quarter has been between 1,084 in Q2-2021 to 1,399 in Q3-2019 (the start of the demonstration).

Exhibit 2
Medicaid Beneficiaries with SUD, by Quarter, CY 2019 - CY 2021

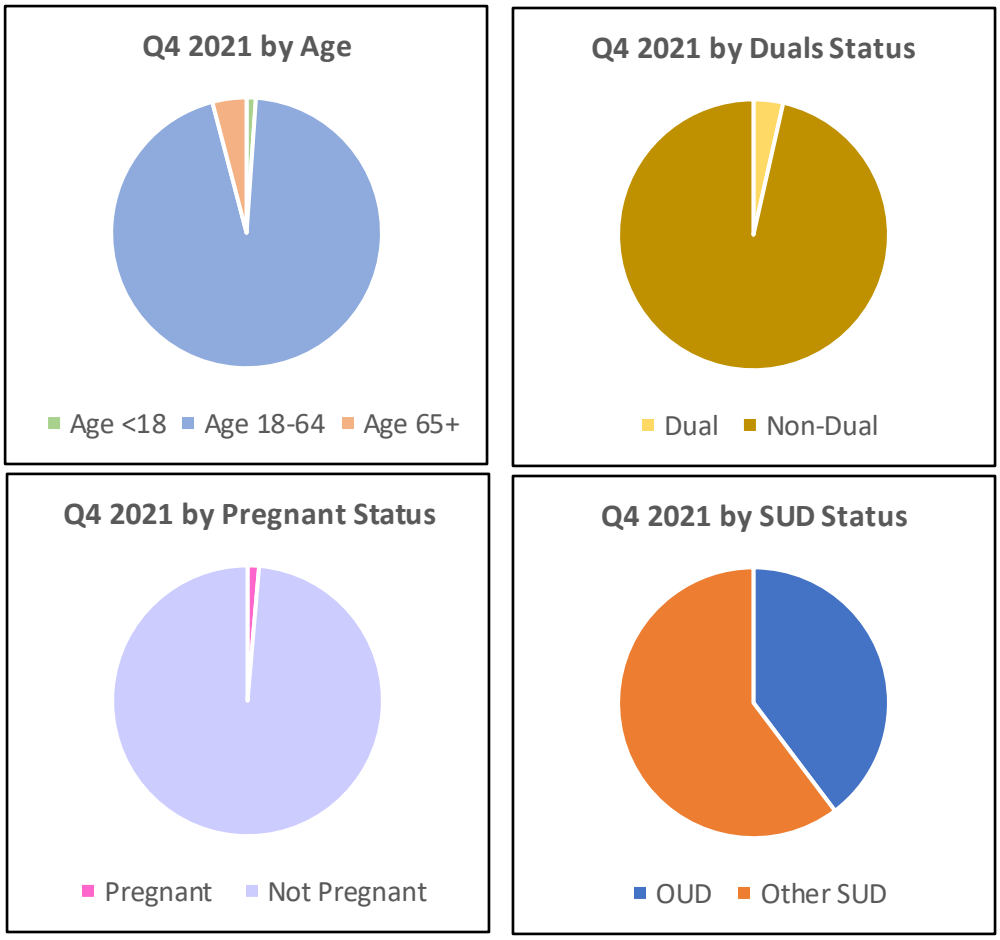




Overall, Medicaid members with a SUD diagnosis represented 7.7 percent of the total Medicaid population in the fourth quarter of CY 2021. Exhibit 3 on the next page shows attributes of the average enrollment of 22,592 beneficiaries with a SUD diagnosis. Only one percent of the total population are adolescents and four percent are elderly. The remaining 95 percent are non-elderly adults. Dual eligibles represent 3.5 percent of the total SUD population. Pregnant women represent just 1.4 percent of the total SUD population. The mix between beneficiaries based on substances used is 40 percent with an opioid use disorder (OUD) and 60 percent some SUD other than OUD.

Exhibit 3
Profile of Medicaid Members with SUD Diagnosis, 4th Quarter CY2021

Total Medicaid Enrollment, Average in Q4 2021	292,816
Total Enrollment with SUD Diagnosis in Q4 2021	22,592
Percent of Total Enrollment with SUD Diagnosis	7.7%



SECTION C: Evaluation Questions and Hypotheses

Defining Relationships: Aims, Primary Drivers and Secondary Drivers

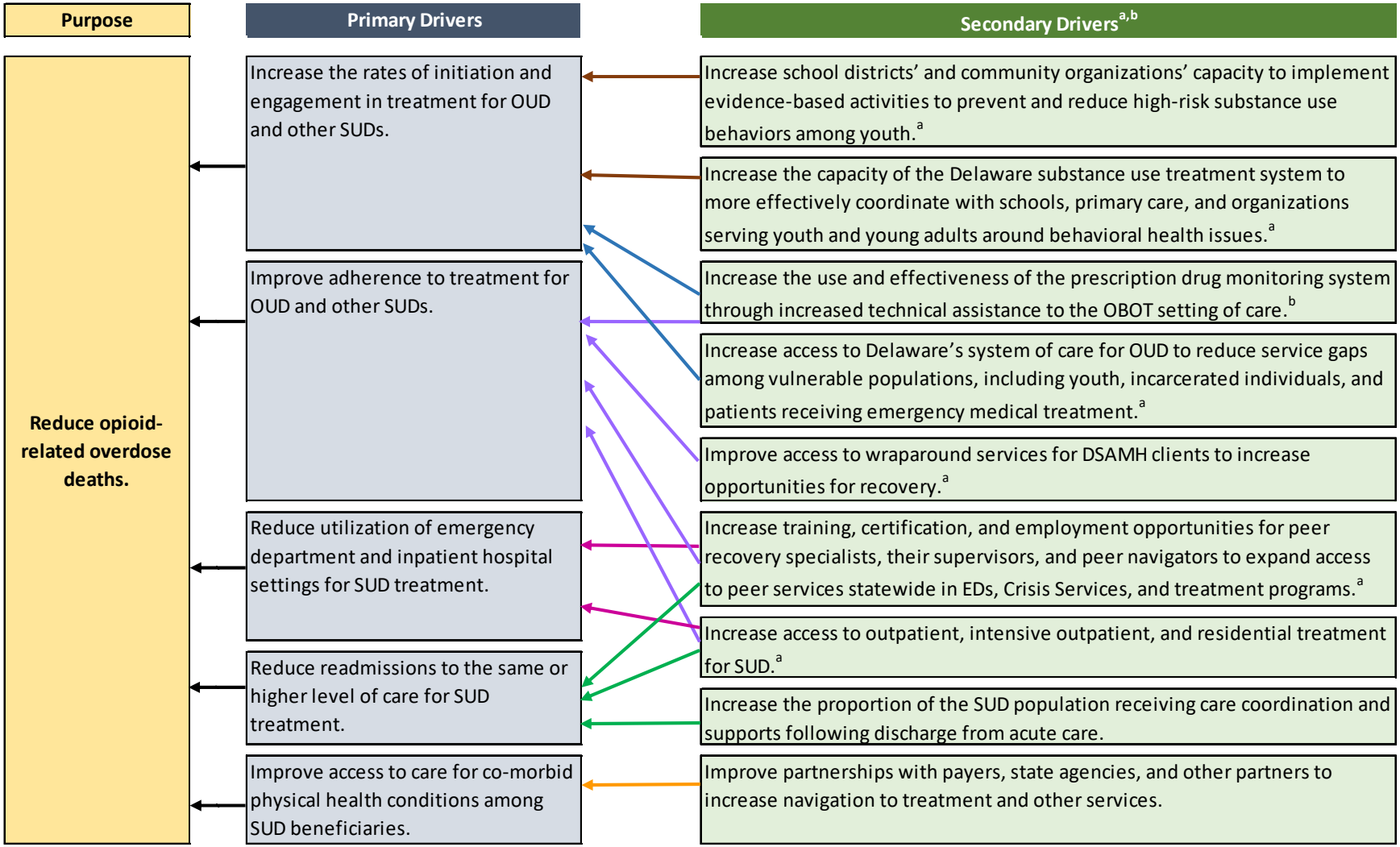
Burns & Associates, a Division of Health Management Associates (HMA-Burns) is serving as the Independent Evaluator for this demonstration. HMA-Burns examined the relationships between the CMS goals and DMMA's interventions included in the approved demonstration and SUD Implementation Plan. HMA-Burns constructed a driver diagram identifying primary and secondary drivers of the principal aim to reduce opioid-related overdose deaths. The driver diagram shown in Exhibit 4 on the next page is part of the approved Evaluation Design Plan.

HMA-Burns chose reduction in opioid-related overdose deaths as the primary aim because it is a measurable health outcome. CMS goals related to improved quality of care were determined to all have the potential to contribute to a reduction in overdose deaths and, therefore, are factored in as primary drivers. In turn, the specific actions described in the Implementation Plan which would be designed to improve these measures of quality of care were considered as secondary drivers.

In order to translate these aims as well as primary and secondary drivers into measurable results, HMA-Burns identified existing, nationally-recognized measures where available for the aims and primary drivers. This includes measures that CMS has defined for the quarterly monitoring reports that states with SUD demonstrations submit to CMS. HMA-Burns added custom measures where needed. The measures that have been identified are used to measure performance during the demonstration period against the pre-demonstration period.

Exhibit 4

Driver Diagram: Reduce Opioid-related Overdose Deaths



[a]Part of federal SOR evaluation and not specifically included in the scope of this evaluation.

[b]Part of federal SUD Capacity Planning evaluation and not specifically included in the scope of this evaluation.

Hypotheses and Research Questions

HMA-Burns converted the primary and secondary drivers shown above into a series of hypotheses and research questions. For each research question, measures were assigned as well as a targeted methodology. This is detailed further in Section D of the report.

In Exhibit 5 on the next page, HMA-Burns organized the hypotheses and research questions shown in the Evaluation Design Plan and mapped them to CMS's milestones. HMA-Burns then mapped each measure identified in the Evaluation Design to one of the research questions shown in Exhibit 5.

Exhibit 5
Mapping Hypotheses and Research Questions to Demonstration Goals

Hypothesis	Research Questions	Demonstration Goal
#1: The demonstration will increase or maintain the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.	Does the demonstration increase access to and utilization of SUD treatment services?	1
#2: The demonstration will increase or maintain adherence to and retention in treatment for OUD.		2
#3: Approved service authorizations improve appropriate utilization of health care services in the post-demonstration period.		1
#4: The demonstration will decrease the rate of emergency department and inpatient hospital visits within the beneficiary population for SUD.		4
#5: The demonstration will increase or maintain the percentage of beneficiaries with SUD who experience care forcomorbid conditions.	Do enrollees who are receiving SUD services experience improved health outcomes?	6
#6: Among beneficiaries receiving care for SUD, the demonstration will reduce or maintain readmissions to SUD treatment.		5
#7: The demonstration will decrease the rate of overdose deaths due to opioids.	Are rates of opioid-related overdose deaths impacted by the demonstration?	3
#8: The demonstration will increase or maintain the use of Delaware's Prescription Drug Monitoring Program.	Do activities post-implementation increase use of Delaware's Prescription Drug Monitoring Program?	1
#9: The demonstration will decrease or maintain per beneficiary per month costs.	How does the demonstration impact cost?	All
#10: The demonstration will increase or maintain per beneficiary per month costs for SUD services versus non-SUD services.		All
#11: The demonstration will decrease or maintain per beneficiary per month costs for SUD-related ED visits and hospital inpatient stays.		All

SECTION D: Methodology Used in Assessment

Evaluation Design

The evaluation is conducted on Medicaid beneficiaries during the pre- and post-demonstration period. The approved Evaluation Design Plan is a mixed-methods approach, drawing from a range of data sources, measures, and analytics to best produce relevant and actionable study findings. The approved Evaluation Design Plan reflects a range of data sources, measures and perspectives. It defines the most appropriate study population and sub-populations and describes the analytic methods included in the evaluation design. The Evaluation Design Plan approved by CMS on April 2, 2021 appears in Appendix A.

The five analytic methods used by the evaluators include:

1. descriptive statistics
2. statistical tests
3. onsite reviews,
4. desk reviews,
5. facilitated interviews.

Target and Comparison Population

The target population is any Delaware Medicaid beneficiary with a diagnosis of SUD enrolled in the demonstration in the study period. HMA-Burns is using the CMS-defined specification for the individuals identified with an SUD. HMA-Burns has created flags to identify sub-populations within the demonstration population which include the following:

1. **Individuals with an OUD:** This flag was created to better understand the utilization and health outcomes of individuals with an OUD compared to other SUDs.
2. **Dual eligible**: Includes the population with an SUD who also meet criteria for being dually-eligible for both the Medicare and Medicaid population.
3. **Age Stratification**: Includes individuals with an SUD age 18 and younger, age 19 to 64, and age 65 and older.
4. **County stratification**: Includes the stratification of members with an SUD based on their home location in one of the three counties in Delaware: New Castle, Kent, or Sussex.
5. **MCO Stratification**: Includes the stratification of members with an SUD based on the MCO that they are enrolled with.

Evaluation Period

Metrics for the demonstration population and sub-populations are computed for a pre- and post-demonstration period. The pre-demonstration period is defined as follows:

- For monthly measures, enrollment or dates of service from January 1, 2016 through December 31, 2018.
- For annual measures, enrollment or dates of services during Calendar Years 2016, 2017, and 2018.

The demonstration period is defined as follows:

- For monthly measures, enrollment or dates of service from January 1, 2019 through December 31, 2023.
- For annual measures, enrollment or dates of services during Calendar Years 2019, 2020, 2021, 2022, and 2023

To simplify the analytic plan, HMA-Burns is counting the first seven months of 2019 (for monthly measures) and CY 2019 data (for annual measures) prior to the approval of the current demonstration period as part of the demonstration period. Although CMS approved Delaware's 1115 waiver in July 2019, waiver-related activities were moving forward in anticipation of approval of the extension.

Evaluation Measures

HMA-Burns is reporting on 29 measures, each of which has been mapped to a demonstration goal. The measures that have been analyzed in this Interim Evaluation utilize measures defined by CMS for the quarterly SUD monitoring reports that states submit to CMS as well as measures defined by the HMA-Burns team that are specific to Delaware's demonstration goals stewards. Many of the CMS measures leverage the specifications developed as part of the National Committee on Quality Assurance's (NCQA's) HEDIS®[3] measures. A summary of these measures, by demonstration goal, appears in Exhibit 6 on the next page.

[3] The Healthcare Effectiveness Data and Information Set (HEDIS) is a registered trademark of the National Committee for Quality Assurance

Exhibit 6
Inventory of Measures Included in the Interim Evaluation, by CMS Milestone

CMS Milestone	Measures Defined by CMS*	Measures Defined by HMA-Burns	Total Measures
TOTAL	**19**	**10**	**29**
Increased rates of identification, initiation, and engagement in treatment	8	5	**13**
Increased adherence to and retention in treatment	2	0	**2**
Reductions in overdose deaths, particularly those due to opioids	3	0	**3**
Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	4	0	**4**
Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	1	2	**3**
Improved access to care for physical health conditions among beneficiaries	1	0	**1**
Other measures not associated to a specific milestone	0	3	**3**

* Part of the measures submitted quarterly to CMS as part of Monitoring Reports

In Section F of the report, each measure is shown on a separate one-page summary of findings report. The measures are organized by SUD milestone. As an introduction to each milestone, a summary exhibit is provided which lists out each measure, the desired outcome, if the outcome was met or not, and if the result was statistically significant. The test applied for statistical significance is also cited.

Data Sources

HMA-Burns proposed to use a number of data sources, including primary and secondary data, to conduct the evaluation. Most of these sources are included in this Interim Evaluation, but all sources will be reported in the Summative Evaluation. The data sources include the following:

- Service utilization reported on encounters with member and provider enrollment files from the Delaware Medicaid Enterprise System (DMES);

- Primary data collected by HMA-Burns from the MCOs for focus studies;
- Secondary data collected by DMMA from Vital Statistics;
- Secondary data from the Delaware Prescription Drug Monitoring Program; and
- Qualitative feedback collected from facilitated interviews.

For each measure where results are reported in Section F of this report, the data source is DMES unless specifically noted. The HMA-Burns team receives utilization, member enrollment, and provider enrollment files from the DMES on a monthly basis in order to track and trend measures over the course of the demonstration period. The data is validated by the HMA-Burns team upon intake and trended against information received in prior months across multiple dimensions. The HMA-Burns team has built a comprehensive database that incorporates utilization and enrollment data going back to CY 2017 up to the present.

Although managed care encounters are the primary source for computing measures, other measures use a combination of encounters, member enrollment, and provider enrollment files. An example of this is the development of maps that were included in the Mid-Point Assessment report. HMA-Burns plotted the home location of individuals with SUD on a map that displayed the provider locations of SUD providers as a way to visualize access to services.

For other measures defined by HMA-Burns, the evaluators used primary data collected from MCOs for Medicaid beneficiaries enrolled in managed care. This was completed for the analysis of SUD authorizations that was reported in the Mid-Point Assessment and that appears in measures under CMS Milestone #1 in this report. HMA-Burns also collected information from each MCO on the status of enrollment in the case management program offered at each MCO for beneficiaries with SUD.

HMA-Burns worked with the DMMA to facilitate the receipt of secondary data from other state agencies—namely, the Delaware Department of Public Health's Office of Vital Statistics and the Delaware Division of Professional Regulation's Prescription Drug Monitoring Program (PMP) database. The files from Vital Statistics were used to map individuals in their records to the Medicaid enrollment roster to compute the overdose death rate among Medicaid beneficiaries. The results from the PMP database were used to track the number of clinicians and number of inquiries into the PMP over time.

Qualitative feedback was collected through in-person interviews (conducted via Zoom) with the MCOs and SUD providers in October and November 2021. Medicaid beneficiary feedback was collected through a short survey (five minutes in length). Results of this feedback were reported on in Delaware's SUD Mid-Point Assessment. For the Summative Evaluation, facilitated interviews will be conducted again towards the end of the demonstration period with SUD providers, beneficiaries of SUD services, and the MCOs.

Analytic Methods

Descriptive Statistics

For utilization-focused measures, HMA-Burns computed as a rate expressed either as a percentage of the total eligible population, on a utilization per 1,000 member basis, or on a per member per month cost basis. The numerator and denominator values are provided to show how the rate was computed. For this Interim Evaluation, for annual measures, results are shown for the four years CY 2018 through

CY 2021. The baseline period is defined as CY 2018. The comparison year for the demonstration period is defined as CY 2021. The rate of change between the baseline and most recent demonstration period is shown.

Statistical Tests

Among the 29 measures examined, tests of significance were run on 22 measures. The test that was applied to assess statistical significance was either t-test or chi-square. For the Summative Evaluation, interrupted time series will be used to assess significance on all measures where t-test was applied in the Interim Evaluation and for many of the measures where chi-square was applied as well.

Onsite Reviews and Desk Reviews

For this Interim Evaluation, desk reviews were completed in lieu of onsite reviews with the MCOs due to the ongoing PHE. HMA-Burns read in data from each MCO using templates that were designed specifically for this evaluation. Data from each MCO was summarized and validated, where necessary, with each MCO individually to ensure that the data reported by the MCO was complete. For the specific focus study of service authorizations of SUD services, the HMA-Burns team reviewed individual authorization records in the software used by each MCO via Zoom meetings in lieu of conducting an onsite review of the sample of records.

Facilitated Interviews

Two members of the HMA-Burns evaluation team conducted an interview session with representatives from both MCOs that contract with DMMA in October 2021. The MCOs were given the questions intended for the facilitated discussion in advance of the interview and were asked to include representatives from their organization that are familiar with SUD service authorization requests, care/case management, provider relations, finance, and contract compliance. Both MCOs complied with this request. The actual session was conducted via Zoom and was 90 minutes in length.

For SUD providers, HMA-Burns solicited interest from the base of providers currently delivering SUD services to Medicaid beneficiaries. Interviews were conducted one-on-one with each provider and with staff from the provider's trade association. A total of six interviews were conducted. Appointments for each interview were set in advance so that the appropriate provider representatives could be present. Participation in each interview ranged from one to six representatives. The HMA-Burns assessment team consisted of the same two members that conducted the MCO interview. Each provider was sent the same set of questions in advance of their interview. Although the evaluation team used the interview guide to cover relevant topics, the providers were encouraged to provide feedback on any other topic important to them as well. Actual interviews were 60 to 90 minutes in duration.

When the initial appointments were made with providers, HMA-Burns also requested provider assistance, where possible, to coordinate gathering feedback from their Medicaid clients. Given the PHE, the feedback from Medicaid members who received SUD treatment were offered either through completion of a hardcopy or online survey. Clients were told upfront the questions that would be asked and that any feedback that they provided would be anonymous. A total of 43 clients provided feedback.

Feedback from all interviews and surveys were categorized into themes. In total, 15 themes resonated with stakeholders. This feedback was included in the SUD Mid-Point Assessment.

SECTION E: Methodological Limitations

Limitations

The HMA-Burns assessment team identified limitations when computing measures and interpreting measures as described in the Evaluation Design Plan. Although the limitations did not impact the computations of results for the time periods reported in this Interim Evaluation, there are limitations on how best to interpret the results that are being reported.

The HMA-Burns team did identify the following items that pose limitations in this evaluation:

1. *Public health emergency*. The obvious limitation in this evaluation is the impact on service utilization and provider supply during the public health emergency period. The current demonstration began just seven months prior to the start of the PHE. Delaware, like most states, saw atypical results during the early period of the PHE both positively (e.g., lower emergency department visits) and negatively (e.g., lower rates on measures related to access to services or follow-up services). For the Summative Evaluation, in addition to adding results from CYs 2022 and 2023 to the analysis, the HMA-Burns team will assess trends not only between the pre-demonstration and current demonstration periods, but also the pace at which utilization and access measures improve as the PHE winds down.

2. *Data limitations in DMES*. There are some limitations in the data as reported in DMMA's data warehouse in the pre-demonstration period of CY 2016 and CY 2017. Information is available for both utilization and enrollment statistics for each Medicaid beneficiary for these two years, but some variables such as MCO assignment are incomplete. For this Interim Evaluation, therefore, results are shown for the years where this information is complete (CYs 2018 through 2021). For the Summative Evaluation, information will be reported using CY 2016 and CY 2017 for analyses such as interrupted time series, but these results may need to be more at the overall demonstration population level and not at the sub-population level.

3. *Small sample size*. For many sub-populations identified in the Evaluation Design Plan, the sample was too low to conduct meaningful evaluation. Because of this and the atypical utilization patterns during the PHE, the results for each measure are reported in this Interim Evaluation for the SUD demonstration population as a whole. For the Summative Evaluation, results at the sub-population level will be reported wherever feasible once more data is available for study.

4. *Exogenous factors may impact results*. Many of the outcome measures are multi-dimensional and influenced by social determinants of health. While changes in the demonstration period related to access to care may be one dimension of various outcomes of interest and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions such as social determinants of health (e.g., housing, employment and previous incarcerations).

5. *Beneficiary feedback*. The PHE prohibited the preferred method of receiving Medicaid beneficiary feedback which is through one-on-one or small group interviews face-to-face. The evaluators will conduct face-to-face interviews with beneficiaries once the PHE has concluded and report beneficiary feedback in the Summative Evaluation.

SECTION F: Results

The findings from HMA-Burns' assessment of each of CMS milestone is shown in Section F. Each CMS milestone serves as a heading. There is a seventh heading at the end of Section F to report on measures that were included in the Evaluation Design Plan but cannot be mapped to a specific CMS milestone.

At the start of each heading in Section F, there is a summary table that lists each measure reviewed that was mapped to the CMS milestone. The table shows the desired outcome for each measure, if the desired outcome was met, and if the results were found to be statistically significant (when testing for significance was conducted). The test used for statistical significance is also shown, where applicable.

After the summary table, each of the individual measures examined appears on its own one-page dashboard report. Information about the research question posed, the measure and measure steward, and the data source used to analyze the measure are provided.

Milestone #1: Increased Rates of Identification, Initiation, and Engagement in Treatment

Summary of Measures

Thirteen measures were examined to assess the rates of identification, initiation, and engagement in treatment. In Exhibit 7 below, it shows that the desired outcome was met in three out of the 13 measures. A test for statistical significance was conducted on eight of the 13 measures. For seven of these eight measures, the outcome was statistically significant.

Exhibit 7
Summary of Findings for Measures Mapped to Milestone 1
Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
	Initiation of Alcohol and Other Drug Dependence Treatment				
1	Alcohol Abuse Only	Increase	Decrease	Yes	Chi-square
2	Opioid Abuse Only	Increase	Decrease	Yes	Chi-square
3	Abuse Other than Alcohol or Opioid	Increase	Decrease	Yes	Chi-square
4	Total AOD Population	Increase	Decrease	Yes	Chi-square
	Engagement of Alcohol and Other Drug Dependence Treatment				
5	Alcohol Abuse Only	Increase	Decrease	Yes	Chi-square
6	Opioid Abuse Only	Increase	Decrease	No	Chi-square
7	Abuse Other than Alcohol or Opioid	Increase	Decrease	Yes	Chi-square
8	Total AOD Population	Increase	Decrease	Yes	Chi-square
9	Average Turnaround Time for Authorization Decisions	>90% within contract timelines	Not Met	N/A	no test run
10	Authorization Denial Rate for SUD Services	<5%	Met	N/A	no test run
11	SUD Authorization Denial Reasons	>90% due to lack of medical necessity	Not Met	N/A	no test run
12	Numer of Clinicians Accessing the PMP	Increase	Increase	N/A	no test run
13	Number of Queries to the PMP	Increase	Increase	N/A	no test run

Individual Measure Results

HMA-Burns utilized NQCA's specification for its HEDIS measure related to the initiation (refer to Exhibit 8) and engagement (refer to Exhibit 9) of alcohol and other drug dependence (AOD) treatment (HEDIS measure IET). For both initiation and engagement, HMA-Burns computed separate results for four populations: alcohol abuse only, opioid abuse only, abuse other than alcohol or opioid, and the total AOD population. Results were computed for measurement years CY 2018 through CY 2021. For the initiation measures, there was a reduction in initiation between the baseline period (CY 2018) and the latest demonstration period (CY 2021) for all four populations. In CY 2021, the initiation rate was similar for alcohol abuse only and for abuse other than alcohol or opioid (near 50%). The initiation rate was lower for opioid abuse only (43%).

The rates of engagement were also lower when comparing the baseline period to the latest demonstration period. However, unlike the initiation rates, the rate of engagement was higher for opioid abuse only than for the other populations (42% in CY 2021 compared to near 20% for alcohol only or abuse other than alcohol or opioid).

HMA-Burns conducted a focus study on SUD service authorizations to determine if the timing of authorization decisions and the rate of authorization requests denied may be contributing to issues related to access to SUD services. The results of this study appear on Exhibit 10. The period of study was all SUD provider authorization requests for the period September 1, 2018 through February 28, 2020 submitted to the MCOs for services requiring authorization by the MCO.

First, HMA-Burns examined the turnaround time for these authorization requests. For pre-service requests 70 percent of requests were determined within three days and 81 percent within 10 days. For concurrent review (e.g. residential treatment), 47 percent were determined within one day.

Second, the rate of approved and denied requests were examined. HMA-Burns found that the approval rate for inpatient hospital SUD stays was 96 percent; for residential treatment stays, it was 97 percent.

Lastly, when authorizations were denied, the reason for the denials was reviewed. For inpatient hospital stays, lack of medical necessity was the reason in more than nine out of ten occurrences. Conversely, for residential treatment, lack of medical necessity was the reason only 32 percent of the time and administrative denials were the remaining 68 percent.

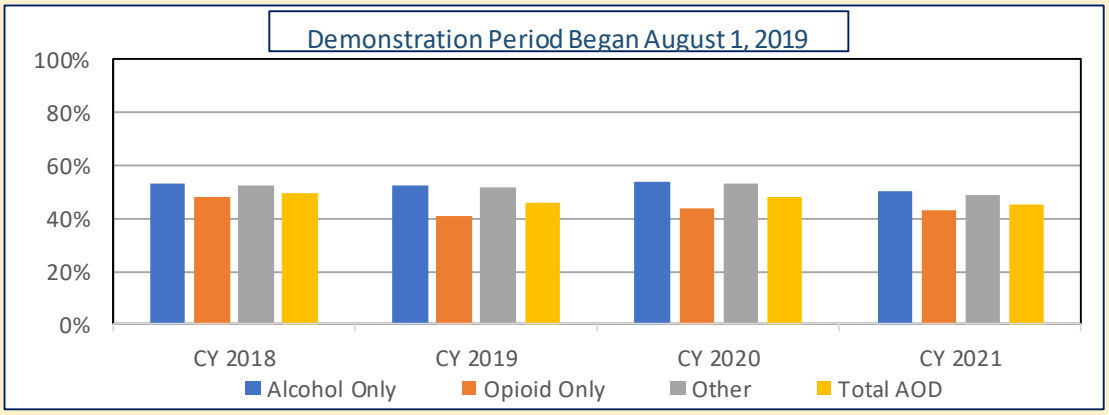
HMA-Burns also examined the use of Delaware's Prescription Drug Monitoring Program (Delaware uses the acronym PMP) over time (refer to Exhibit 11). Measures include the number of clinicians accessing the PMP and the number of queries to the PMP. From the start of CY 2019 to the end of CY 2021, the average number of clinicians accessing the PMP has grown more than four-fold. The number of queries has increased more than five-fold.

Exhibit 8
Results for Interim Evaluation Measures #1 through #4
Initiation of Alcohol and Other Drug Dependence Treatment

Hypothesis:
The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.

Measure Used to Test Hypothesis:
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment
Measure Steward: NCQA, National Quality Forum #0004 [CMS Monitoring Metric #15]

Results for the Demonstration Population



	Study Period	Numerator	Denominator	Rate	
Alcohol Abuse Only	CY 2018	1,732	3,252	53.3%	
	CY 2019	1,756	3,339	52.6%	
	CY 2020	1,725	3,200	53.9%	
	CY 2021	1,755	3,469	50.6%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-5.3%
Opioid Abuse Only	CY 2018	2,800	5,857	47.8%	
	CY 2019	1,988	4,850	41.0%	
	CY 2020	1,840	4,175	44.1%	
	CY 2021	1,922	4,457	43.1%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-10.9%
Abuse Other than Alcohol or Opioid	CY 2018	1,789	3,417	52.4%	
	CY 2019	1,689	3,269	51.7%	
	CY 2020	1,723	3,259	52.9%	
	CY 2021	1,700	3,458	49.2%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-6.5%
Total AOD Population	CY 2018	5,264	10,621	49.6%	
	CY 2019	4,417	9,660	45.7%	
	CY 2020	4,250	8,842	48.1%	
	CY 2021	4,348	9,562	45.5%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-9.0%

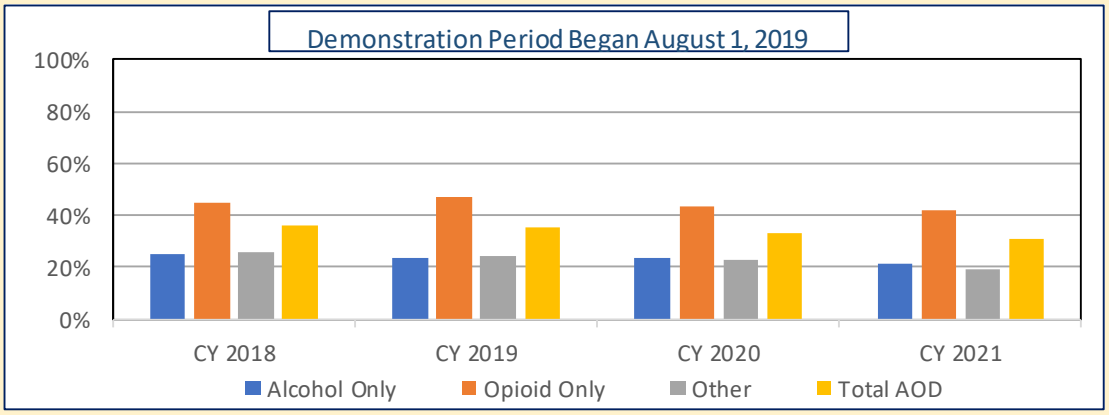
	Alcohol Only	Opioid Only	Other	Total AOD
Desired Outcome:	Increase	Increase	Increase	Increase
Actual Outcome:	Decrease	Decrease	Decrease	Decrease
Statistical Review:	Chi-Square	Chi-Square	Chi-Square	Chi-Square
Probability:	0.0287	<.0001	0.0081	<.0001
Finding:	Significant	Significant	Significant	Significant

Exhibit 9
Results for Interim Evaluation Measures #5 through #8
Engagement of Alcohol and Other Drug Dependence Treatment

Hypothesis:
The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.

Measure Used to Test Hypothesis:
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment
Measure Steward: NCQA, National Quality Forum #0004 [CMS Monitoring Metric #15]

Results for the Demonstration Population



	Study Period	Numerator	Denominator	Rate	
Alcohol Abuse Only	CY 2018	431	1,732	24.9%	
	CY 2019	413	1,756	23.5%	
	CY 2020	407	1,725	23.6%	
	CY 2021	381	1,755	21.7%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-14.6%
Opioid Abuse Only	CY 2018	1,251	2,800	44.7%	
	CY 2019	941	1,988	47.3%	
	CY 2020	801	1,840	43.5%	
	CY 2021	812	1,922	42.2%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-5.8%
Abuse Other than Alcohol or Opioid	CY 2018	458	1,789	25.6%	
	CY 2019	413	1,689	24.5%	
	CY 2020	390	1,723	22.6%	
	CY 2021	321	1,700	18.9%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-35.6%
Total AOD Population	CY 2018	1,893	5,264	36.0%	
	CY 2019	1,567	4,417	35.5%	
	CY 2020	1,412	4,250	33.2%	
	CY 2021	1,347	4,348	31.0%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-16.1%

	Alcohol Only	Opioid Only	Other	Total AOD
Desired Outcome:	Increase	Increase	Increase	Increase
Actual Outcome:	Decrease	Decrease	Decrease	Decrease
Statistical Review:	Chi-Square	Chi-Square	Chi-Square	Chi-Square
Probability:	0.0266	0.098	<.0001	<.0001
Finding:	Significant	Not Significant	Significant	Significant

Exhibit 10
Results for Interim Evaluation Measures #9 through #11
SUD Service Authorization Requests

Hypothesis:
Approved service authorizations improve appropriate utilization of health care services in the post-demonstration period.

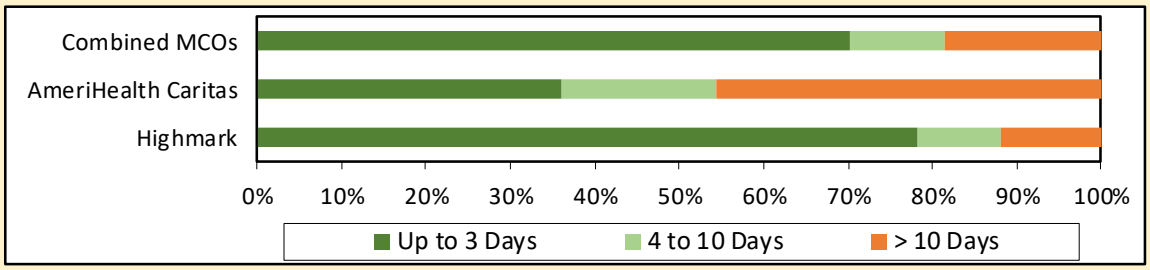
Measure Used to Test Hypothesis:
1. Average Turnaround Time for SUD Authorization Decisions
2. Authorization Denial Rate for SUD Services
3. SUD Authorization Denial Reasons

Measure Steward: HMA-Burns

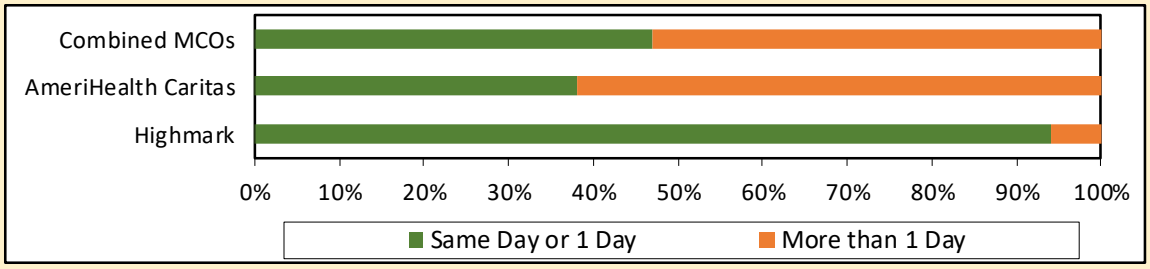
Data source: Data reported by Medicaid MCOs to the evaluators for SUD authorization requests for the period September 1, 2019 - February 28, 2020

Results for Turnaround Time for SUD Authorization Decisions

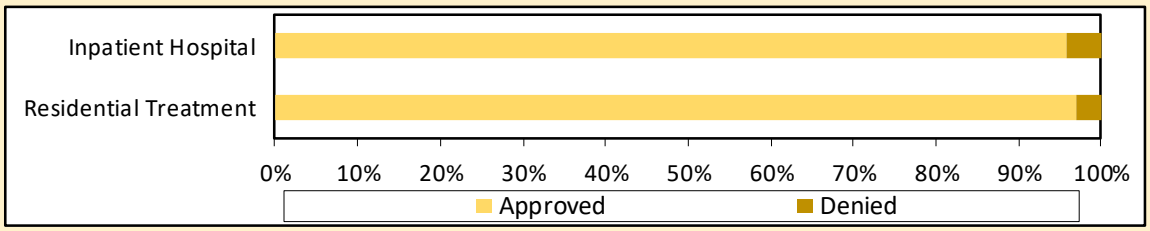
Pre-Service Requests for the Six Month Period (n = 3,188)



Concurrent Review Requests for the Six Month Period (n = 2,763)



Results for Denial Rate of SUD Authorization Decisions



Results for Reasons for Denials of SUD Authorization Decisions

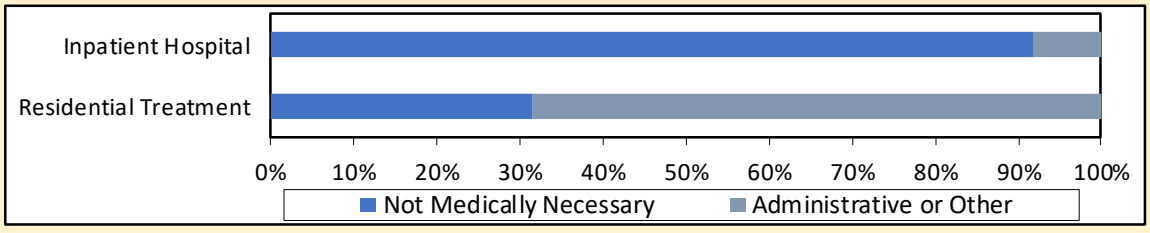


Exhibit 11
Results for Interim Evaluation Measures #12 and #13
Statistics on Use of Delaware's Prescription Drug Monitoring Program Database

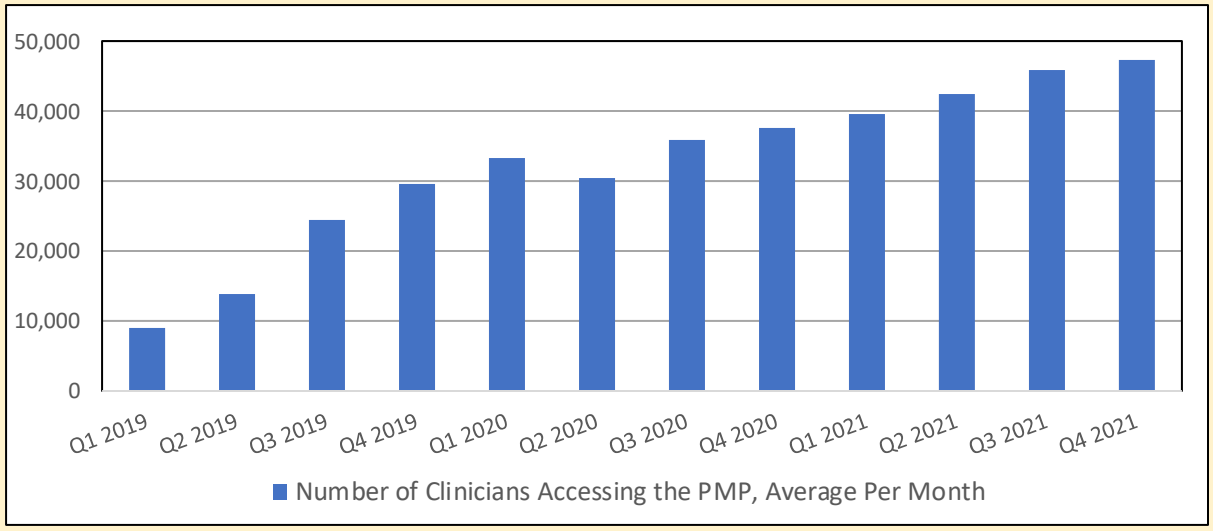
Hypothesis:
The demonstration will increase or maintain the use of Delaware's Prescription Drug Monitoring Program (in Delaware, the abbreviation used is PMP).

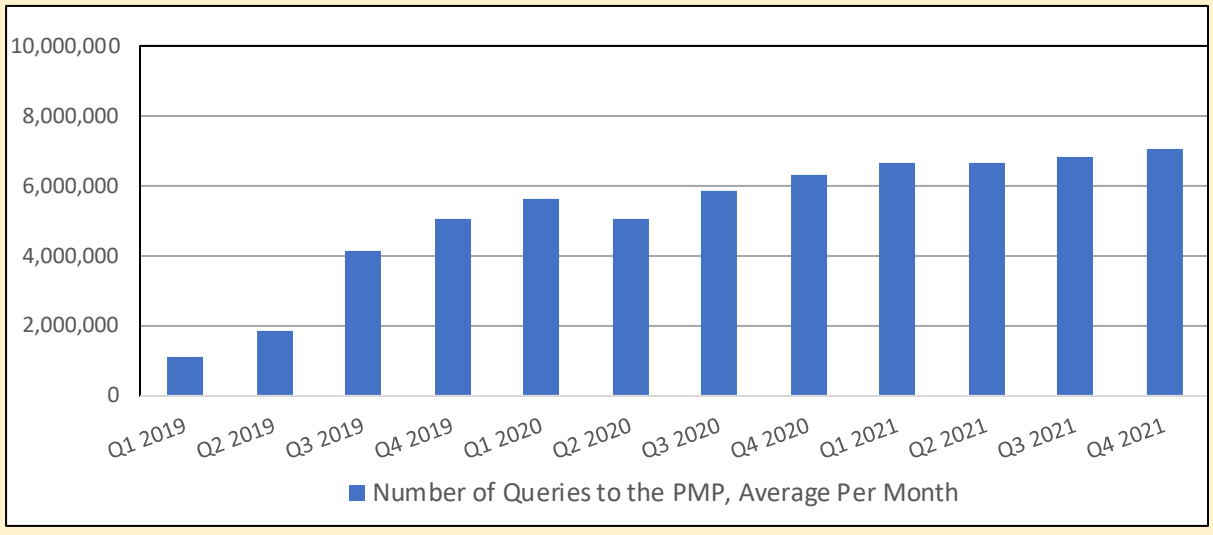
Measure(s) Used to Test Hypothesis:
1. Number of clinicians accessing the PMP
2. Number of queries to the PMP

Measure Steward: HMA-Burns
Data Source: Delaware Division of Professional Regulation submitted to DMMA https://dpr.delaware.gov/boards/pmp

Desired Trend:	Increase in number of clinicians accessing the PM	**Finding:**	Increased
Desired Trend:	Increase in number of queries to the PMP	**Finding:**	Increased

Results [Note: Data only available since January 2019]





Milestone #2: Increased Adherence to and Retention in Treatment

Summary of Measures

Two measures were examined to assess the adherence to and retention in treatment. In Exhibit 12 below, it shows that the desired outcome was met in one of the two measures. A test for statistical significance was conducted on both measures. The results were statistically significant in both measures.

Exhibit 12
Summary of Findings for Measures Mapped to Milestone 2
Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
14	Continuity of Pharmacotherapy for Opioid Use Disorder	Increase	Decrease	Yes	Chi-square
15	Percentage of Beneficiaries with a SUD Diagnosis Who Used SUD Services Per Month	Increase	Increase	Yes	T-test

Individual Measure Results

Exhibit 13 shows that the continuity of pharmacotherapy for opioid use disorder has decreased from 15.2 percent in CY 2018 to 11.5 percent in CY 2021.

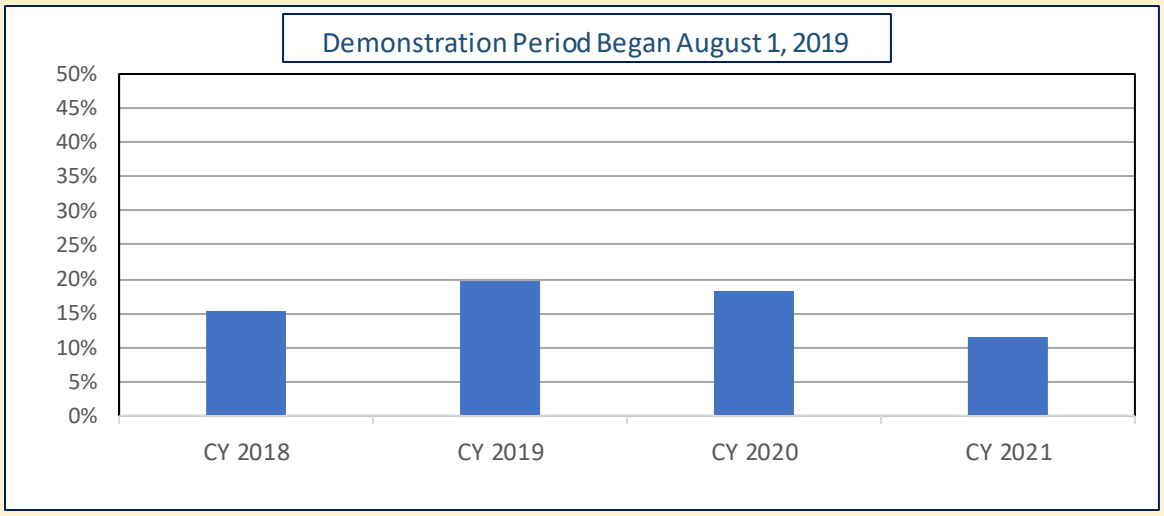
In Exhibit 14, HMA-Burns used the results from two CMS monitoring measures to compute the percentage of beneficiaries with a SUD diagnosis who used any SUD service in the month. The use of SUD services among this population increased steadily over the four-year period, from 44.1 percent of SUD members in CY 2018 to 49.7 percent in CY 2021. HMA-Burns used CMS Metric #6 as the definition of any SUD service.

Exhibit 13
Results for Interim Evaluation Measure #14
Continuity of Pharmacotherapy for Opioid Use Disorder

Hypothesis:
The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.

Measure Used to Test Hypothesis:
Continuity of Pharmacotherapy for Opioid Use Disorder
Measure Steward: National Quality Forum #3175 [CMS Monitoring Metric #22]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018	196	1,287	15.2%
CY 2019	363	1,842	19.7%
CY 2020	400	2,181	18.3%
CY 2021	287	2,490	11.5%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			-32.1%

Desired Outcome:	Increase
Actual Outcome:	Decrease
Statistical Review:	Chi-Square
Probability:	0.0213
Finding:	Significant

Exhibit 14

Results for Interim Evaluation Measure #15

Percentage of Beneficiaries with a SUD Diagnosis Who Used Any SUD Service Each Month

Hypothesis:

The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.

Measures Used to Test Hypothesis:

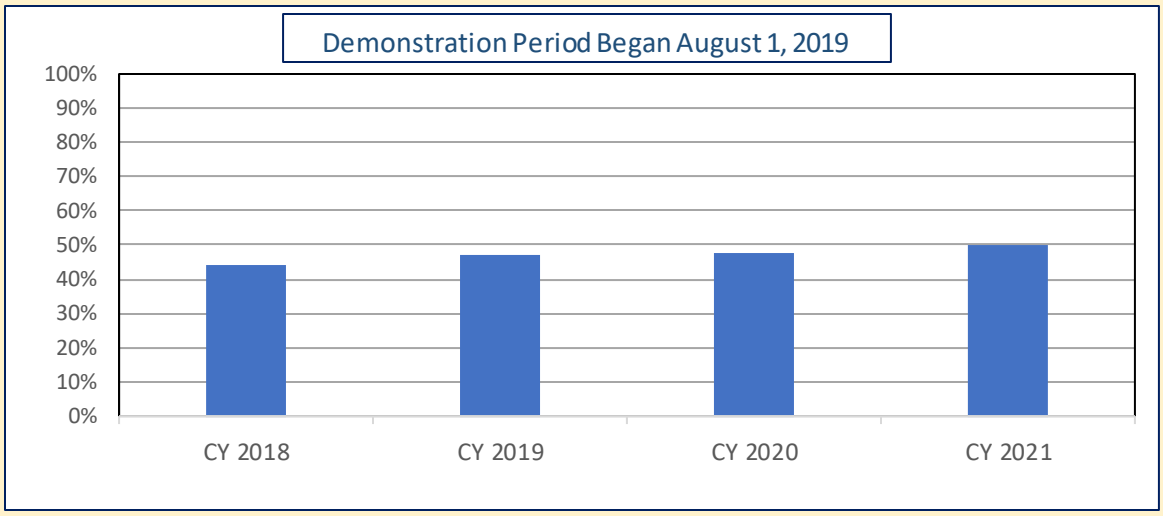
Numerator: Medicaid Beneficiaries with Any SUD Treatment

Measure Steward: CMS [CMS Monitoring Metric #6]

Denominator: Medicaid Beneficiaries SUD Diagnosis (monthly)

Measure Steward: CMS [CMS Monitoring Metric #3]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018 Average	9,515	21,580	44.1%
CY 2019 Average	10,773	22,948	46.9%
CY 2020 Average	10,898	22,972	47.4%
CY 2021 Average	11,131	22,389	49.7%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			11.3%

Desired Outcome:	Increase
Actual Outcome:	Increase
Statistical Review:	T-test
Probability > [t]:	<.0001
Finding:	Significant

Milestone #3: Reductions in Overdose Deaths, Particularly those Due to Opioids

Summary of Measures

Three measures were examined to assess the reductions in overdose deaths. In Exhibit 15 below, it shows that the desired outcome was met in two of the three measures. Tests for statistical significance were not conducted on all three measures and the results were statistically significant for all three measures.

Exhibit 15

Summary of Findings for Measures Mapped to Milestone 3

Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
16	Rate of overdose deaths per 1,000 adult Medicaid beneficiaries	Decrease	Increase	Yes	Chi-square
17	Use of Opioids at High Dosage in Persons Without Cancer	Decrease	Decrease	Yes	Chi-square
18	Concurrent Use of Opioids and Benzodiazepines	Decrease	Decrease	Yes	Chi-square

Individual Measure Results

HMA-Burns examined data files submitted to the DMMA under agreement from the Delaware's Vital Statistics division to map cause of death information for Medicaid beneficiaries who expired. As of this report, data is only available through the end of CY 2020. HMA-Burns computed the overdose death rate among Medicaid beneficiaries using the specifications provided in CMS's Metric #27. The overdose death rate was steady near 9.5 deaths per 1,000 in CYs 2018 and 2019, but it increased to 12.0 deaths per 1,000 in CY 2020 (refer to Exhibit 16).

The use of opioids at high dosage in persons without cancer decreased significantly over the four years examined, from a rate of 9.3 percent in CY 2018 to 7.1 percent in CY 2021 (refer to Exhibit 17).

The rate of concurrent use of opioids and benzodiazepines also decreased significantly, from 11.2 percent in CY 2018 to 8.2 percent in CY 2021 (refer to Exhibit 18).

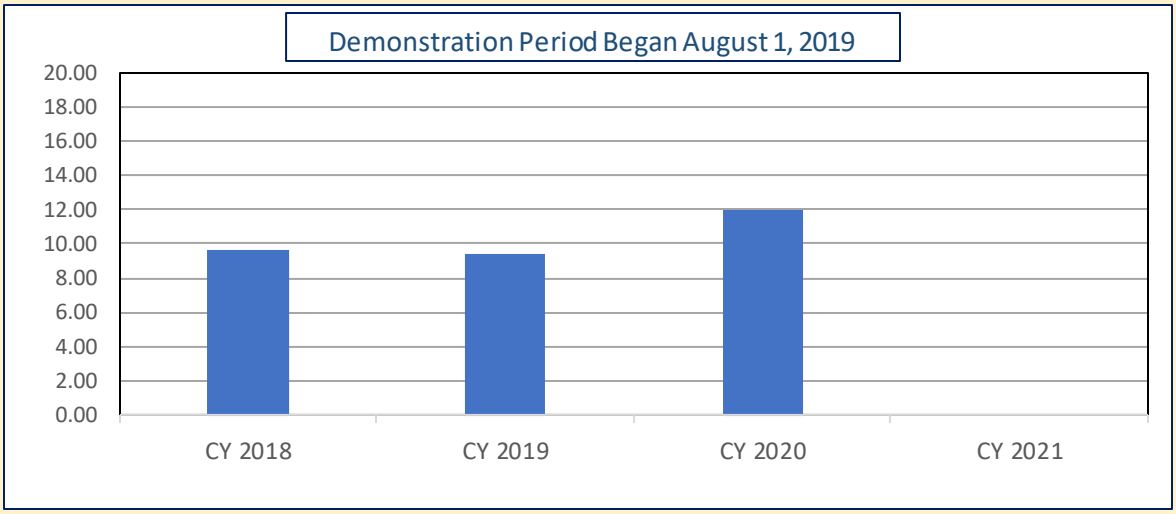
Exhibit 16
Results for Interim Evaluation Measure #16
Overdose Death Rate

Hypothesis:

The demonstration will decrease the rate of overdose deaths due to opioids.

Measure Used to Test Hypothesis:
Overdose death rate among Medicaid beneficiaries
Measure Steward: CMS [CMS Monitoring Metric #27]

Results



Study Period	Numerator	Denominator	Rate
CY 2018	2,873	298,293	9.631
CY 2019	2,817	298,421	9.440
CY 2020	3,531	293,482	12.031
CY 2021	Data not available yet from Vital Statistics		
Change Baseline (CY 2018) to Demonstration Period (CY 2020):			19.9%

Desired Outcome:	Decrease
Actual Outcome:	Increase
Statistical Review:	Chi-square
Probability:	<.0001
Finding:	Significant

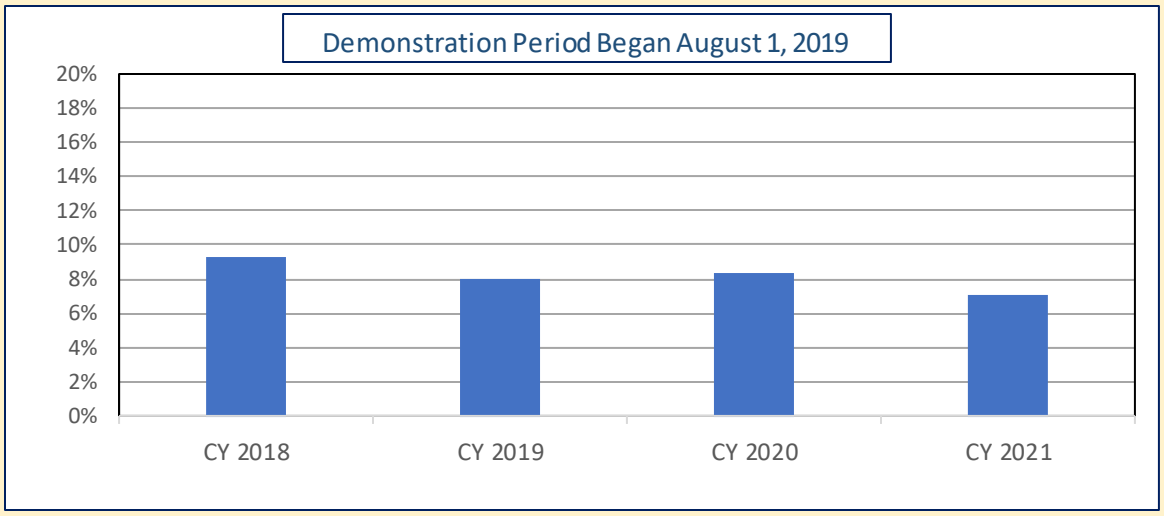
Exhibit 17
Results for Interim Evaluation Measure #17
Use of Opioids at High Dosage in Persons Without Cancer

Hypothesis:

The demonstration will decrease the rate of overdose deaths due to opioids.

Measure Used to Test Hypothesis:
Use of Opioids at High Dosage in Persons Without Cancer
Measure Steward: National Quality Forum #2940 [CMS Monitoring Metric #18]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018	652	6,974	9.3%
CY 2019	401	5,034	8.0%
CY 2020	359	4,286	8.4%
CY 2021	301	4,256	7.1%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			-32.2%

Desired Outcome:	Decrease
Actual Outcome:	Decrease
Statistical Review:	Chi-Square
Probability:	<.0001
Finding:	Significant

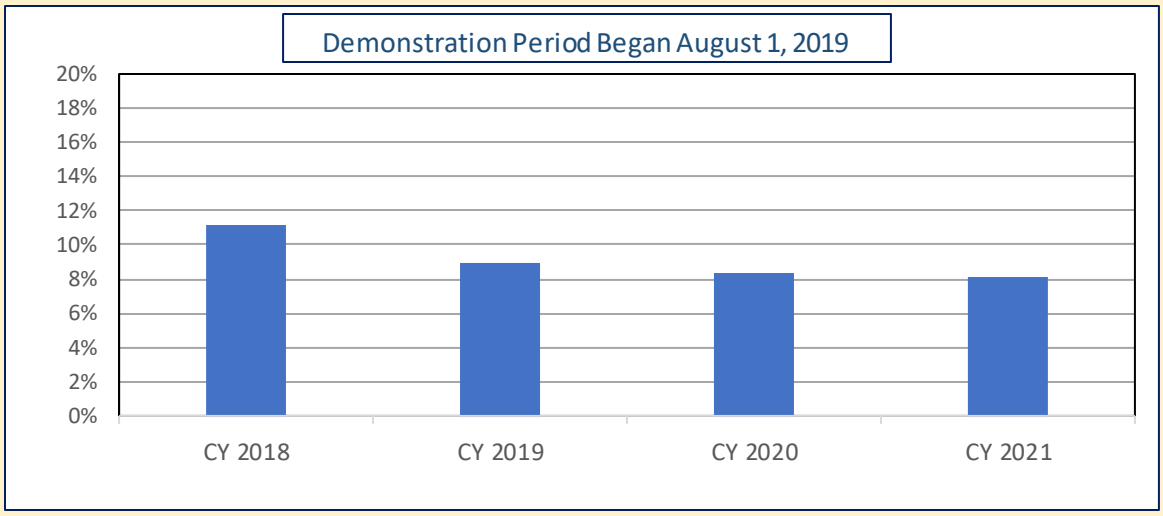
Exhibit 18
Results for Interim Evaluation Measure #18
Concurrent Use of Opioids and Benzodiazepines

Hypothesis:

The demonstration will decrease the rate of overdose deaths due to opioids.

Measure Used to Test Hypothesis:
Concurrent Use of Opioids and Benzodiazepines
Measure Steward: National Quality Forum #3389 [CMS Monitoring Metric #21]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018	971	8,666	11.2%
CY 2019	539	5,999	9.0%
CY 2020	419	5,039	8.3%
CY 2021	402	4,918	8.2%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			-37.1%

Desired Outcome:	Decrease
Actual Outcome:	Decrease
Statistical Review:	Chi-Square
Probability:	<.0001
Finding:	Significant

Milestone #4: Reduced Utilization of Emergency Departments and Inpatient Settings for Treatment Where the Utilization is Preventable or Medically Inappropriate

Summary of Measures

Four measures were examined to assess inpatient hospital utilization, emergency department (ED) utilization, and follow-up from the ED. The desired outcome was met in three of the four measures examined. Tests for statistical significance were conducted on all four measures. Results were statistically significant in two of the four measures.

Exhibit 19
Summary of Findings for Measures Mapped to Milestone 4
Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
19	Rate of emergency department visits for SUD per 1,000 Medicaid beneficiaries, Age 18-64	Decrease	Decrease	Yes	T-test
20	Inpatient Stays for SUD Per 1,000 Medicaid Beneficiaries, Age 18-64	Decrease	Decrease	Yes	T-test
21	Follow-up After Discharge from the Emergency Department for Alcohol or Other Drug Dependence, 7 days	Increase	Decrease	No	Chi-square
22	Follow-up After Discharge from the Emergency Department for Alcohol or Other Drug Dependence, 30 days	Increase	Increase	No	Chi-square

Individual Measure Results

HMA-Burns computed the rate of ED visits for SUD on a per 1,000 Medicaid beneficiary basis using CMS's Metric #23 specification. Because children are a significant portion of the total Medicaid population, the measure was computed for the total population and for members ages 18-64 only. The ED visit rate declined for both measures. Notably, the reduction was greater in the age 18-64 population, from a rate of 12.1 visits per 1,000 in CY 2018 to 10.5 visits per 1,000 in CY 2021. This reduction is a statistically significant improvement (refer to Exhibit 20).

Similar to the ED measure, HMA-Burns also computed the inpatient stays per 1,000 Medicaid beneficiaries for the total population and for members ages 18-64 only. There was a reduction found in inpatient utilization for both measures, but the reduction was more notable among members ages 18-64, from 8.8 per 1,000 in CY 2018 to 7.8 per 1,000 in CY 2021 (refer to Exhibit 21).

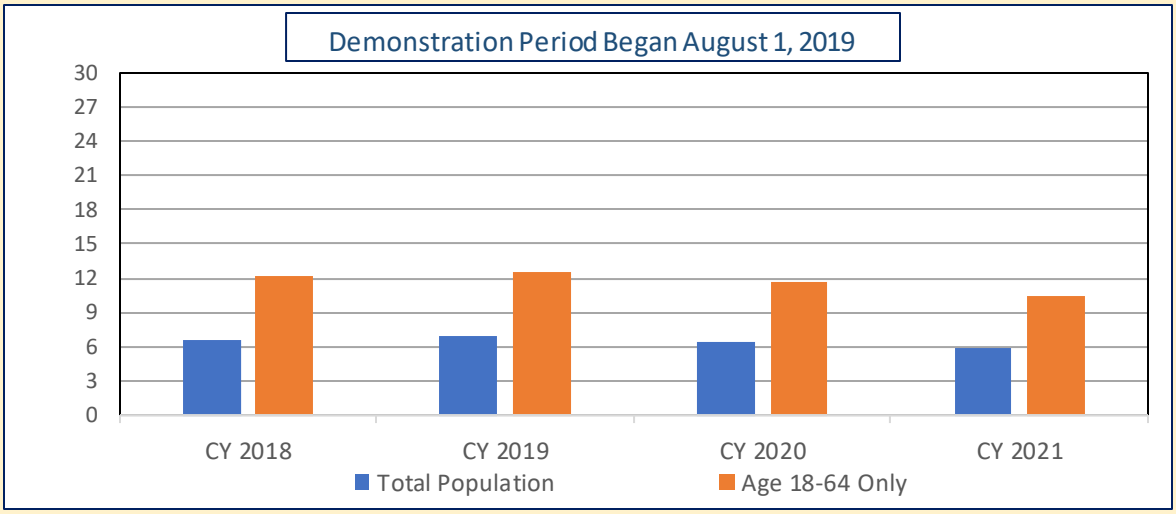
Follow-up after an ED visit for alcohol or other drug dependence was examined at the 7-day and 30-day thresholds. There was a slight decrease in the follow-up rate at seven days, but an improved follow-up rate at 30 days, from 16.5 percent in CY 2018 to 17.3 percent in CY 2021 (refer to Exhibit 22).

Exhibit 20
Results for Interim Evaluation Measure #19
Emergency Department Visits for SUD Per 1,000 Medicaid Beneficiaries

Hypothesis:
The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.

Measure Used to Test Hypothesis:
ED Visits for SUD Per 1,000 Medicaid Beneficiaries
Measure Steward: CMS [CMS Monitoring Metric #23]

Results



	Study Period	Numerator	Denominator	Rate	
Total Demon-stration Population	CY 2018	19,582	2,976,587	6.6	
	CY 2019	20,402	2,979,910	6.8	
	CY 2020	19,886	3,105,517	6.4	
	CY 2021	20,320	3,427,811	5.9	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-11.0%
Age 18-64 Only	CY 2018	18,870	1,558,332	12.1	
	CY 2019	19,612	1,554,083	12.6	
	CY 2020	19,267	1,643,160	11.7	
	CY 2021	19,712	1,884,817	10.5	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-15.8%

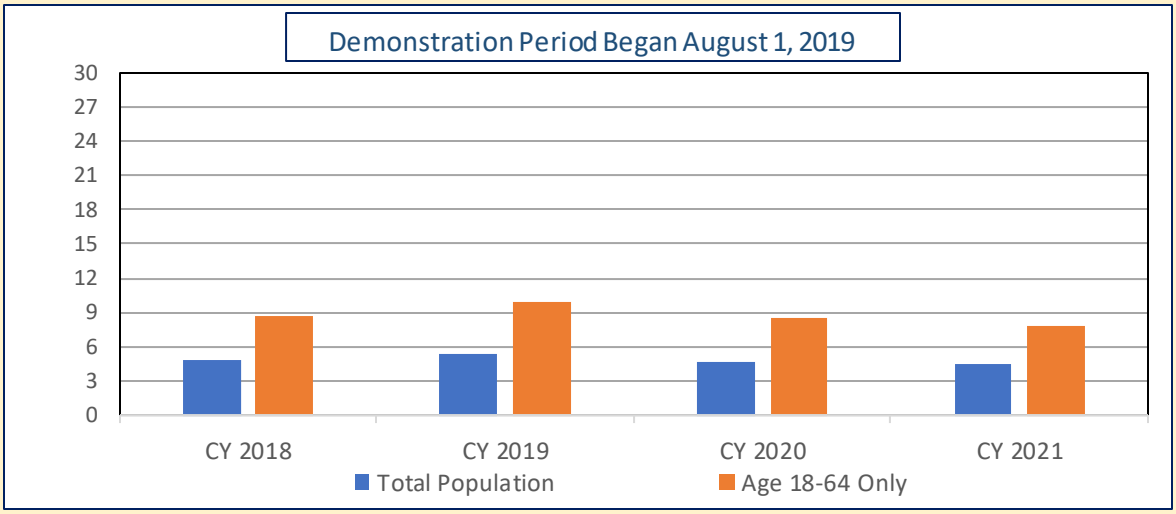
	Total Population	Age 18-64 Only
Desired Outcome:	Decrease	Decrease
Actual Outcome:	Decrease	Decrease
Statistical Review:	T-test	T-test
Probability > [t]:	0.0163	0.0029
Finding:	Significant	Significant

Exhibit 21
Results for Interim Evaluation Measure #20
Inpatient Stays Per 1,000 Medicaid Beneficiaries

Hypothesis:
The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.

Measure Used to Test Hypothesis:
Inpatient Stays Per 1,000 Medicaid Beneficiaries
Measure Steward: CMS [CMS Monitoring Metric #24]

Results



	Study Period	Numerator	Denominator	Rate	
Total Demonstration Population	CY 2018	14,130	2,976,587	4.7	
	CY 2019	15,956	2,979,910	5.4	
	CY 2020	14,607	3,105,517	4.7	
	CY 2021	15,376	3,427,811	4.5	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-5.8%
Age 18-64 Only	CY 2018	13,639	1,558,332	8.8	
	CY 2019	15,270	1,554,083	9.8	
	CY 2020	14,014	1,643,160	8.5	
	CY 2021	14,721	1,884,817	7.8	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-12.1%

	Total Population	Age 18-64 Only
Desired Outcome:	Decrease	Decrease
Actual Outcome:	Decrease	Decrease
Statistical Review:	T-test	T-test
Probability > [t]:	0.1893	0.0144
Finding:	Not Significant	Significant

Exhibit 22

Results for Interim Evaluation Measures #21 and #22

Follow-up After Emergency Department Visit for Alcohol or Other Drug Dependence

Hypothesis:

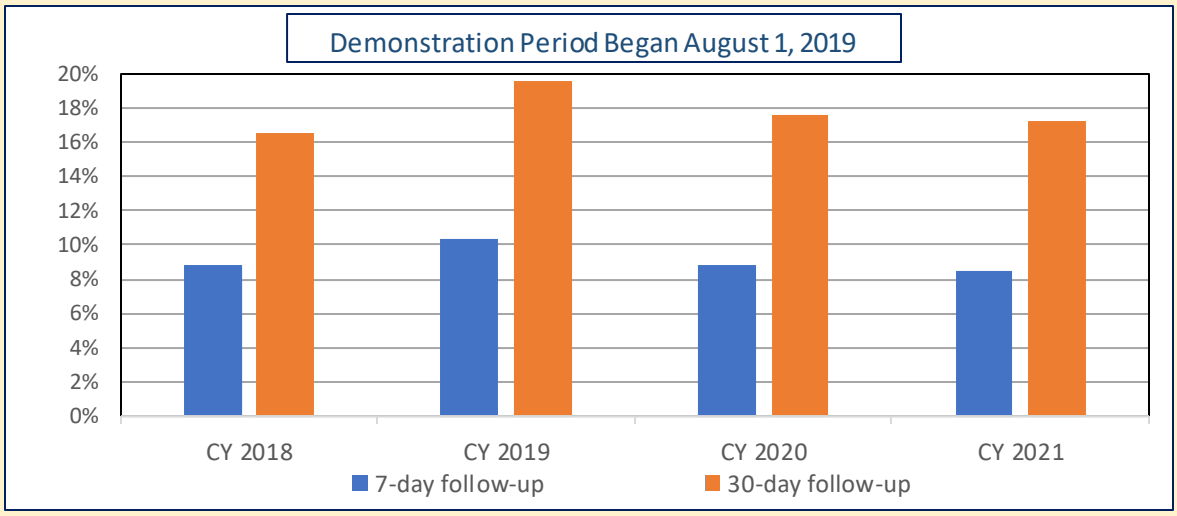
The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.

Measure Used to Test Hypothesis:

Follow-up After ED Visit for Alcohol or Other Drug Dependence

Measure Steward: NCQA, National Quality Forum #3488 [CMS Monitoring Metric #17(1)]

Results for the Demonstration Population



	Study Period	Numerator	Denominator	Rate	
7-day follow-up	CY 2018	159	1,813	8.8%	
	CY 2019	203	1,963	10.3%	
	CY 2020	174	1,968	8.8%	
	CY 2021	170	2,011	8.5%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-3.7%
30-day follow-up	CY 2018	299	1,813	16.5%	
	CY 2019	384	1,963	19.6%	
	CY 2020	347	1,968	17.6%	
	CY 2021	347	2,011	17.3%	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				4.4%

	7-day follow-up	30-day follow-up
Desired Outcome:	Increase	Increase
Actual Outcome:	Decrease	Increase
Statistical Review:	Chi-Square	Chi-Square
Probability:	0.7275	0.5294
Finding:	Not Significant	Not Significant

Milestone #5: Fewer Readmissions to the Same or Higher Level of Care Where the Readmission is Preventable or Medically Inappropriate

Summary of Measures

Three measures were examined to assess readmissions and related care coordination and transitions of care of members after a hospital admission for SUD. The desired outcome was met in all three measures. A test for statistical significance was conducted on one of the three measures and the outcome was statistically significant.

Exhibit 23
Summary of Findings for Measures Mapped to Milestone 5
Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
23	Readmissions Among Beneficiaries with SUD	Decrease	Decrease	Yes	Chi-square
24	Proportion of Beneficiaries with SUD Receiving Care Coordination Following Discharge from an Index Hospital Stay	Increase	Increase	N/A	no test run
25	Service Utilization After a Hospital or Residential Treatment Stay for SUD	Increase	Increase	N/A	no test run

Individual Measure Results

HMA-Burns used CMS's Metric #25 to examine the rate of readmissions among beneficiaries with SUD. The readmission rate decreased from 25.4 percent in CY 2018 to 23.9 percent in CY 2021 (refer to Exhibit 24).

HMA-Burns received case management rosters from both of the Medicaid MCOs for the period October 1, 2019 through September 30, 2020. Separately, individuals with an inpatient hospital stay for SUD were identified during this time period. HMA-Burns then matched the individual client with the SUD inpatient stays against the case management rosters to determine the percentage of members enrolled in case management at their MCO after discharge from the inpatient hospital stay. In Exhibit 25, the results are shown for two 6-month time periods. The percentage of members enrolled in case management after a SUD hospital stay is low, but it did improve from six percent of members in the first 6-month study period to eight percent of members in the second 6-month study period.

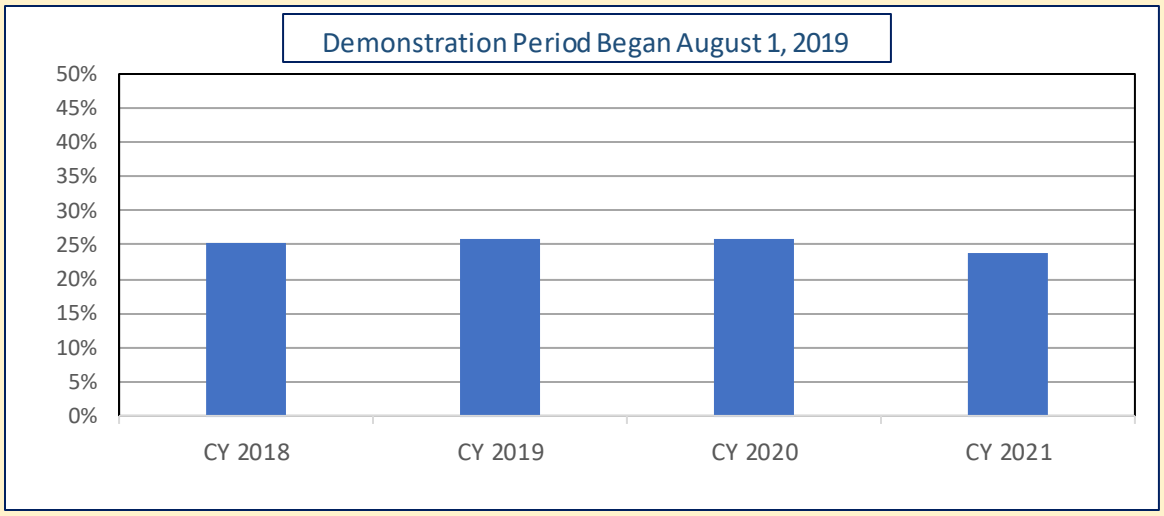
Using the same time periods and the same SUD inpatient hospital stays, HMA-Burns tracked the utilization of a number of services for members in the 12 weeks prior to admission to the hospital for their SUD-related stay and the 12 weeks post-discharge from this hospital stay (refer to Exhibit 26). When comparing utilization pre-admission and post-discharge, the percentage of members with an ED visit went down in their post-discharge from hospital 12-week period compared to their ED use in the pre-admission period. Utilization of intensive outpatient services for SUD and medication assisted treatment increased in the post-discharge hospital period for one of the 6-month study periods as well.

Exhibit 24
Results for Interim Evaluation Measure #23
Readmissions Among Beneficiaries with SUD

Hypothesis:
Among beneficiaries receiving care for SUD, the demonstration will reduce hospital readmissions.

Measure Used to Test Hypothesis:
Readmissions Among Beneficiaries with SUD
Measure Steward: CMS [CMS Monitoring Metric #25]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018	2,748	10,834	25.4%
CY 2019	2,979	11,558	25.8%
CY 2020	2,897	11,225	25.8%
CY 2021	2,610	10,912	23.9%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			-6.0%

Desired Outcome:	Decrease
Actual Outcome:	Decrease
Statistical Review:	Chi-Square
Probability:	0.0134
Finding:	Significant

Exhibit 25
Results for Interim Evaluation Measure #24
Case Management of SUD Clients

Hypothesis:
Among beneficiaries receiving care for SUD, the demonstration will reduce hospital readmissions.

Measure Used to Test Hypothesis:
Proportion of beneficiaries with SUD receiving case management following discharge from an index inpatient stay

Measure Steward: HMA-Burns

Data source: Data reported by Medicaid MCOs to the evaluators of case management rosters for the period October 1, 2019 - September 30, 2020

Results for Enrollment in Case Management

	Both MCOs Combined	AmeriHealth Caritas	Highmark Health Options
Pre-PHE Study Population: Oct 1, 2019 – Mar 31, 2020			
Number of SUD Clients with an Inpatient Index Stay	1,360	639	721
Of these, Percent Enrolled in Case Management	6%	9%	3%
PHE Period: Apr 1, 2020 – Sept 30, 2020			
Number of SUD Clients with an Inpatient Index Stay	747	374	373
Of these, Percent Enrolled in Case Management	8%	14%	2%

Exhibit 26
Results for Interim Evaluation Measure #25
Transitions of Care for SUD Clients

Hypothesis:

Among beneficiaries receiving care for SUD, the demonstration will reduce hospital readmissions.

Measure Used to Test Hypothesis:
Proportion of beneficiaries with SUD receiving timely SUD services following discharge from an index inpatient stay (hospital or residential treatment)

Measure Steward: HMA-Burns

Data source: State encounter data and enrollment files

Results for Service Utilization After a Hospital or Residential Treatment Stay for SUD

	Pre-PHE Study Population: Oct 1, 2019 – Mar 31, 2020		PHE Study Population: April 1, 2020 – Sept 30, 2020	
	Both MCOs Combined		Both MCOs Combined	
	in the 12 weeks before anchor event	in the 12 weeks after anchor event	in the 12 weeks before anchor event	in the 12 weeks after anchor event
Total Denominator Population	**1,360**		**747**	
Percent of Individuals with				
ED Utilization	40%	**23%**	43%	**25%**
Outpatient Hospital, SUD service	53%	49%	60%	52%
Intensive Outpatient	23%	**28%**	29%	17%
Medication Assisted Treatment	30%	**33%**	37%	36%
Outpatient Hospital, NonSUD service	6%	9%	4%	**12%**
Professional Claim other than above	22%	**41%**	13%	**36%**

Percentages highlighted in green indicate an improvement in utilization for the service after discharge from the hospital or residential treatment stay compared to prior being admitted to the hospital or residential treatment stay.
For ED utilization, a lower percentage is preferred.

Milestone #6: Improved Access to Care for Physical Health Conditions Among Beneficiaries

Summary of Measures

One measure was examined to assess improved access to care for physical health conditions among SUD beneficiaries. The desired outcome was not met for this measure. The result was determined to be statistically significant.

Exhibit 27

Summary of Findings for Measures Mapped to Milestone 6

Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
26	Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD	Increase	Decrease	Yes	Chi-square

Individual Measure Results

HMA-Burns used NCQA's AAP HEDIS measure that CMS uses as SUD monitoring metric #32 to measure the access to preventive/ambulatory health services for adult Medicaid beneficiaries with SUD. The rate is high in each year studied, but the rate did go down from 91.9 percent in CY 2018 to 91.1 percent in CY 2021.

Exhibit 28

Results for Interim Evaluation Measure #26

Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD

Hypothesis:

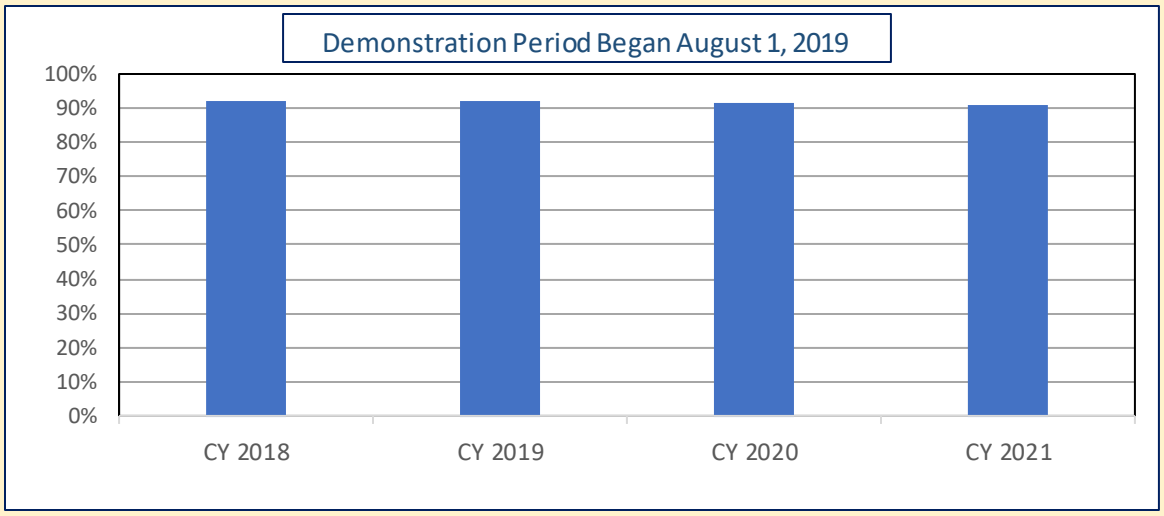
The demonstration will increase the percentage of beneficiaries with SUD who experience care for comorbid conditions.

Measure Used to Test Hypothesis:

Access to Preventive/Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD

Measure Steward: CMS [CMS Monitoring Metric #32]

Results for the Demonstration Population



Study Period	Numerator	Denominator	Rate
CY 2018	16,340	17,784	91.9%
CY 2019	17,344	18,852	92.0%
CY 2020	18,386	20,059	91.7%
CY 2021	19,235	21,122	91.1%
Change Baseline (CY 2018) to Demonstration Period (CY 2021):			-0.9%

Desired Outcome:	Increase
Actual Outcome:	Decrease
Statistical Review:	Chi-Square
Probability:	0.0042
Finding:	Significant

Cost-Related Measures in the Evaluation Design Plan

Summary of Measures

HMA-Burns also included three cost-related measures in the Evaluation Design Plan. So far in the demonstration, the desired outcome has been met for all three measures. A test for statistical significance was conducted on all three measures. The desired outcomes were found to be statistically significant in two of the three measures.

Exhibit 29

Summary of Findings for Other Measures Not Mapped to a Specific Milestone

Results Shown Below are for the Total Demonstration Population

	Measure Examined	Desired Outcome	Actual Outcome	Statistically Significant?	Statistical Test
27	Per member per month expenditures for all services among the SUD population	Stable or Increase	Stable	No	T-test
28	Per member per month expenditures for SUD services among the SUD population	Increase	Increase	Yes	T-test
29	Per member per month expenditures for non-SUD services among the SUD population	Decrease	Decrease	Yes	T-test

Individual Measure Results

All three of the cost measures appear in Exhibit 30 on the next page. HMA-Burns identified the individuals in the study using CMS monitoring metric #4 for the years CY 2018 through CY 2021. Total expenditures for services were accumulated for each member. The expenditures were then segregated between SUD services (using the definition for SUD services from CMS monitoring metric #28) and non-SUD services (all other services not defined as SUD services).

The per member per month expenditures for all services among SUD beneficiaries has remained steady, from $1,534 in CY 2018 to $1,538 in CY 2021. But the mix of expenditures has changed. The expenditures for SUD services per member per month has increased 24.8 percent, from $530 in CY 2018 to $705 in CY 2021. But the expenditures for non-SUD services per member per month has decreased 20.6 percent, from $1,005 in CY 2018 to $833 in CY 2021.

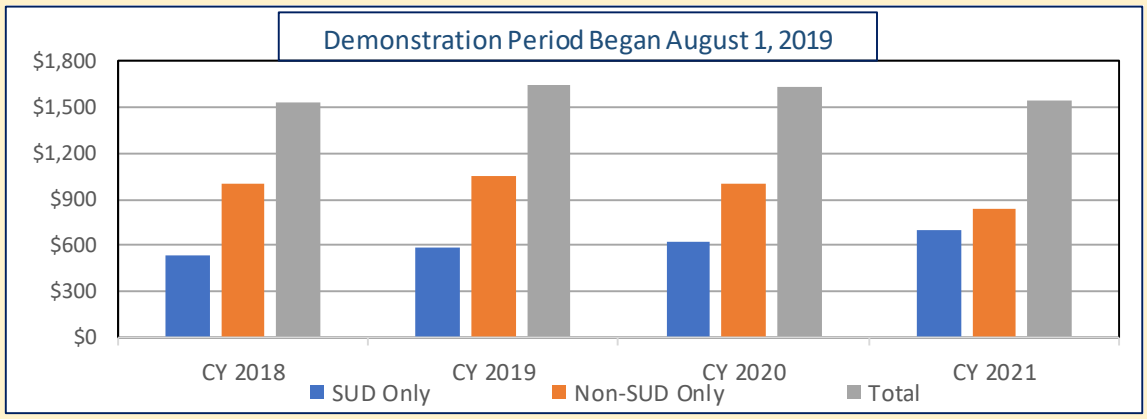
Exhibit 30
Results for Interim Evaluation Measures #27 through #29
Per Member Per Month Expenditures Among the SUD Population

Hypotheses:
1. The demonstration will increase/maintain per beneficiary per month total costs for SUD
2. The demonstration will decrease/maintain per beneficiary per month total costs for non-SUD
3. The demonstration will decrease/maintain per beneficiary per month total costs.

Measures Used to Test Hypothesis:
1. Per Member Per Month SUD Service Spending for Beneficiaries with SUD
2. Per Member Per Month non-SUD Service Spending for Beneficiaries with SUD
3. Per Member Per Month Total Spending for Beneficiaries with SUD

Measure Steward: HMA-Burns (numerator) and CMS (denominator)
Numerators computed from payments summed from Medicaid claims and encounters
Denominator for each month uses results from CMS Monitoring Metric #4

Results for the Demonstration Population



	Study Period	Numerator	Denominator	PMPM	
SUD Services Only	CY 2018	$142,133,543	268,186	$529.98	
	CY 2019	$167,743,497	283,950	$590.75	
	CY 2020	$179,158,715	284,912	$628.82	
	CY 2021	$195,175,562	276,824	$705.05	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				24.8%
Non-SUD Services Only	CY 2018	$269,429,055	268,186	$1,004.64	
	CY 2019	$300,515,232	283,950	$1,058.34	
	CY 2020	$286,926,905	284,912	$1,007.07	
	CY 2021	$230,559,025	276,824	$832.87	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				-20.6%
Total	CY 2018	$411,562,598	268,186	$1,534.62	
	CY 2019	$468,258,729	283,950	$1,649.09	
	CY 2020	$466,085,620	284,912	$1,635.89	
	CY 2021	$425,734,587	276,824	$1,537.93	
	Change Baseline (CY 2018) to Demonstration Period (CY 2021):				0.2%

	SUD Only	Non-SUD Only	Total
Desired Outcome:	Increase/Steady	Decrease/Steady	Decrease/Steady
Actual Outcome:	Increase	Decrease	Steady
Statistical Review:	T-test	T-test	T-test
Probability > [t]:	<.0001	0.0005	0.9248
Finding:	Significant	Significant	Not Significant

SECTION G: Conclusions

Assessment of the Effectiveness of the Demonstration

When considering the driver diagram shown in the Evaluation Design Plan, Delaware did not meet the specific aim identified outright but did see positive impacts due to the demonstration. The section below summarizes the trends related to each of the CMS milestones.

1. **Increased rates of identification, initiation, and engagement in treatment.** Delaware did not see an increase in the initiation or engagement in treatment during the initial years of the demonstration when compared to the pre-demonstration period. There has been a significant ramp up in the use of the state's Prescription Drug Monitoring Program, both in number of clinicians using it and the number of inquiries.
2. **Increased adherence to and retention in treatment**. The percentage of beneficiaries with a SUD diagnosis who used SUD services each month increased 11.3 percent during the initial years of the demonstration (CY 2019, CY 2020, and CY 2021). But the continuity of pharmacotherapy for OUD decreased during this time period.
3. **Reduction in overdose deaths, particularly those due to opioids.** While overdose deaths did increase in CY 2020, there were positive trends observed in the use of opioids at high dosage in persons without cancer (drop from 9.3% in CY 2018 to 7.1% in CY 2021) and the rate of concurrent use of opioids and benzodiazepines (drop from 11.2% in CY 2018 to 8.2% in CY 2021).
4. **Reduced utilization of emergency department and inpatient hospital settings**. The rate of ED visits for SUD on a per 1,000 Medicaid beneficiary basis for the total population and for members ages 18-64 both declined. Notably, the reduction was greater in the age 18-64 population, from a rate of 12.1 visits per 1,000 in CY 2018 to 10.5 visits per 1,000 in CY 2021.

   Similar to the ED measure, inpatient stays per 1,000 Medicaid beneficiaries for the total population and for members ages 18-64 both declined, but the reduction was more notable among members ages 18-64, from 8.8 per 1,000 in CY 2018 to 7.8 per 1,000 in CY 2021.

   When assessing trends in follow-up from the ED for a visit related to alcohol or other drug dependence, the follow-up rate decreased during the demonstration at the 7-day mark but increased at the 30-day mark.
5. **Fewer readmissions to the same or higher level of care**. The rate of readmissions among beneficiaries with SUD decreased from 25.4 percent in CY 2018 to 23.9 percent in CY 2021.

   When comparing utilization pre-admission and post-discharge from a hospital SUD-related stay, the percentage of members with an ED visit went down in the 12 weeks after they were discharged compared to their ED use in the 12-week period prior to admission. Utilization of intensive outpatient services for SUD and medication assisted treatment increased in the post-discharge hospital period for one of the 6-month study periods as well.
6. **Improved access to care for physical health conditions among beneficiaries.** For individuals with an SUD diagnosis, access to preventive or ambulatory care decreased between the pre-demonstration period and the initial years of the demonstration.

7. **Reduce the cost of the SUD population in the demonstration period**. The per member per month expenditures for all services among SUD beneficiaries has remained steady, from $1,534 in CY 2018 to $1,538 in CY 2021. But the mix of expenditures has changed. The expenditures for SUD services per member per month has increased 24.8 percent, from $530 in CY 2018 to $705 in CY 2021. But the expenditures for non-SUD services per member per month has decreased 20.6 percent, from $1,005 in CY 2018 to $833 in CY 2021.

The PHE likely had a confounding effect in enabling Delaware to fully meet these aims during the demonstration period.

When considering the CMS Milestones, Delaware saw success in each milestone with the exception of Milestone 6, Improved Access to Care for Physical Health Conditions Among Beneficiaries. Exhibit 31, which appears on the next page, summarizes the results of each of the measures by CMS milestone. Among 29 measures reviewed, there were 15 where the desired outcome was met. Of these, eight measures had an outcome that was statistically significant in the desired direction.

The DMMA was also successful in large part in the activities it set out to do in its SUD Implementation Plan. Among the eight activities identified, five were completed in full and the remainder are in progress.

Exhibit 31
Summary of Measures Examined by CMS Milestone

CMS Milestone		Total Measures	Measures with Results Trending in the Intended Direction	Measures with Results Trending in the Wrong Direction	Total Measures Where Tests Were Run for Statistical Significance	Of these, the Total Where Trend in Intended Direction and Statistically Significant	Of these, the Total Where Trends in Wrong Direction and Statistically Significant	Of these, the Total Where There Was No Statistically Significant Change
ALL MEASURES		**29**	**15**	**14**	**22**	**8**	**11**	**3**
1	Increased rates of identification, initiation, and engagement in treatment	13	3	10	8	0	8	0
2	Increased adherence to and retention in treatment	2	1	1	2	1	1	0
3	Reductions in overdose deaths, particularly those due to opioids	3	2	1	3	2	1	0
4	Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services	4	3	1	4	2	0	2
5	Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate	3	3	0	1	1	0	0
6	Improved access to care for physical health conditions among beneficiaries	1	0	1	1	0	1	0
	Cost-related measures not tied to a specfic milestone	3	3	0	3	2	0	1

Assessment of Opportunities for Improvement

Delaware saw progress towards its aim to expand SUD-specific services to its Medicaid population through the initial phase of the SUD demonstration period. This occurred through the expansion of coverage for short-term stays in residential and hospital inpatient treatment settings that qualify as institutions for mental disease (IMDs), new services added across the ASAM continuum, and a concentrated effort to increase access to services that had previously been covered. Despite these notable actions, there remain opportunities for continued improvement. The HMA-Burns evaluation team has identified the opportunities below for the DMMA to continue to build upon the strong foundation established during the initial SUD demonstration period.

1. The DMMA is encouraged to develop a mechanism for periodic review (e.g. annual or every two years) of the method used by high-volume SUD providers to determine how they assess patient need for SUD services. This may be a shared responsibility between the State agencies, DMMA and DSAMH, and/or a shared responsibility between the DHSS and its contracted MCOs.
2. The DMMA is encouraged to facilitate an educational session with the providers and the MCOs on the application of the tools commonly used to assess patient need for substance use treatment and how these tools align with ASAM. Additional focus of training could be targeted on the application of state Senate Bill 109 which relates to authorization of residential treatment days.
3. The DMMA should outreach to the existing provider base about its capacity and interest to be licensed at each Delaware ASAM level, including steps that could be taken to increase provider participation in Medicaid such as a value-based payment model. Specific areas of need to expand the provider base include services to adolescents and pregnant women and their children.
4. The DMMA should also outreach to existing providers and potential other entities about options to build a supportive housing network of providers statewide. In interviews conducted for the Mid-Point Assessment, both providers and members mentioned the need for supportive housing options for those receiving medication assisted treatment.
5. The DMMA should encourage or require its MCOs to implement a SUD-specific quality improvement program that focuses on one or more of the SUD-related measures, such as follow-up visits from the ED or the rate of initiation and engagement in treatment.
6. The DMMA should revise MCO reporting to collect SUD appeals and grievances to comply with the requirement to report this data in the waiver monitoring report to CMS.
7. The DMMA should consider both incentives and penalties for providers who do not participate with the MCOs in transitions of members across ASAM levels of care.
8. The DMMA should add accountability standards in its MCO contracts to ensure a higher level of documented transitions of its members across ASAM levels of care.

SECTION H: Interpretations, Policy Implications, and Interactions with Other State Initiatives

Policy Implications

Understandably, the public health emergency required states to amend existing policies and procedures in order to ensure that services were continually rendered when needed to Medicaid beneficiaries. As the PHE unwinds, many of these policies will be rescinded. It will be important for the DMMA to monitor the effects of PHE-related policy decisions on access to care for its beneficiaries with SUD.

The DMMA issued a Request for Proposals in December 2021 and announced notices of award in July 2022. The effective date of the new contract is January 1, 2023. The notice was to award to the two incumbent MCOs as well as a new third MCO. In addition to the change in the number of MCOs, the new model contract has components that have been added or strengthened from the current contract, most notably related to care coordination and case management and the requirement by the MCOs to develop value-based purchasing agreements with providers. It will be important for the DMMA to assess how these new contract requirements—among others—has an impact on improved access to SUD care and health outcomes for beneficiaries with SUD.

Interactions with Other State Initiatives

During the initial SUD demonstration period, the DMMA undertook other initiatives that had a direct impact on the demonstration. As it continues in its demonstration renewal, the DMMA will be mindful of these initiatives as well as new initiatives as they relate to the provisions of SUD services.

1. DMMA was awarded a SUPPORT Act planning grant to assess and expand capacity to treat substance use disorder (SUD) in Medicaid. One direct result of the work under this grant was engagement with providers on the costs to deliver each SUD service. The rates paid for many SUD services will increase significantly starting January 1, 2023. This is the first rate increase in over six years.
2. DMMA developed a Medicaid accountable care organization (ACO) program for the purposes of improving health outcomes while reducing costs through value based purchasing arrangements. Four health care provider groups were authorized as ACOs in September 2020. The ACOs are authorized to contract directly with each MCO under contract with the DMMA, provided that the ACO has participation from at least 5,000 Medicaid enrollees.

State of Delaware Interpretations from the Evaluation Findings

Over the past several years, DMMA has worked to create coverage policies that ensure access to SUD treatment. Even prior to the SUPPORT Act requirements, we covered all forms of medications for opioid use disorder (MOUD) with no prior authorization and had naloxone available with no copay. Delaware's persistently high overdose rates, however, indicated that we needed to do more.

Through our SUD 1115 demonstration and the SUPPORT Act planning grant, and through partnerships with DSAMH, our MCOs, and other stakeholders, DMMA has taken additional steps to improve the continuum of care available. Under the planning grant, we conducted a rate study that included SUD

provider input and developed proposed rates for SUD services. As we continue to work with providers on the implementation of those rates, we will assess readiness and willingness of providers to expand to other levels of care. We have opportunities to provide technical assistance under both SUPPORT Act and State Opioid Response grant (SOR) funding on topics such as the ASAM criteria, Senate Bill 109, office-based opioid treatment (OBOT) implementation, and early intervention. Residential treatment services, including those that target specific populations such as adolescents, will require partnering with DSAMH and the Department of Services for Children & their Families (DSCYF). As part of our SUPPORT Act demonstration project, we have created a provider directory with information about availability across levels of care, including opioid treatment programs (OTP) and OBOTs. All of these efforts will help DMMA and our partners to monitor our existing system and evaluate our efforts to expand services such as early intervention and residential treatment.

Specific DMMA comments to address HMA-Burns recommendations by CMS Milestone are below.

Regarding ***access to critical levels of care for SUD treatment***, Delaware's persistently high overdose death rate has catalyzed cross-agency efforts to improve access to care.

- DMMA's contracts with the MCOs require that the plans use ASAM criteria for utilization management, and DMMA expects that the plans have the same expectations of providers. Through a focus study or EQRO compliance review we can assess how well the MCOs are monitoring the use of ASAM. We also plan to collaborate with DSAMH on credentialing and licensing requirements for providers.
- Under the SOR grant, DSAMH is providing funding and technical assistance to a large number of providers to begin universal screening for SUD. We plan to partner with DSAMH to engage this cohort and help us to better understand what their barriers are to providing early intervention.

Regarding the ***use of evidence-based SUD-specific patient placement criteria***, both the SOR grant to DSAMH and the SUPPORT demonstration project have resources reserved for technical assistance. Education on ASAM criteria and the application of Senate Bill 109 can be topics of some of that assistance. Between the DMMA and DSAMH divisions, we will be able to educate the majority of providers in the state.

Regarding the ***use of nationally recognized SUD-specific program standards for residential treatment***, residential treatment services were highlighted in our SUPPORT act planning grant rate study as an area of concern. As we work with DSAMH on potential rate changes, we can collaboratively review the state standards for credentialing and licensing.

Regarding ***sufficient provider capacity at critical levels of care***, DMMA is engaged in a number of activities to grow the base of SUD providers:

- The development of a provider directory that includes ASAM levels was a deliverable from the SUPPORT demonstration project.
- As part of the SUPPORT planning grant rate study, DMMA engaged with providers on the costs to deliver SUD services and solicited feedback both informally (in meetings) and formally (through a public notice) prior to finalizing the rates that will become effective January 1, 2023.
- Housing insecurity is a concern statewide and at various levels of government. DMMA has engaged with CSH, an organization with supportive housing expertise, to assess the

opportunities for Medicaid funding for housing supports in Delaware. We are engaged in efforts both internally and externally to increase supportive housing for a variety of populations.

- The DSCYF is our partner in delivering Medicaid-funded SUD services to adolescents. DMMA will continue to work with DSCYF to ensure adequate treatment availability for adolescents who need SUD care, including residential services.
- DMMA has a variety of efforts to encourage value-based payment (VBP), such as bundled services. The new MCO contracts effective in January 2023 have specific provisions related to expanding the use of VPB in provider reimbursement.

Regarding the ***implementation of comprehensive treatment and prevention strategies to address opioid abuse***, DMMA is already developing a SUD- and pregnancy-related PIP to encourage low barrier MOUD for those who need it. We are currently in the development phase, but plan to ask the MCOs to design and implement interventions that lead to increased engagement with MOUD in pregnancy. Additionally, expanding the availability of OBOT services was a major focus of our SUPPORT demonstration project. Activities included supporting providers in developing functioning OBOT models via technical assistance, enhanced reimbursement, and strengthening referral networks.

Regarding ***improved care coordination and transition between levels of care***,

- DMMA revised the reporting specifications for the MCOs in the January 2023 contract to include in the next version of the MCO reporting manual.
- DMMA has worked with the MCOs to increase their capacity for internal chart audits, with the expectation of raising care coordination standards and creating uniformity in the care received by complex members. In future EQRO reviews, we plan to examine a sample of care coordination records where there is a known SUD diagnosis.

SECTION I: Lessons Learned and Recommendations

Lessons Learned

As it worked to implement many new initiatives in the initial years of its demonstration while navigating the public health emergency, Delaware's DMMA learned some lessons to be mindful of moving forward.

1. Data systems can often inhibit the effective implementation of new program initiatives. Gaining a thorough understanding of systems changes is important when standing up new programs as well as an appreciation for the time commitment involved. This held true with the rate changes that will be implemented for SUD services in January 2023.
2. Enhancing the linkages between state agencies for citizens who are eligible for multiple programs is important for both continuity of care and for health outcomes. The DMMA has added language to its managed care contracts to ensure proper linkages for individuals that are eligible for Medicaid and other publicly-funded programs in the state as well as for the justice-involved population.

Recommendations

Delaware's DMMA offers the following recommendations to other states from what was learned from the evaluation of our own demonstration.

1. Delaware recommends to other states to convene its providers and managed care entities on a regular basis to communicate what is happening on the ground, particularly at the introduction of a new service, expansion of an existing service, or fundamental change in billing or reimbursement of existing services. In addition to providing a forum for multiple viewpoints to successfully implement demonstration activities, these meetings foster collaboration between stakeholders and offer the state the ability to share its vision with all parties.
2. Delaware recommends to other states that feedback be given to MCOs on a regular basis with a quick turnaround on any reports submitted by the MCOs to the state. DMMA offers feedback to its MCOs after the submission of quarterly reports to DMMA both to assess the integrity of the data submitted on reports as well as to discuss the interpretation of the findings reported.
3. The coordination and communication among entities that deliver supports to vulnerable populations is essential to ensure that each beneficiary receives the supports that they need. This coordination includes written protocols on the scope of each entity's area of responsibility, the procedures that will be followed by each entity, and the protocols for the seamless transfer of information about beneficiaries, when applicable.

APPENDIX: Approved Evaluation Design Plan

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

April 2, 2021

Stephen M. Groff
Medicaid Director
Division of Medicaid and Medical Assistance
Department of Health and Social Services
1901 N. Dupont Highway
New Castle, DE 19720

Dear Mr. Groff:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Substance Use Disorder (SUD) / the Diamond State Health Plan (DSHP) Evaluation Design, which is required by the Special Terms and Conditions (STC) #88 of Delaware's section 1115 demonstration entitled, "Delaware Diamond State Health Plan 1115 Demonstration" (Project Number 11-W-00036/4), and effective through December 31, 2023. CMS has determined that the evaluation design, which was submitted on May 29, 2020 and revised on February 25, 2021, meets the requirements set forth in the STCs and our evaluation design guidance, and therefore, approves the state's SUD / DSHP evaluation design.

CMS added the approved evaluation design to the demonstration's Special Terms and Conditions (STC) as Attachment H. A copy of the STCs, which includes the new attachment are enclosed with this letter. 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 as a standalone document, separate from the STCs, on Medicaid.gov.

Please note that an interim evaluation report, consistent with the approved evaluation design, is due to CMS one year prior to the expiration of the demonstration, or at the time of the extension application, if the state chooses to extend the demonstration. Likewise, a summative evaluation report, consistent with this approved design, is due to CMS within 18 months of the end of the demonstration period. In accordance with 42 CFR 431.428 and the STCs, we look forward to receiving updates on evaluation activities in the demonstration monitoring reports.

We appreciate our continued partnership with Delaware on the Diamond State Health Plan section 1115 demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly -S
Digitally signed by Danielle Daly -S
Date: 2021.04.02 14:59:28 -04'00'

Danielle Daly
Director
Division of Demonstration Monitoring and Evaluation

Andrea J. Casart -S
Digitally signed by Andrea J. Casart -S
Date: 2021.04.05 06:09:51 -04'00'

Andrea J. Casart
Director
Division of Eligibility and Coverage Demonstrations

cc: Talbatha Myatt, State Monitoring Lead, CMS Medicaid and CHIP Operations Group

EVALUATION DESIGN PLAN FOR DELAWARE'S 1115 SUBSTANCE USE DISORDER (SUD) WAIVER

FINAL DRAFT
FEBRUARY 25, 2021

BURNS & ASSOCIATES, INC.
A DIVISION OF HEALTH MANAGEMENT ASSOCIATES

Evaluation Team Members:

Mark Podrazik, Principal Investigator
Ryan Sandhaus
Debbie Saxe
Shawn Stack
Kara Suter

TABLE OF CONTENTS

LISTING OF EXHIBITS

Abbreviations List

Abbreviation	Meaning
ASAM	American Society for Addiction Medicine
CMS	Centers for Medicare and Medicaid Services
B&A	Burns & Associates, Inc.
CY	Calendar Year
DHSS	Delaware Department of Health and Social Services
DMES	Delaware Medicaid Enterprise System
DMMA	Division of Medicaid and Medical Assistance
DR	Desk Review
DS	Descriptive Statistics
DSAMH	Division of Substance Abuse and Mental Health
DSHP	Diamond State Health Plan
DSHP-Plus	Diamond State Health Plan Plus
DXC	DXC Technologies
EDW	Enterprise Data Warehouse
E&M	Evaluation & Management
ED	Emergency Department
EQRO	External Quality Review Organization
FFS	Fee-For-Service
FG	Focus Groups

Abbreviation	Meaning
FI	Facilitated Interviews
ITS	Single Segment Interrupted Time Series
LTSS	Long-Term Services and Supports
MCO	Managed Care Organization
MLTSS	Managed Long-Term Services and Supports
NCQA	National Committee for Quality Assurance
NQF	National Quality Forum
OR	Onsite Reviews
OUD	Opioid Use Disorder
PDMP	Prescription Drug Monitoring Program
PROMISE	Promoting Optimal Mental Health for Individuals through Supports and Empowerment
RCT	Randomized Control Trials
SFY	State Fiscal Year
SPMI	Severe and Persistent Mental Illness
ST	Statistical Tests
START	Substance Use Treatment and Recovery Transformation
STC	Special Terms and Conditions
SUD	Substance Use Disorder

SECTION I: GENERAL BACKGROUND INFORMATION

I.A Introduction

Like many states, the opioid epidemic has led Delaware's policymakers and providers to rethink the way in which it addresses substance use disorder (SUD) treatment more broadly. According to its 2019 Annual Report, the Division of Forensic Science reported a total of 438 deaths from drug and alcohol intoxication, up approximately 10 percent from the total of 400 in 2018.[1]

On June 29, 2018, the state submitted an amendment to its waiver demonstration intended to expand SUD services by including expenditure authority for services in institutions for mental diseases (IMD) as well as maintaining existing non-SUD services for beneficiaries. Delaware received approval of its request on July 31, 2019 with an effective period from August l, 2019 through December 31, 2023. As of April 2020, Delaware is one of 28 states to have received approval for SUD demonstrations under waiver.[2]

Exhibit I.1 provides a brief background on the waiver demonstration.

Exhibit I.1
Delaware's Current Section 1115 Waiver

The Delaware Diamond State Health Plan demonstration was initially approved in 1995 and implemented on January l, 1996. The demonstration mandatorily enrolls most Medicaid beneficiaries into managed care organizations (MCOs) to create efficiencies in the Medicaid program and enable the expansion of coverage to certain individuals who would otherwise not be eligible for Medicaid. Some population and service categories remain fee for service (FFS). In 2014, the demonstration was amended to expand eligibility for individuals with incomes up to and including 133 percent of the Federal Poverty Level (FPL) and to provide long- term care services and support (LTSS) to eligible individuals through a mandated managed care delivery system, entitled Diamond State Health Plan Plus (DSHP-Plus) program. In 2015, the state implemented a program called Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE), which enhanced behavioral health services and supports for recipients with severe and persistent mental illness (SPMI).

Under this demonstration, one of the 12 goals is to increase enrollee access and utilization of appropriate SUD treatment services by decreasing the use of medically inappropriate and avoidable high-cost emergency and hospital services; increase initiation of follow-up SUD treatment after emergency department discharge; and reduce SUD readmission rates. Delaware proposes to test whether it can enhance the effectiveness of the SUD treatment system in Medicaid by maintenance and expansion of SUD residential services as part of a coordinated, full continuum of care resulting in increased access and improved health outcomes for individuals with SUD.[3]

[1] Division of Forensic Science 2019 Annual Report issued May 7, 2020, page 10. https://forensics.delaware.gov/contentFolder/pdfs/2019%20DFS%20Annual%20Report.pdf
[2] Kaiser Family Foundation Issue Brief https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/
[3] Delaware Diamond State Health Plan 1115(a) Demonstration Special Terms and Conditions, accessed at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/de/de-dshp-ca.pdf

Under the broader waiver demonstration goal stated above, as set forth in the Implementation Plan, Delaware is aligning the six goals for the SUD waiver component with the milestones outlined by CMS as follows:[4]

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

In accordance with CMS guidance contained in SMD #17-003, Delaware submitted an Implementation Plan in draft form to CMS on October 30, 2019. The Plan describes the planned activities in the waiver period organized by CMS milestone. In cooperation with CMS, Delaware identified its own milestones in its approved Implementation Plan which include:

1. Access to critical levels of care for opioid use disorder (OUD) and other SUDs;
2. Widespread use of evidence-based, SUD-specific patient placement criteria;
3. Use of nationally recognized, evidence-based, SUD program standards to set residential treatment provider qualifications;
4. Sufficient provider capacity at each level of care, including medication-assisted treatment (MAT);
5. Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and
6. Improved care coordination and transitions between levels of care.

I.B Delaware Context

Unlike other states who are seeking to adopt the use of the American Society for Addiction Medicine (ASAM) levels of care for both assessments, placement and provider criteria of care, Delaware has almost 10 years of experience with organizing its system around these principles. In April 2017, DHSS Secretary Dr. Kara Odom Walker asked Johns Hopkins University to conduct a review of Delaware's addiction treatment system. In July 2018, the Johns Hopkins team issued a 33-page report that proposed four main strategies[5]:

1. Increase the capacity of the treatment system,
2. Engage high-risk populations in treatment,
3. Create incentives for quality care, and
4. Use data to guide reform and monitor progress.

Recent action relates to strategies to address the recommendations generated from the SUD system review conducted by Johns Hopkins in 2018. Both the Section 1003 capacity planning grant and the State's Substance Use Treatment and Recovery Transformation (START) initiative address specific

[4] State Medicaid Director Letter #17-003 Re: Strategies to Address the Opioid Epidemic, November 1, 2017, available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf
[5] https://news.delaware.gov/2018/07/24/14-month-review-johns-hopkins-team-releases-major-recommendations-strengthening-delawares-substance-use-disorder-treatment-system/

recommendations from the system assessment. Delaware's specific context requires consideration when evaluating the effect of the SUD demonstration waiver monitoring with other ongoing federal initiatives.

Exhibit I.2 summarizes the specific actions identified by Delaware. These actions are categorized by CMS SUD monitoring milestone in the State's approved SUD implementation plan.

Exhibit I.2
Summary of Actions by Monitoring Milestone and Special Term and Condition (STC)
(excerpted from the State's Implementation Plan)

MILESTONE AND STC	SUMMARY OF ACTIONS NEEDED
1. Access to Critical Levels of Care for OUD and other SUDs (STC #31(a)(i))	There are no anticipated actions needed by DMMA for fulfillment of this milestone.
2. Use of Evidence-based, SUD-specific Patient Placement Criteria and Patient Placement (STC #31(a)(ii and iii)	In conjunction with Milestone #6, DMMA's EQRO will perform a focus study to assess MCO and provider application of the ASAM criteria in 2021 (for review of 2020 activities.) Expected report release by August 2021.
3. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities and Standards of Care (STC #31(a)(iv)-(vi))	There are no anticipated actions needed by DMMA for fulfillment of this milestone.
4. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD (STC #31(a)(vii))	By December 2020, as described in Delaware's SUPPORT ACT Project Planning Grant, Delaware will: 1.Estimate the number and percentage of OUD and other SUD among Medicaid-beneficiaries, and OUD and other SUD treatment and recovery needs. 2. Complete a workforce assessment to determine SUD provider and service capacity for Medicaid beneficiaries. 3. Conduct a gaps analysis to determine service gaps to treating the OUD and other SUD needs of Medicaid-covered SUD treatment and recover services.
5. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD (STC #31(a)(viii))	There are no anticipated actions needed by DMMA for fulfillment of this milestone.
6. Improved Care Coordination and Transitions between Levels of Care (Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities.) (STC #31(a)(x))	DMMA will assess MCO performance on Care Coordination and Transitions between Levels of Care for individuals with OUD and other SUD.
7. SUD HIT Plan (STC #31(a)(ix))	There are no anticipated actions needed by DMMA for fulfillment of this milestone.

SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Defining Relationships: Aims, Primary Drivers, and Secondary Drivers

Burns & Associates, a division of Health Management Associates (B&A), the State's Independent Evaluator, examined the relationships between the CMS goals and Delaware Medicaid interventions included in the demonstration waiver, the approved Implementation Plan, and other activities already underway in Delaware as part of other federal initiatives and grants. As part of the examination of the relationships between goals and the interventions, B&A constructed a driver diagram to identify the primary and secondary drivers of a principle aims: reduce overdose deaths. The driver diagram is shown in Exhibit II.1 on the next page.

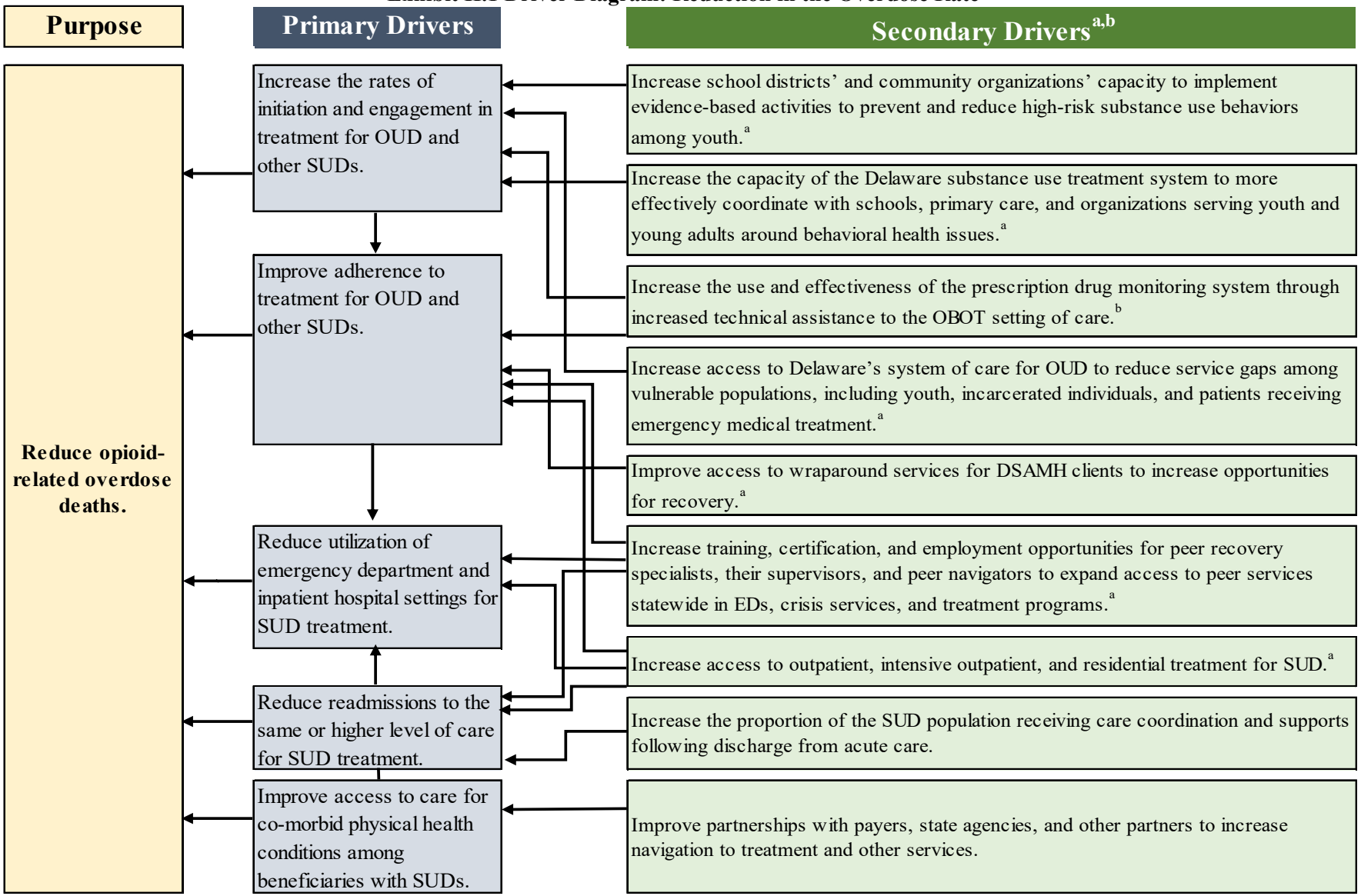
Overdose deaths is an important measurable health outcome of interest and, therefore, is the aim of the driver diagram. CMS's goals represent primary drivers all of which identified as having the potential to contribute to a reduction in overdose deaths. The specific actions described in the concurrent federal initiatives and grants are considered secondary drivers.

The aim and primary drivers were matched with metrics to aid in the assessment of performance and the development of meaningful findings. Where possible, B&A adopted the same metrics used as part of the State's monitoring protocol. These measures, in the post-waiver implementation period, will be used as targets such that performance in the post-waiver period will be considered positive should changes occur in the post- versus pre-waiver period. Use of the state's prescription drug monitoring website (PDMP) was identified as a secondary driver of interest. If more providers use the PDMP, then more beneficiaries would be potentially engaged in treatment.

Reductions or maintenance of per beneficiary costs in the SUD population is also of interest to CMS and the State. B&A plans to follow the three-part approach described in Appendix C of CMS's Technical Guidance to examine the relationships between waiver implementation and spending. The three analyses will attempt to answer whether investments in SUD services, made as part of the waiver, result in demonstrable reductions in non-SUD services spending. Further, the drivers of any non-SUD savings in the post-waiver period will be examined.

A more detailed description of the data, measures and analysis to be used are described in Section III of the Evaluation Design document.

Exhibit II.1 Driver Diagram: Reduction in the Overdose Rate



a Secondary driver is part of federally-required SOR evaluation and not specifically included as part of the scope of the 1115 waiver evaluation.

b Secondary driver is part of federally-required SUD Capacity Planning evaluation and not specifically included as part of the scope of the 1115 waiver evaluation.

II.B Hypotheses and Research Questions

In quantitative research, testing of hypotheses is a commonly-used technique to operationalize a research question. It is a technique to find out if support for a formulated hypothesis is supported by the data.

Five research questions and eleven hypotheses in the evaluation design were developed around the six CMS-stated goals:

1. Increased rates of identification, initiation, and engagement in treatment;
2. Increased adherence to and retention in treatment;
3. Reductions in overdose deaths, particularly those due to opioids;
4. Reduced utilization of emergency departments and inpatient settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services;
5. Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate; and
6. Improved access to care for physical health conditions among beneficiaries.

Hypotheses and Research Questions

Exhibit II.2 on the next page summarizes the five research questions and eleven hypotheses included in the evaluation design plan with a reference to the CMS goal that each hypothesis relates to.

Exhibit II.3
Eleven Hypotheses and Corresponding CMS Goal, by Research Question

CMS Goal	R or H #	Five Research Questions (blue shading) and Eleven Hypotheses
	Q 1	**Does the demonstration increase access to and utilization of SUD treatment services?**
#1	H 1.1	• The demonstration will increase or maintain the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.
#2	H 1.2	• The demonstration will increase or maintain adherence to and retention in treatment for OUD.
#1	H 1.3	• Approved service authorizations improve appropriate utilization of health care services in the post-waiver period.
#4	H 1.4	• The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.
	Q 2	**Do enrollees who are receiving SUD services experience improved health outcomes?**
#6	H 2.1	• The demonstration will increase or maintain the percentage of beneficiaries with SUD who experience care for comorbid conditions.
#5	H 2.2	• Among beneficiaries receiving care for SUD, the demonstration will reduce or maintain readmissions to SUD treatment.
	Q 3	**Are rates of opioid-related overdose deaths impacted by the demonstration?**
#3	H 3.1	• The demonstration will decrease the rate of overdose deaths due to opioids.
	Q 4	**Do activities post-implementation increase use of Delaware's Prescription Drug Monitoring Program?**
#1	H 4.1	• The demonstration will increase or maintain the use of Delaware's PDMP.
	Q 5	**How does the demonstration impact cost?**
All	H 5.1	• The demonstration will decrease or maintain per beneficiary per month costs.
All	H 5.2	• The demonstration will increase or maintain per beneficiary per month costs for SUD services versus non-SUD services.
All	H 5.3	• The demonstration will decrease or maintain per beneficiary costs for SUD-related ED visits and inpatient stays.

SECTION III: METHODOLOGY

III.A Evaluation Design

The evaluation design is a mixed-methods approach, drawing from a range of data sources, measures and analytics to best produce relevant and actionable study findings. B&A tailored the approach for each of the five research questions described in Section II, Evaluation Questions and Hypotheses. The evaluation plan reflects a range of data sources, measures and perspectives. It also defines the most appropriate study population and sub-populations, as well as describes the four analytic methods included in the evaluation design.

The five analytic methods proposed for use across the five hypotheses and eleven research questions include:

1. Descriptive statistics (DS),
2. Statistical tests (ST),
3. Onsite reviews (OR)
4. Desk reviews (DR) and,
5. Facilitated interviews (FI).

Exhibit III.1 on the next page presents a chart displaying which method(s) are used for each hypothesis. It also includes a brief description of the indicated methods as well as the sources of data on which they rely. The five methods are ordered and abbreviated as described above.

Exhibit III.1
Summary of Five Analytic Methods by Hypotheses

		Method					Analytic Method Examples
	Hypothesis Description	DS	ST	OR	DR	FI	
H1.1	The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.	X	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi-square or t-test of significance. ITS completed in Summative Evaluation. **OR**: Care Coordination and Transitions to Care focus studies (2 rounds for each). **FI**: Interviews with Medicaid MCOs. Data sources: claims and enrollment data from state data warehouse, care coordination data from MCOs
H1.2	The demonstration will increase or maintain adherence to and retention in treatment for OUD.	X	X	X	X	X	
H1.3	Approved service authorizations improve appropriate utilization of health care services in the post-waiver period.	X	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests of significance. **OR**: Service Authorizations focus studies (2 rounds). Data sources: claims and enrollment data, authorization records submitted by MCOs (validated by B&A)
H1.4	The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population.	X			X		**DS**: trends tracked separately for subpopulations defined in the SUD Monitoring Protocol. ITS completed in Summative Evaluation. Data sources: claims, reports submitted by MCOs
H2.1	The demonstration will increase the percentage of beneficiaries with SUD who experience care for comorbid conditions.	X	X		X	X	**DS**: trends in frequencies and percentages. **ST**: chi-square or t-test of significance. ITS completed in Summative Evaluation. **FI**: Interviews with Medicaid MCOs. Data sources: claims and enrollment data from state data warehouse
H.2.2	Among beneficiaries receiving care for SUD, the demonstration will reduce readmissions for SUD treatment.	X	X		X		**DS**: trends in frequencies and percentages. **ST**: ITS will be completed in Summative Evaluation. **FI**: chi-square or t-test of significance. Data sources: claims and enrollment data from state data warehouse
H3.1	The demonstration will decrease the rate of overdose death due to opioids.	X	X		X		**ST**: chi square or t-tests of significance comparing target population to baseline. ITS will be completed in Summative Evaluation. Data sources: claims and enrollment data from state data warehouse
H4.1	The demonstration will increase the use of Delaware's PDMP.	X			X		**DS**: trends in frequencies and percentages. Data sources: information from the state's PDMP
H5.1	The demonstration will decrease or maintain per beneficiary per month costs.	X	X		X		**DS**: trend rates stratified by subpopulation identified in the SUD Monitoring Protocol. **ST**: ITS will be completed in the Summative Evaluation. Data sources: claims, member enrollment data.
H5.2	The demonstration will increase or maintain per beneficiary per month costs for SUD services versus non-SUD services.	X	X		X		
H5.3	The demonstration will decrease or maintain per beneficiary costs for SUD-related ED visits and inpatient stays.	X	X		X		

DS = Descriptive Statistics; ST = Statistical Tests; OR = Onsite Reviews; DR = Desk Reviews; FI = Facilitated Interviews

III.B Target and Comparison Populations

Target Population

The target population is any Delaware Medicaid beneficiary with a diagnosis of Substance Use Disorder (SUD) in the study period. B&A will use the approved specification, described in the CMS-approved Monitoring Plan, for identification of beneficiaries with SUD. Having a positive SUD Indicator Flag will serve as an indicator of exposure to the changes in the waiver.

While the key study population is the overall SUD population, a standardized set of sub-populations will be identified and examined. B&A will sub-set the SUD population, at minimum, by common demographic groups, by delivery system (i.e., managed care or FFS), and by geographic region. In addition, there are nuances in the 1115 waiver changes which warrant identification and stratification of the data into a number of sub-populations. See Figure 2 in Section I of the evaluation plan for a summary of the waiver policy changes.

- ASAM Levels: (specifically, levels 2.1; 3.1; 3.5; 4; OTP; and RS). It is possible that outcomes may differ among the SUD population based on their access to services. B&A will examine the outcomes by those accessing a particular level of care for differences in health outcomes or cost in the post-waiver period compared to the pre-wavier period.

- Risk Scores: Similarly, outcomes may differ among the SUD population for some types of clinically similar groups compared to others. Therefore, B&A will examine outcomes by categorized groups of clinically-similar beneficiaries to examine whether there are differences in health outcomes or cost among clinically-similar groups of SUD beneficiaries.

- IMD Services: IMD coverage is expanding beyond the existing availability through specialized waiver services (e.g., PROMISE). B&A will flag those individuals who previously had access to IMD coverage.

- Opioid Use Disorder (OUD): It is likely that those beneficiaries with OUD, compared to those with other types of SUD, may have different health outcomes and access a different mix of services. Therefore, it is possible that the waiver impacts these populations differently; therefore, the OUD beneficiaries will be identified and examined as a sub-population. B&A will use the specification for OUD described in the CMS-approved Monitoring Plan.

- New Member/COVID: Beneficiaries who became newly eligible for Medicaid due to the financial impact of the pandemic will be separately identified. A combination of aid category and time of enrollment will be used to identify this population.

Comparison Groups

Two ideal comparison groups described in the CMS technical advisory guidance on selection of comparison groups include another state Medicaid population and/or prospectively collected information prior to the start of the intervention.[6] Specifically, a SUD population with similar demographics, in another state without those waiver flexibilities described in Delaware, would be an ideal comparator. However, identifying whether such a state exists or the ability to obtain data from another state given the sensitivity of SUD privacy concerns as it relates to data sharing is not feasible; therefore, it is outside the

[6] Comparison Group Evaluation Design. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/comparison-grp-eval-dsgn.pdf.

scope of this evaluation. Similarly, the other example of a control group described in the design guide is to collect prospective data. To our knowledge, there is no known prospective data collection on which to build baselines.

Given the lack of an available and appropriate comparison group, B&A will use an analytic method which creates a pre-waiver and current waiver (intervention) group upon which to compare outcomes. See Section III.F for more details on the analytic methods.

III.C Evaluation Period

Monthly Metrics

For those metrics which are computed monthly, the pre-waiver period will be defined as a three year period before waiver approval. The pre-waiver period is defined as enrollment or dates of service from August 1, 2016 through July 31, 2019. The post-waiver period is defined as enrollment or dates of service from August 1, 2019 through December 31, 2023.

Annual Metrics

For those metrics which are computed as annual metrics, particularly those with national measure stewards, B&A will assign calendar year 2019 data into the pre-waiver period since only five months of CY 2019 are in the post-waiver period. Before making a final decision on this matter, B&A will conduct tests to determine the sensitivity to change whether CY 2019 is included in the pre-waiver period or is omitted entirely from the evaluation. If the results of models are sensitive to including CY2019 annual metric in the pre-waiver period, it will be omitted from any statistical modeling—although it will be depicted descriptively.

It should be noted that, while this is the expected current evaluation period, modifications may be warranted to better reflect differences in the time period upon which one would expect to see a change in outcome resulting from waiver activities. At this time, there was little data or similar studies available on which to base specific alternatives to the proposed current evaluation period. B&A, therefore, will examine time series data in order to identify whether the current evaluation period should be delayed. For example, if review of the data shows a distinctive change in the fourth quarter of 2019, the current period would be adjusted such that the first, second and third quarter data would not be considered in the interrupted time series analysis described in Section III.F.

III.D Evaluation Measures

The measures included in the evaluation plan directly relate to the aims and the primary and secondary driver described in Section II. The measures include those with national measure stewards, those specified by CMS, and evaluator-derived metrics. The metrics will be computed monthly, quarterly and annually and reported per the CMS technical specifications. The majority of the measures are also included in Delaware's monitoring protocol.

Exhibit III.2 on the next page of the evaluation design summarizes the list of measures included in the evaluation plan. A comprehensive list of measures as well as a description of numerators and denominators can be found in the detailed matrices in Section III.G.

Exhibit III.2 Summary of Metrics and Steward, by Research Question and Hypothesis

Q/H #	Measure Steward	Research Question and Metric(s)
Q 1		**Does the demonstration increase access to and utilization of SUD treatment services?**
H 1.1	NQF #0004	• Initiation and engagement of alcohol and other drug dependence treatment
H 1.2	NQF #3175	• Continuity of pharmacotherapy for OUD
H 1.2	CMS	• Percentage of beneficiaries with a SUD diagnosis who used SUD services per month
H 1.3	B&A	• Average turnaround time for authorization decisions
H 1.3	B&A	• Rate of approved and denied authorizations
H 1.3	B&A	• Frequency and percentage of denial reason codes
H 1.4	CMS	• Emergency department visits for SUD-related diagnoses and specifically for OUD
H 1.4	CMS	• Inpatient admissions for SUD and specifically OUD
H 1.4	NCQA	• Follow-up after discharge from the emergency department for alcohol or other drug (AOD) dependence
Q 2		**Do enrollees who are receiving SUD services experience improved health outcomes?**
H 2.1	NCQA	• Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD
H 2.2	CMS	• Plan all-cause readmissions
H 2.2	B&A	• The proportion of beneficiaries with SUD receiving care coordination following discharge from index hospital stay
H 2.2	NQF #3453	• Continuity of care after inpatient or residential treatment from SUD
Q 3		**Are rates of opioid-related overdose deaths impacted by the demonstration?**
H 3.1	NQF #2940	• Use of opioids at high dosage in persons without cancer
H 3.1	B&A	• Rate of overdose deaths, specifically overdose deaths due to any opioid
H 3.1	PQA	• Concurrent use of opioids and benzodiazepines
Q 4		**Do activities post-implementation increase the use of the Delaware's Prescription Drug Monitoring Program?**
H 4.1	B&A	• Number of clinicians accessing the PDMP
H 4.1	B&A	• Number of queries to the PDMP
Q 5		**How does the demonstration impact cost?**
H 5.1	CMS	• Per beneficiary per month spending: total and by service category
H 5.2	CMS	• Per beneficiary per month spending: SUD, IMD and non-SUD
H 5.3	CMS	• Per beneficiary per month spending: SUD treatments by category of service

III.E Data Sources

As described in section III.A, Evaluation Design, B&A will use existing secondary data sources as well as collect primary data. The evaluation design relies most heavily on the use of Delaware Medicaid administrative data, i.e., enrollment, claims and encounter data. Supplemental administrative data, such as prior approval denials and authorizations, will also be incorporated. Primary data will be limited and include data created by surveys, desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses appears below.

Delaware Medicaid Administrative Data

Claims and encounters with dates of service (DOS) from January 1, 2016 and ongoing will be collected from the Delaware Medicaid Enterprise System (DMES) Data Warehouse (EDW), facilitated by DMMA's EDW vendor, Gainwell (formerly DXC) Technologies. Managed care encounter data has the same record layout as fee-for-service and includes variables such as charges and payments at the header and line level. Payment data for MCO encounters represents actual payments made to providers. In total, three MCOs will have encounter data in the dataset, but not every MCO will have data for all years in the evaluation. Delaware has contracted with Highmark and AmeriHealth Caritas DE from 2018 to present. Prior to 2018, Highmark and United Healthcare Community Plan were the contracted MCOs. This means that United Healthcare Community Plan will only have encounter data in the pre-waiver period, while Highmark and AmeriHealth Caritas DE will have data in the pre-waiver and post-waiver period.

A data request specific to the 1115 Evaluation Design Plan will be given to DMMA and the data will be delivered to B&A in an agreed-upon format. The initial EDW data set will include historical data up to the point of the delivery. Subsequent data will be sent to B&A on a monthly basis. The last query of the EDW will occur on January 1, 2025 for claims with DOS in the study period. All data delivered to B&A from the DMMA will come directly from the DMES EDW. B&A will leverage all data validation techniques used by Gainwell before the data is submitted to the EDW. B&A will also conduct its own validations upon receipt of each monthly file from the DMES to ensure accuracy and completeness when creating our multi-year historical database.

When additional data is deemed necessary for the evaluation, B&A will outreach directly to the MCOs when they are determined to be the primary source. B&A will build data validation techniques specific to the ad hoc requests from the MCOs.

Additional data from the MCOs and the State will be collected on prior authorizations, denials, denial reason codes as well as data on care coordination activities. There could be some data validity or quality issues with these sources as they are not as rigorously collected as claims and encounters data. That being said, we will use a standard quality review and data cleaning protocol in order to validate these data, as well as provide detailed specifications and reporting tools to the MCOs and the state to minimize potential for differences in reporting of the requested ad-hoc data.

Delaware Vital Statistic Data

In collaboration with DMMA, vital statistics cause of death data will be transferred from the Department of Health to the evaluators for purposes of calculating overdose rates. More information on vital statistics can be found at: https://dhss.delaware.gov/dhss/dph/ss/vitalstats.html.

Delaware Prescription Drug Monitoring Program (PDMP) Data

In accordance with state guidelines, the states PDMP collects information on queries and unique users which will be provided by the Division of Financial Regulation in collaboration from DMMA. Where possible, data available in the public domain via quarterly reports will be collected and used. Information on the Delaware's PDMP can be found at: https://dpr.delaware.gov/boards/pmp/.

Facilitated Interview Data

B&A will construct facilitated interview guide instruments as a means to collect primary data for the focus studies. The types of respondents that the evaluators propose to interview include the MCOs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, B&A will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

III.F Analytic Methods

Exhibit III.1 depicted the five analytic methods to be used in the analysis. A detailed discussion of each method is described below. This includes, where applicable, B&A's approach to address the impact of the COVID-19 pandemic within each method.

Method #1: Descriptive Statistics

In order to facilitate ongoing monitoring, all measures will be summarized on an ongoing basis over the course of the waiver. The descriptive statistics will be stratified by ASAM level of care, by MCE and FFS delivery systems, and/or by region where possible. For reporting purposes, the descriptive studies will be subject to determination of a minimum number of beneficiaries in an individual reported cell (i.e., minimum cell size) and subject to blinding if the number falls below this threshold. While a conventional threshold is 10 or fewer observations, given the sensitivity of SUD and the public dissemination of report findings, a higher threshold may be established by the evaluators upon review of the final data.

Results will primarily be reported in terms of longitudinal descriptive statistics of defined groups of SUD beneficiaries and using regional maps where possible.

COVID-19 Considerations

For metrics where descriptive trends is the appropriate methodology, the evaluators propose to include a marker of pre- and post- COVID overlaid onto any graphs so one can visually inspect if there is an obvious change in the particular outcome starting mid-2020 and adding a comparator group.

In both cases, newly eligible members who became Medicaid eligible as a result of COVID will be identified by aid category and benefit plan and treated as a subpopulation in the analysis. This will allow the evaluators to continue to include those newly eligible members for which enrollment is unrelated to the pandemic (e.g., aged, blind and disabled, pregnant women, children, etc.)

Method 2: Statistical Tests

T-test or Chi-square test

Tests will be used to determine whether the observed differences in the mean value or rate differs for the most recent evaluation two-year period compared to the two-year period prior to waiver implementation. To assess if results for each metric compared to the pre-waiver timeframe are not due to chance alone, the evaluators will use chi-square tests for categorical data and t-tests for continuous data. Testing of the assumptions of normality and adjustments will be made before performing the final statistics and discussed below.

COVID-19 Considerations

For those metrics where simple statistics (chi square or t-test) is the appropriate quantitative methodology, the evaluators propose testing two separate post years to baseline to estimate the treatment effects before, during and after the pandemic. In both cases, members who became newly-eligible for Medicaid as a result of COVID will be identified by aid category and benefit plan and treated as a subpopulation in the analysis. By doing this, B&A will be able to continue to include other newly-eligible members for which enrollment in Medicaid is unrelated to the pandemic (e.g., aged, blind and disabled, pregnant women, newborns).

T-test

The t test is a type of inferential statistics. It is used to determine whether there is a significant difference between the means of two groups. Conceptually, it represents how many standardized units of the means of the pre- and post-populations differ. There are generally five factors to contribute whether a statistically significant difference between the pre- and post-periods will be considered significant:[7]

William Sealy Gosset .pdf(1905) first published a t-test. He worked at the Guiness Brewery in Dublin and published under the name Student. The test was called Studen*t* Test (later shortened to *t* test).

1. How large is the difference? The larger the difference, the greater the likelihood that a statistically significant mean difference exists and confidence increased.
2. How much overlap is there between the groups? The smaller the variances between the two groups, the greater probability a difference exists, hence increasing confidence in results.
3. How many subjects are in the two samples? The larger the sample size, the more stable and hence, confidence in results.
4. What alpha level is being used to test the mean difference? It is much harder to find differences between groups when you are only willing to have your results occur by chance 1 out of a 100 times ($p < .01$) as compared to 5 out of 100 times ($p < .05$) but confidence in results is less.
5. Is a directional (one-tailed) or non-directional (two-tailed) hypothesis being tested? Other factors being equal, smaller mean differences result in statistical significance with a directional hypothesis so less confidence can be assigned to the results.

The assumptions underlying the t-test include:

- The samples have been randomly drawn from their respective population.
- The scores in the population are normally distributed.

[7] T-test. https://researchbasics.education.uconn.edu/t-test/#. Accessed May 14, 2020.

- The scores in the populations have the same variance (s1=s2). A different calculation for the standard error may be used if they are not.

There are two types of errors associated with the t-test:

- Type I error —whereby the evaluator would detect a difference between the groups when there really was not a difference. The probability of making a Type I error is the chosen alpha level; therefore, an alpha level at $p < .05$, results in a 5% chance that you will make a Type I error.
- Type II error —whereby the evaluator detects no difference between the groups when there really was one.

The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program. Assumptions will be tested and addressed if detected, including tests of normality and variance in the pre- and post- data. Metrics which are continuous will be tested using a t-test. The lowest level of reliable granularity available and reliable will be used for conducting tests (i.e., monthly or quarterly observations instead of annual).

Chi-square test

A chi-square test may be used in lieu of the t-test for some categorical variables. Chi-square may be preferable to t-test for comparing rates. All χ^2 tests are two sided.

The chi-square test for goodness of fit determines how well the frequency distribution from that sample fits the model distribution. For each categorical outcome tested, the frequency of patients in the pre- and post-period would be tested. The chi-square test for goodness of fit would determine if the observed frequencies were different than expected; in other words, whether the difference in the pre- and post-outcomes were significantly different statistically than what would have been expected given the pre-period. The null hypothesis, therefore, is that the expected frequency distribution of all wards is the same. Rejecting the null would indicate the differences were statistically significant (i.e., exceeded difference than would be expected at a given confidence level).

The chi-square formula is: $\chi 2=\sum i=1k(O^i-E^i)2/E^i$

The assumptions of the chi-square are:

- Simple random sample
- Sample size. Small samples subject to Type II error.
- Expected cell count. Recommended 5-10 expected counts.
- Independence. Evaluation of the appropriateness of a McNemar's test may be warranted.

The evaluators will consider results significant at a level of probability of $p < .05$. A test statistic will be generated in the SAS© statistical program. Annually-reported categorical metrics for chi-square testing will either be derived from pooled population data (i.e., create on rate in pooled years of pre- and post-data) or two calendar year time periods (i.e., compare last year pre-waiver to last year post-waiver). Final approach will be determined upon examination of the data.

Interrupted Time Series (ITS)

Interrupted time series (ITS) is a quasi-experimental method used to evaluate health interventions and policy changes when randomized control trials (RTC) are not feasible or appropriate.[8,9,10] As it would not be ethical or consistent with Medicaid policy to withhold services resulting from waiver changes from a sub-set of beneficiaries for purposes of evaluation, an RTC is therefore, not possible. Per CMS technical guidance, the ITS is the preferred alternative approach to RTC in the absence of an available, adequate comparison group for conducting cost-related evaluation analyses. The ITS method is particularly suited for interventions introduced at the population level which have a clearly defined time period and targeted health outcomes.[11,12,13]

An ITS analysis relies on a continuous sequence of observations on a population taken at equal intervals over time in which an underlying trend is "interrupted" by an intervention. In this evaluation, the waiver is the intervention and it occurs at a known point in time. The trend in the post-waiver is compared against the expected trend in the absence of the intervention.

While there are no fixed limits regarding the number of data points because statistical power depends on a number of factors like variability of the data and seasonality, it is likely that a small number of observations paired with small expected effects may be underpowered.[14] The expected change in many outcomes included in the evaluation are likely to be small; therefore, the evaluators will use 72 monthly observations where possible and 24 quarterly observations where monthly data are not deemed reliable.

In order to determine whether monthly or quarterly observations will be created, a reliability threshold of having a denominator of a minimum number of 100 observations at the monthly or quarterly level will be used. If quarterly reporting is not deemed reliable under this threshold, the measure and/or stratification will not be tested using ITS. Instead, these measures will be computed using calendar year data in the pre- and post- period and reported descriptively.

---

[8] Bonell CP, Hargreaves J, Cousens S et al.. Alternatives to randomisation in the evaluation of public health interventions: Design challenges and solutions. J Epidemiol Community Health 2009;65:582-87.

[9] Victora CG , Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. Am J Public Health 2004;94:400–05.

[10] Campbell M , Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. . Framework for design and evaluation of complex interventions to improve health. BMJ 2000;321:694.

[11] Soumerai SB. How do you know which health care effectiveness research you can trust? A guide to study design for the perplexed. Prev Chronic Dis 2015;12:E101.

[12] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

[13] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

[14] James Lopez Bernal, Steven Cummins, Antonio Gasparrini; Interrupted time series regression for the evaluation of public health interventions: a tutorial, International Journal of Epidemiology, Volume 46, Issue 1, 1 February 2017, Pages 348–355, https://doi.org/10.1093/ije/dyw098

ITS Descriptive Statistics

All demographic, population flags, and measures will be computed and basic descriptive statistics will be created: mean, median, minimum, maximum, standard deviation. These data will be inspected for identification of anomalies and trends.

To identify underlying trends, seasonal patterns and outliers, scatter plots of each measure will be created and examined. Moreover, each outcome will undergo bivariate comparisons; a Pearson correlation coefficient will be produced for each measure compared to the others as well as each measure in the pre- and post- periods.

Regression Analysis

Wagner et al. described the single segmented regression equation as[15]:

$$\hat{Y}_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time\_after\_intervention}_t + e_t$$

Where: Y_t is the outcome

time indicates the number of months or quarters from the start of the series

intervention is a dummy variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment

time_after_intervention is 0 in the pre-intervention segment and counts the quarters in the post-intervention segment at time t

β_0 estimates the base level of the outcome at the beginning of the series

β_1 estimates the base trend, i.e. the change in outcome in the pre-intervention segment

β_2 estimates the change in level from the pre- to post-intervention segment

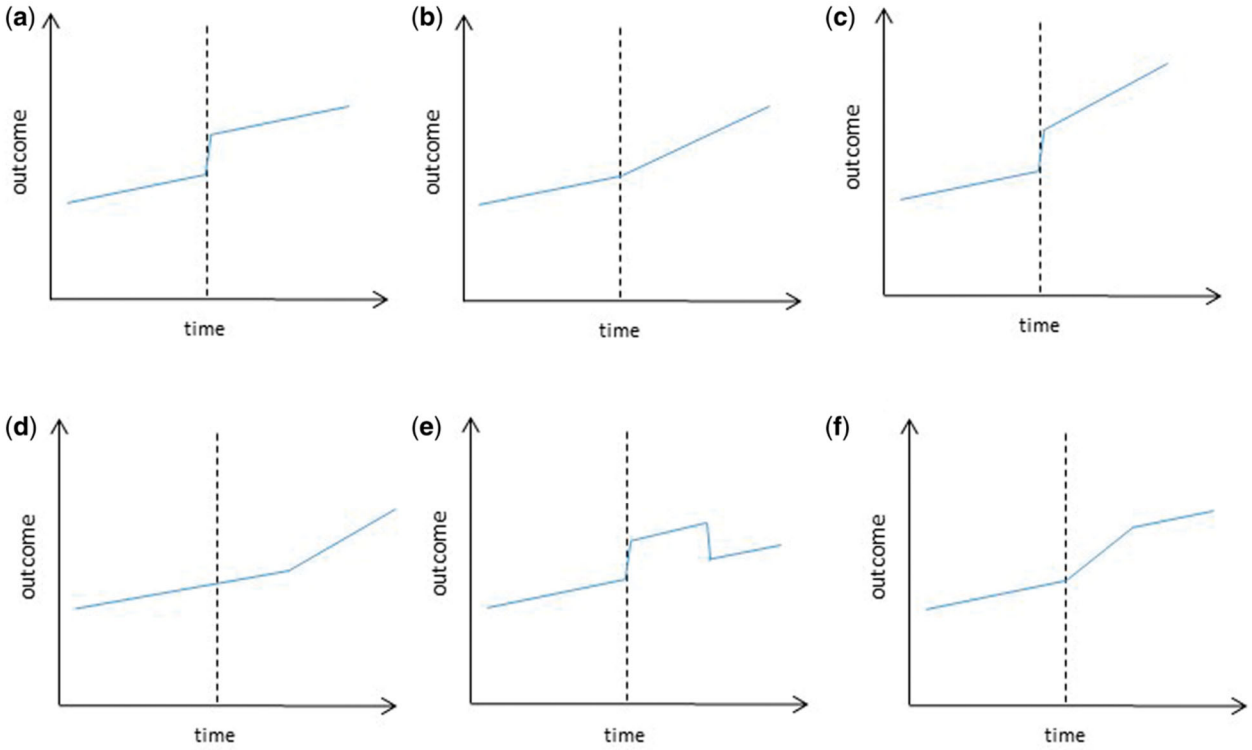
β_3 estimates the change in trend in the post-intervention segment

e_t estimates the error

Visualization and interpretation will be done as depicted in the Exhibit III.3. Each outcome will be assessed for one of the following types of relationships in the pre- and post-waiver period: (a) Level change; (b) Slope change; (c) Level and slope change; (d) Slope change following a lag; (e) Temporary level change; (f) Temporary slope change leading to a level change.

[15] Wagner AK , Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299-309.

Exhibit III.3 Illustration of Potential ITS Relationships[16]



Seasonality and Autocorrelation

One strength of the ITS approach is that it is less sensitive to typical confounding variables which remain fairly constant, such as population age or socio-economic status, as these changes relatively slowly over time. However, ITS may be sensitive to seasonality. To account for seasonality in the data, the same time period, measured in months or quarters, will be used in the pre- and post-waiver period. Should it be necessary, a dummy variable can be added to the model to account for the month or quarter of each observation to control for the seasonal impact.

An assumption of linear regression is that errors are independent. When errors are not independent, as is often the case for time series data, alternative methods may be warranted. To test for the independence, the evaluators will review a residual time series plot and/or autocorrelation plots of the residuals. In addition, a Durbin-Watson test will be constructed to detect the presence of autocorrelation. If the Durbin-Watson test statistic value is well below 1.0 or well above 3.0, there is an indication of serial correlation. If autocorrelation is detected, an autoregressive regression model, like the Cochrane-Orcutt model, will be used in lieu of simple linear regression.

Other assumptions of linear regression are that data are linear and that there is constant variance in the errors versus time. Heteroscedasticity will be diagnosed by examining a plot of residuals verses predicted values. If the points are not symmetrically distributed around a horizontal line, with roughly constant variance, then the data may be nonlinear and transformation of the dependent variable may be warranted.

[16] From: Interrupted time series regression for the evaluation of public health interventions: a tutorial Int J Epidemiol. 2016;46(1):348-355. doi:10.1093/ije/dyw098. Int J Epidemiol.

Heteroscedasticity often arises in time series models due to the effects of inflation and/or real compound growth. Some combination of logging and/or deflating may be necessary to stabilize the variance in this case.

For these reasons and in accordance with CMS technical guidance specific to models with cost-based outcomes, the evaluators will use log costs rather than untransformed costs, as costs are often not normally distributed. For example, many person-months may have zero healthcare spending and other months very large values. To address these issues, B&A will use a two-part model that includes zero costs (logit model) and non-zero costs (generalized linear model).

Controls and Stratification

As described in Section III.B, the regression analysis will be run both on the entire SUD target population and stratified by relevant sub-populations. The sub-population level analysis may reveal waiver effects that would otherwise be masked if only run on the entire SUD population. Similarly, common demographic covariates such as age, gender, and race will be included in these models to the extent they improve the explanatory power of the ITS models.

COVID-19 Considerations

For those metrics where multivariate analysis is the appropriate quantitative methodology, the evaluators propose to construct a 0/1 dummy variable that indicates if the observations are post-March 2020 until a defined "post" COVID period for use as a control in the regression model. Members who became newly-eligible for Medicaid as a result of COVID will be identified by aid category and benefit plan and treated as a subpopulation in the analysis. This will allow the evaluators to continue to include those newly-eligible members for which enrollment is unrelated to the pandemic (e.g., aged, blind and disabled, pregnant women, newborns).

Method #3: Onsite Reviews

In order to fill gaps and address questions for which claims-based data and other sources are insufficient, a number of onsite reviews are proposed. These onsite reviews will seek to gain insight on nuanced differences in approach, use and effectiveness of different MCO and DMMA approaches to the following topics:

- Care Coordination and Transitions to Care
- Service Authorization

The onsite reviews rely on creating a standardized set of questions that will capture information on process, documentation and beneficiary-level records if applicable. The questions may include onsite documentation gathering and data validation related to those topics described above. In some cases, the onsite reviews will employ a sampling approach whereby a limited number of beneficiaries are selected based on a set of criteria. Internal records specific to those beneficiaries stored at each MCO will be reviewed. The sample criteria would be developed to reflect the representativeness with the demonstration population or sub-population served by each MCO. This will help aid in the comparability of the results of the onsite review across MCOs. Finally, the same reviewer (or group of reviewers) will be used for all MCO reviews to strengthen inter-reliability.

Method #4: Desk Reviews

A limited number of desk reviews will supplement the other study methods included in the evaluation. These reviews will focus on hypotheses which are directed at assessment of process outcomes like avoidance of implementation delays, system changes according to schedules, transparency of policy and rates, and utility of stakeholder tools and analytics. Each desk review will use a questionnaire that asks for the information sought, the documentation reviewed, and the finding. Any gaps in information will also be noted as findings. The evaluator will review publicly available information and/or documentation specifically requested from the DMMA and/or the MCOs.

Method #5 Facilitated and/or Focus Group Interviews

As needed, B&A will construct facilitated interview guide instruments as a means to collect primary data for the focus studies. Intended respondents will include the MCOs, SUD providers and SUD beneficiaries. Where focused interviews are used to collect data, B&A will use semi-structured interview protocols that are intended to be standardized within the population being interviewed. The interview protocols will vary, however, for each population interviewed due to the type of information that is intended to be collected. Although semi-structured in nature, each stakeholder will have the opportunity to convey additional information that he/she would like to convey to the evaluators in an open-ended format at the conclusion of each interview.

B&A will ensure that, for each population that interviews are conducted, there is sufficient representation within the population among those being surveyed. Sampling may be completed by using geographic location, provider size (large and small), and beneficiary age, to name a few

III.G Other Additions

Starting on the next page, a matrix summarizing the methods for each hypothesis and research question described in Section III.A – III.F is presented.

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Does the demonstration increase access to and utilization of SUD treatment services?***						
Demonstration Goal #1: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.						
Evaluation Hypothesis #1.1: The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.						
Primary Driver (Increase the rates of initiation and engagement for OUD and other SUDs)	Initiation and engagement of alcohol and other drug dependence treatment	NQF #0004	Initiation: number of patients who began initiation of treatment through an inpatient admission, outpatient visits, intensive outpatient encounter or partial hospitalization within 14 days of the index episode start date	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year	Claims data	***For both measures***: Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS will be conducted in the Summative Evaluation.
	Initiation and engagement of alcohol and other drug dependence treatment	NQF #0004	Engagement: Initiation of treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any alcohol or drug diagnosis within 30 days after the date of the initiation encounter	Patients who were diagnosed with a new episode of alcohol or drug dependency during the first 10 and ½ months of the measurement year	Claims data	
Demonstration Goal #2: Increased adherence to and retention in treatment.						
Evaluation Hypothesis #1.2: The demonstration will increase the percentage of beneficiaries who are referred and engage in treatment for OUD and other SUDs.						
Primary Drivers (Increase the rates of initiation and engagement in treatment for OUD and other SUDs.)	Continuity of pharmacotherapy for OUD	NQF #3175	Number of participants who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than seven days	Individuals who had a diagnosis of OUD and at least one claim for an OUD medication	Claims data	Descriptive statistics; chi square or t-tests of significance comparing target population in the pre- and post- periods. ITS in the Summative Eval.
	Percentage of beneficiaries with a SUD diagnosis (including beneficiaries with an OUD diagnosis) who used SUD services per month	CMS-specified	Number of enrollees who receive a service during the measurement period by service type	Number of enrollees	Claims data	Descriptive statistics; chi square or t-tests of significance comparing target population in the pre- and post- periods. ITS in the Summative Eval.

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Demonstration Goal #1: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.						
Evaluation Hypothesis #1.3: Approved service authorizations improve appropriate utilization of health care services in the post-waiver period.						
Primary Drivers (Increase the rates of initiation and engagement in treatment for OUD and other SUDs.)	Average turnaround time for authorization decisions	Burns & Associates	Total number of days turnaround time for monthly authorizations for SUD, residential and inpatient requests	Total number of monthly SUD authorizations requests (approved and denied), residential and inpatient requests	MCO-submitted report	Descriptive statistics (frequencies and percentages)
	Rate of approved and denied authorizations	Burns & Associates	Number of monthly (1) approvals and (2) denials for SUD authorizations, residential and inpatient requests	Total number of monthly SUD authorizations requests, residential and inpatient	MCO-submitted report	Descriptive statistics (frequencies and percentages)
	Frequency and percentage of denial reason codes	Burns & Associates	Count of monthly denied SUD authorization requests, by denial reason code, residential and inpatient	Total number of monthly denied authorizations requests for SUD, residential and inpatient	MCO-submitted report	Descriptive statistics (frequencies and percentages)
Demonstration Goal #4: Reduced utilization of emergency department and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services.						
Evaluation Hypothesis #1.4: The demonstration will decrease the rate of emergency department and inpatient visits within the beneficiary population for SUD.						
Primary Driver (Reduced utilization of emergency department and inpatient hospital settings for SUD treatment)	Emergency department visits for SUD-related diagnoses and specifically for OUD	CMS-specified	The number of ED visits with a SUD diagnosis present during the measurement period	Beneficiaries enrolled in Medicaid for at least one month (30 consecutive days) during the measurement period.	Claims data	***For all measures***: Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.
	Inpatient admissions for SUD and specifically OUD	CMS-specified	The number of inpatient admissions with (1) a SUD primary diagnosis and (2) an OUD primary diagnosis	Total number of beneficiary member months (result of this formula then expressed as per 1,000 member months)	Claims data	
	Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence	NCQA	1. Members who had a follow-up visit to an ED visit with a SUD indicator within 7 days of discharge within the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months	Claims data	
		NCQA	2. Same as above for members who had a follow-up visit within 30 days.	Individuals with an ED visit (with SUD indicator) within the previous rolling 12 months	Claims data	

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Do enrollees who are receiving SUD services experience improved health outcomes?***						
Demonstration Goal #6: Improved access to care for physical health conditions among beneficiaries.						
Evaluation Hypothesis #2.1: The demonstration will increase the percentage of beneficiaries with SUD who experience care for comorbid conditions.						
Primary Driver (Improve access to care for co-morbid physical health conditions among beneficiaries with SUD)	Access to preventive/ ambulatory health services for adult Medicaid beneficiaries with SUD	NCQA	Number of beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period	Number of beneficiaries with a SUD diagnosis	Claims data	Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.
Demonstration Goal #5: Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate.						
Evaluation Hypothesis #2.2: Among beneficiaries receiving care for SUD, the demonstration will reduce readmissions to SUD treatment.						
Primary Driver (Reduce readmissions to the same or higher level of care for SUD)	Plan All-Cause Readmissions	CMS-specified	At least one acute unplanned readmission for any diagnosis within 30 days of the date of discharge from the index hospital stay, that is on or between the 2nd day and end of the measurement year	Medicaid beneficiaries age 18 and older with a discharge from an acute inpatient stay on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.
Secondary Driver (Increase the proportion of the SUD population receiving care coordination and supports following discharge from acute care.)	The proportion of beneficiaries with SUD receiving care coordination following discharge from index hospital stay	Burns & Associates	Number of beneficiaries within 30 days of the date of discharge from the SUD-related index hospital stay who received care coordination and supports.	Number of beneficiaries with a SUD-related index hospital stay.	MCO-submitted report with follow-up validation by evaluators	Descriptive statistics (frequencies and percentages)
	Percentage of discharges from inpatient or residential treatment for SUD for Medicaid beneficiaries, ages 18-64, which were followed by a SUD treatment. Two rates are reported, continuity within 7 and 14 days after discharge.	NQF	Number of beneficiaries within 7 and 14 days who received a SUD treatment following discharge from an inpatient or residential SUD provider in a 12-month period.	Number of beneficiaries with an inpatient or residential SUD stay in 12-month period.	Claims data	*Interim Evaluation*: Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population in the pre- and post-period. *Summative Evaluation*: ITS

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Are rates of opioid-related overdose deaths impacted by the demonstration?***						
Demonstration Goal #3: Reductions in overdose deaths, particularly those due to opioids.						
Evaluation Hypothesis #3.1: The demonstration will decrease the rate of overdose deaths due to opioids.						
Aim (Reduce opioid related overdose deaths)	Use of opioids at high dosage in persons without cancer	NQF #2940	Number of beneficiaries with opioid prescription claims where the morphine equivalent dose for 90 consecutive days or longer is greater than 120 mg	Number of beneficiaries with two or more prescription claims for opioids filled on at least two separate dates, for which the sum of the days' supply is greater than or equal to 15	Claims and administrative data	Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.
	Rate of overdose deaths, specifically overdose deaths due to any opioid	Burns & Associates	Number of overdose deaths per month and per year	Total number of beneficiary member months (result of this formula then expressed as per 1,000 member months)	Vital statistics, claims data	Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.
	Concurrent use of opioids and benzodiazepines	PQA	Number of beneficiaries with concurrent use of prescription opioids and benzodiazepines	Number of beneficiaries with two or more prescription claims for opioids filled on two or more separate days, for which the sum of the supply is 15 or more days	Claims data	Descriptive statistics (frequencies and percentages); chi square tests or t-tests of significance comparing target population in the post-period to the baseline pre-period. ITS in the Summative Eval.

Driver	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #4: ***Do activities post-implementation increase the use of Delaware's Prescription Drug Monitoring Program?***						
Demonstration Goal #1: Increased rates of identification, initiation, and engagement in treatment for OUD and other SUDs.						
Evaluation Hypothesis #4.1: The demonstration will increase or maintain the use of Delaware's PDMP.						
Primary Driver (Increase the rates of initiation and engagement for OUD and other SUDs)	Number of clinicians accessing the PDMP	Burns & Associates	Number of clinicians accessing the PDMP monthly	N/A	PDMP data	Descriptive statistics (frequencies and percentages)
	Number of queries to the PDMP	Burns & Associates	Number of queries accessing the PDMP monthly	N/A	PDMP data	Descriptive statistics (frequencies and percentages)
Evaluation Question #5: How d*oes the demonstration impact cost?*						
Evaluation Hypothesis #5.1: The demonstration will decrease or maintain per beneficiary per month costs.						
All	Per beneficiary per month costs in total and by categories of service in the SUD population	CMS-specified	Total monthly costs for SUD beneficiaries. Categories include inpatient, outpatient, pharmacy, long term care, IMDs and other.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	Descriptive statistics; chi square tests or t-tests of significance comparing target population in pre- and post-period. ITS in the Summative Eval.
Evaluation Hypothesis #5.2: The demonstration will increase or maintain per beneficiary per month costs for SUD services.						
All	Per beneficiary per month costs for SUD services, IMDs, and non-SUD services in the SUD population	CMS-specified	Total costs for SUD beneficiaries. Categories include SUD-IMDs, other SUD, non-SUD.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	Descriptive statistics; chi square tests or t-tests of significance comparing target population in pre- and post-period. ITS in the Summative Eval.
Evaluation Hypothesis #5.3: The demonstration will decrease or maintain per beneficiary costs for SUD-related ED visits and inpatient stays.						
All	Per beneficiary per month costs in total SUD treatment costs, by categories of services in the SUD population	CMS-specified	Total costs for SUD treatment. Categories include inpatient, ED visits, non-ED outpatient, pharmacy and long term care.	1. Total member months for beneficiaries with an SUD diagnosis. 2. Total member months for all enrolled beneficiaries.	Claims data	Descriptive statistics; chi square tests or t-tests of significance comparing target population in pre- and post-period. ITS in the Summative Eval.

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the SUD waiver evaluation. That being said, the proposed design is feasible and is a rational explanatory framework for evaluating the impact of the SUD waiver on the SUD population. Moreover, to fill gaps left by the limitations of this study design, a limited number of qualitative methods are proposed to provide a more holistic and comprehensive evaluation.

Since Delaware's population will be small compared to other states, some metrics and/or sub-populations may not be meaningful for reporting and insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the population size exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results. We recommend a threshold for minimum numbers of observations. For any measures below this threshold, the expectation of statistical testing would be waived.

While CMS may prefer comparator group from another state, in the last two years, the proliferation of the SUD waiver authority across the country renders few comparable states to Delaware. Moreover, this would require significantly more resources and cooperation with another state on sharing data. Therefore, B&A is recommending using statistical tests comparing the pre- and post-waiver period to test hypotheses in the absence of a control group.

Another limitation is the length of time of the evaluation period. In some cases, the time period may be insufficient to observe descriptive or statically significant differences in outcomes in the SUD population. Therefore, it is expected that not all outcomes included in the study will show a demonstrable change descriptively, although we do expect some process measures to show a change during this time frame.

Moreover, with any study focused on the SUD population and potentially rare outcome measures, such as overdose rates, insufficient statistical power to detect a difference is a concern. For any observational studies, especially if the exposures and the outcomes being assessed are rare, it is difficult to find statistically significant results. It is not unexpected, therefore, that many of the outcome measure sample sizes will be too small to observe statistically significant results.

Related to the issues mentioned above, many of the outcome measures are multi-dimensional and influenced by social determinants of health. While changes under the waiver related to access to care may be one dimension of various outcomes of interest, and may contribute to improvements, it may be difficult to achieve statistically significant findings in the absence of data on other contributing dimensions, like social determinants of health such as housing, employment, and previous incarcerations.

Section V, Special Considerations, will summarize the unique challenges in this study

SECTION V: SPECIAL METHODOLOGICAL CONSIDERATIONS

Delaware's SUD waiver is new. There are no identified implementation delays or any other outstanding concerns. Therefore, the proposed Evaluation Design Plan provides more than adequate rigor in the observational study design, especially when considering the range of supplemental evaluation methods proposed for inclusion. As described in detail in Section IV, Methodological Limitations, the study mitigates known limitations to the extent feasible drawing upon the range of options to fill gaps in the observational study design. Moreover, this Evaluation Design Plan is consistent with, and expands upon, CMS approved 1115 demonstration waiver SUD evaluation plans available on the CMS State Waivers List.[17]

An important special consideration in Delaware is the narrow focus of the SUD waiver and the State's above average performance on some metrics when compared to other states. Given the sophistication of Delaware's SUD system in the pre-waiver period compared to other states, there may be less room for improvement and, hence, less demonstrable changes in some metrics. For example, Delaware already adopted the use of ASAM criteria and other SUD system improvements in the pre-waiver period.

Also, observed changes in outcome metrics in the current waiver period will be difficult, if not impossible, to attribute to one specific demonstration component or activities outside the demonstration itself but occurring simultaneously (e.g., activities supported through federal grants) given the interrelationship of the components themselves. For many outcome measures, changes in the post-waiver period will be difficult, if not impossible, to attribute to coinciding related activities resulting from the combination of waiver, planning grant, and START initiative activities. Therefore, it will be important to use statistical tests of significance so that findings are properly put into context.

Lastly, the evaluators recognize that the utilization patterns that will occur relatively early in this demonstration period will be severely disrupted due to the COVID-19 pandemic. The predictability of future utilization patterns remains uncertain as of the date of this document. The evaluators are prepared to work with CMS in the event that guidance is provided to states for all waiver evaluations as to options that CMS will offer with respect to how to account for the acute period of the pandemic. The initial plan for handling COVID-19 effects are addressed in Section III. Methodology.

[17] Medicaid State Waivers List can be accessed at: https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html

ATTACHMENT A: INDEPENDENT EVALUATOR

Process

Burns & Associates, a division of HMA, (B&A) submitted a proposal through a competitive bid process to be retained for professional services with the Delaware Department of Health and Social Services (DHSS). The current contract was entered into effective March 1, 2019 with an end date of February 28, 2022.

The DHSS has the authority under this professional services agreement to seek proposals from vendors for targeted scope of work activities. The Division of Medicaid and Medical Assistance (DMMA), one of the Divisions under the DHSS, requested that B&A submit a proposal to conduct evaluation activities specifically related to the Substance Use Disorder (SUD) component of Delaware's 1115 Diamond State Health Plan Waiver Demonstration Project. B&A submitted a proposal based upon the criteria set forth in the waiver's Special Terms and Conditions as approved by the Centers for Medicare and Medicaid Services (CMS). The DMMA accepted the proposal from B&A and proceeded with contracting with B&A to perform the evaluation of Delaware's SUD Waiver. B&A provided a proposed budget to complete all activities required for the waiver evaluation as well as a modified budget to encompass activities through February 28, 2022.

Vendor Qualifications

B&A was founded in 2006 and works almost exclusively with state Medicaid agencies or related social services agencies in state government. Since that time, B&A has worked with 33 state agencies in 26 states. The B&A team proposed to complete the evaluation of Delaware's 1115 SUD waiver serves as the independent evaluator of Indiana's 1115 SUD waiver, including development of the approved Evaluation Design Plan, Interim Evaluation and MidPoint Assessment. B&A has also conduced independent assessments of Indiana's 1915(b) waiver for Hoosier Care Connect and has served as the External Quality Review Organization (EQRO) for Indiana since 2007. B&A has written an External Quality Review (EQR) report each year since that time which has been submitted to CMS. B&A has also conducted independent evaluations for state agencies in Minnesota, New York and Oklahoma. B&A was acquired by Health Management Associates as of September 1, 2020.

Assuring Independence

In accordance with standard term and condition (STC) 86 Independent Evaluator, Attachment F – Developing the Evaluation Design, B&A attests to having no conflicts to perform the tasks needed to serve as an independent evaluator on this engagement. B&A's Principal Investigator is prepared to deliver a signed attestation to this effect upon request.

ATTACHMENT B: EVALUATION BUDGET

As part of the procurement process, Burns & Associates, a Division of HMA, (B&A) was required to submit a cost proposal that presents the level of effort to complete all deliverables associated with the independent evaluation of Delaware's SUD waiver. The DMMA asked B&A to propose the level of effort to complete the deliverables due by the independent evaluator as well as the effort to provide technical assistance to compute the metrics due to CMS from the State each quarter as part of waiver updates. Presently, the State only has the authority to contract with B&A through February 28, 2022, and there are deliverables due to CMS after February 28, 2022 which are reflected in the evaluation budget.

In an effort to show the complete level of effort that would be proposed to complete all deliverables, Exhibit B.1 Proposed Hours for SUD Waiver Evaluation found on page B-2 enumerates the proposed staffing and level of effort by labor category for each component of the evaluation. Likewise, Exhibit B.2 Proposed Costs for SUD Waiver Evaluation as found on page B-3 summarizes the total amount to complete all deliverables associated with the independent evaluation for each deliverable due to CMS. The total estimated cost for the independent evaluation of Delaware's SUD Demonstration Waiver is $1,688,220 to complete all deliverables through June 30, 2025.

EXHIBIT B.1 PROPOSED HOURS FOR SUD WAIVER EVALUATION							
Mark Podrazik	Kara Suter	Debbie Saxe	Ryan Sandhaus	Shawn Stack	Akhilesh Pasupulati	Barry Smith	TOTAL
Project Director	Project Informatics	Project Manager	Statistician	Senior Consultant	SAS Programmer	Consultant	
749	2,028	834	2,767	154	112	734	7,378

Task	Task Name							
SECTION A: PROJECT MANAGEMENT		**138**	**97**	**170**	**263**	**26**	**0**	**8**	**702**
1	Kickoff Meeting	10	12	12	6	0	0	0	40
2	Project Management	90	36	158	26	26	0	0	336
3	Obtain and Read in Data for Project	38	49	0	231	0	0	8	326
SECTION B: MONITORING ACTIVITIES		**177**	**902**	**256**	**1914**	**0**	**0**	**438**	**3687**
4	Build and Maintain Data Warehouse for Project	16	64	0	136	0	0	20	236
5	Produce Monitoring Protocol	17	92	26	12	0	0	2	149
6	Create Monitoring Reports	144	746	230	1766	0	0	416	3302
	One-time activities	*16*	*42*	*6*	*38*	*0*	*0*	*0*	*102*
	Ongoing activities each quarter	*128*	*704*	*224*	*1728*	*0*	*0*	*416*	*3200*
SECTION C: EVALUATION ACTIVITIES		**434**	**1029**	**408**	**590**	**128**	**112**	**288**	**2989**
7	Develop Evaluation Design	21	124	33	30	0	0	0	208
8	Produce Mid Point Assessment	176	175	135	76	86	44	110	802
9	Prepare Interim Evaluation	96	372	89	256	0	68	98	979
10	Prepare Summative Evaluation	141	358	151	228	42	0	80	1000

PROPOSED COSTS FOR SUD WAIVER EVALUATION							
Mark Podrazik	Kara Suter	Debbie Saxe	Ryan Sandhaus	Shawn Stack	Akhilesh Pasupulati	Barry Smith	TOTAL
Project Director	Project Informatics	Project Manager	Statistician	Senior Consultant	SAS Programmer	Consultant	
$250.00	$230.00	$230.00	$230.00	$230.00	$215.00	$200.00	
$187,250	$466,440	$191,820	$636,410	$35,420	$24,080	$146,800	$1,688,220

Task	Task Name							
SECTION A: PROJECT MANAGEMENT		**$34,500**	**$22,310**	**$39,100**	**$60,490**	**$5,980**	**$0**	**$1,600**	**$163,980**
1	Kickoff Meeting	$2,500	$2,760	$2,760	$1,380	$0	$0	$0	$9,400
2	Project Management	$22,500	$8,280	$36,340	$5,980	$5,980	$0	$0	$79,080
3	Obtain and Read in Data for Project	$9,500	$11,270	$0	$53,130	$0	$0	$1,600	$75,500
SECTION B: MONITORING ACTIVITIES		**$44,250**	**$207,460**	**$58,880**	**$440,220**	**$0**	**$0**	**$87,600**	**$838,410**
4	Build and Maintain Data Warehouse for Project	$4,000	$14,720	$0	$31,280	$0	$0	$4,000	$54,000
5	Produce Monitoring Protocol	$4,250	$21,160	$5,980	$2,760	$0	$0	$400	$34,550
6	Create Monitoring Reports	$36,000	$171,580	$52,900	$406,180	$0	$0	$83,200	$749,860
	One-time activities	*$4,000*	*$9,660*	*$1,380*	*$8,740*	*$0*	*$0*	*$0*	*$23,780*
	Ongoing activities each quarter	*$32,000*	*$161,920*	*$51,520*	*$397,440*	*$0*	*$0*	*$83,200*	*$726,080*
SECTION C: EVALUATION ACTIVITIES		**$108,500**	**$236,670**	**$93,840**	**$135,700**	**$29,440**	**$24,080**	**$57,600**	**$685,830**
7	Develop Evaluation Design	$5,250	$28,520	$7,590	$6,900	$0	$0	$0	$48,260
8	Produce Mid Point Assessment	$44,000	$40,250	$31,050	$17,480	$19,780	$9,460	$22,000	$184,020
9	Prepare Interim Evaluation	$24,000	$85,560	$20,470	$58,880	$0	$14,620	$19,600	$223,130
10	Prepare Summative Evaluation	$35,250	$82,340	$34,730	$52,440	$9,660	$0	$16,000	$230,420

ATTACHMENT C: TIMELINE AND MILESTONES

As part of the procurement process, Burns & Associates (B&A) was required to submit a work plan, including major tasks and milestones, to complete the entire scope of work. Presently, the State only has the authority to contract with B&A through February 28, 2022. There are deliverables due to CMS after February 28, 2022. In an effort to show the complete level of effort that would be proposed to complete all deliverables, B&A is showing a work plan that covers the entire evaluation period.

B&A has built a work plan that is constructed around the development of each deliverable identified as part of CMS required deliverables and the State's obligations related to monitoring and evaluation (M&E) activities. A summary of the work plan is shown beginning on the next page. Tasks are further detailed out by sub-task for internal tracking as well. Tasks are scheduled out by month.

The main sections of the work plan are as follows:

- Section A, ***Project Management***, includes Tasks 1, 2 and 3. The tasks in the section will be conducted across the entire engagement.
    - Deliverables in this section:
        - Monthly status and other project management reports
        - Reports on data validation of information received from the data warehouse

- Section B, ***Monitoring Activities***, includes Tasks 4, 5 and 6. It is anticipated that the work in this section will start immediately upon contract execution and continue until March 31, 2024.
    - Deliverable in this section:
        - Creation and maintenance of the analytic data warehouse specific to this project
        - Final Monitoring Protocol (April 30, 2020)
        - Quarterly/Annual Reports to CMS, in particular completion of CMS SUD Monitoring Reports Part A and B.
            - Quarterly reports due 60 days after each demonstration quarter
            - Annual reports due 90 days after each demonstration quarter
            - 16 deliverables in all—6 for quarters Q42020 – Q12022, then 10 additional quarters after this time period

- Section C, ***Evaluation Activities***, includes Task 7 through 10. It is expected that the work in this section will start immediately upon contract execution and continue until June 30, 2025.
    - Deliverable in this section:
        - Evaluation Design (Draft due May 15, 2020, Final due May 31, 2020)
        - Draft Version of Mid-Point Assessment (November 15, 2021)
        - Final Version of Mid-Point Assessment (December 31, 2021)
        - Detailed outline of the Interim Evaluation (August 31, 2022)
        - Draft Version of Interim Evaluation (November 30, 2022)
        - Final Version of Interim Evaluation (December 31, 2022)
        - Detailed outline of the Summative Evaluation (December 31, 2024)
        - Draft Version of Summative Evaluation (May 15, 2025)
        - Final Version of Summative Evaluation (June 30, 2025)