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 MEDICAID DEMONSTRATION WAIVER

FINAL DRAFT
FEBRUARY 25, 2021

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

Evaluation Team Members:

Mark Podrazik, Principal Investigator

Akhilesh Pasupulati
Ryan Sandhaus
Debbie Saxe
Barry Smith
Shawn Stack

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Listing of Exhibits

Abbreviations List

Abbreviation	Meaning
ACA	Affordable Care Act
AIDS	Acquired Immunodeficiency Syndrome
B&A	Burns & Associates, Inc.
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
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
ESRD	End Stage Renal Disease
FFS	Fee-For-Service
FG	Focus Groups
FI	Facilitated Interviews
FPL	Federal Poverty Level
HCBS	Home and Community-Based Services
HCPCS	Healthcare Common Procedure Coding System
HIV	Human Immunodeficiency Virus
I/DD	Intellectual and Developmental Disabilities
ICF/IDD	Intermediate Care Facilities for the Intellectually/ Developmentally Disabled

Abbreviation	Meaning
IMDs	Institutions for Mental Disease
ITS	Single Segment Interrupted Time Series
LOC	Level of Care
LTC	Long-Term Care
LTSS	Long-Term Services and Supports
MCO	Managed Care Organization
MLTSS	Managed Long-Term Services and Supports
NCQA	National Committee for Quality Assurance
NEMT	Non-Emergency Medical Transportation
NF	Nursing Facility
OPPS	Outpatient Prospective Payment System
OR	Onsite Reviews
PACE	Program for All Inclusive Care for the Elderly
PCP	Primary Care Provider
PROMISE	Promoting Optimal Mental Health for Individuals through Supports and Empowerment
PS	Provider Surveys
QCMMR	Quality and Care Management Measurement and Reporting
QCMMR Plus	Quality and Care Management Measurement and Reporting Plus
QI	Qualifying Individuals
QMB	Qualified Medicare Beneficiaries
RCT	Randomized Control Trials
SFY	State Fiscal Year
SLMB	Specified Low Income Medicare Beneficiary
SPMI	Severe and Persistent Mental Illness
SSI	Supplemental Security Income
STC	Special Terms and Conditions
SUD	Substance Use Disorder
TCM	Targeted Case Management
TEFRA	Tax Equity and Fiscal Responsibility Act

SECTION I: GENERAL BACKGROUND INFORMATION

I.A INTRODUCTION[1]

Delaware has had a long-standing Section 1115(a) demonstration which was originally approved in 1995 and then implemented effective January 1, 1996. The demonstration waiver was selected as a mechanism to allow Delaware to improve the health status of low-income Delawareans through use of a managed care delivery system. The waiver was also created to expand access to healthcare to more individuals throughout the State using the savings achieved through mandatory enrollment of eligible populations into managed care.

Over the years, Delaware has amended the waiver to add populations and services to the demonstration. The most current extension was approved on July 31, 2019. The latest waiver renewal contains an amendment intended to expand substance use disorder (SUD) services in the demonstration by including expenditure authority for services in institutions for mental diseases (IMD) as well as maintaining existing non-SUD services for beneficiaries.

Delaware continues to use the Diamond State Health Plan (DSHP) 1115 Demonstration to improve the health status of low-income Delawareans by using the goals as described in Section I.C to guide the administration and implementation of the demonstration.

I.B NAME, APPROVAL DATE AND TIME PERIOD COVERED

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: Demonstration extension from August 1, 2019 through December 31, 2023.

Note that this 1115 Evaluation Design Plan covers the non-SUD portion of Delaware's 1115 Diamond State Health Plan waiver. The 1115 SUD Evaluation Design Plan will be submitted as a separate independent evaluation plan.

I.C DEMONSTRATION GOALS[2]

Delaware's goals in operating the demonstration are to improve the health status of low-income Delawareans by:

1. Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to home and community-based services (HCBS);
2. Rebalancing Delaware's LTC system in favor of HCBS;

[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] Ibid, pages 9-10 of 166

3. Promoting early intervention for individuals with, or at-risk, for having, LTC needs;
4. Increasing coordination of care and supports;
5. Expanding consumer choices;
6. Improving the quality of health services, including LTC services, delivered to all Delawareans;
7. Creating a payment structure that provides incentives for resources to shift from institutions to community-based long-term care services and supports (LTSS) services where appropriate;
8. Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles;
9. Improving overall health status and quality of life of individuals enrolled in Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE);
10. Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population; and
11. Increase enrollee access and utilization of appropriate 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.
12. Increasing access to dental services; decrease the percent of emergency department visits for non-traumatic dental conditions in adults; increase follow up with dentists after an emergency department visit for non-traumatic dental conditions in adults; and increase the number of adults with diabetes who receive an oral exam annually.

The approved waiver has five demonstration components:

1. The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.
2. The DSHP Plus program provides LTSS to certain individuals under the State Plan, and to certain demonstration populations.
3. The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.
4. Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.

5. Coverage for high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as IMDs.

I.D BRIEF DESCRIPTION AND HISTORY OF IMPLEMENTATION[3]

Delaware's Diamond State Health Plan 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.

Delaware achieved its objective of implementation of mandatory managed care focused on primary care in 1996 and invested the resulting waiver savings in Delaware's Medicaid eligibility coverage expansion to uninsured adults up to 100 percent of the federal poverty level (FPL). Long before Medicaid expansion under the Affordable Care Act, Delaware was a pioneer in coverage expansion for individuals who would otherwise not be eligible for Medicaid. Delaware built upon this success with the eventual expansion of coverage for family planning services, leading up to participating in Medicaid expansion under the Affordable Care Act (ACA) in 2014.

The demonstration has previously been renewed on June 29, 2000, December 12, 2003, December 21, 2006, January 31, 2011, and September 30, 2013.

Through an amendment approved by CMS in 2012, Delaware was authorized to the create 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. Additionally, this amendment expanded HCBS to include: (1) cost-effective and medically necessary home modifications; (2) chore services; and (3) home delivered meals.

In 2013, the demonstration was renewed and amended to provide authority to extend the low-income adult demonstration population to individuals with incomes up to 100 percent of the FPL until December 31, 2013. After that date, the demonstration population was not necessary because it was included under the approved state plan as the new adult eligibility group authorized under the ACA. The new adult group, for individuals with incomes up to 133 percent of the FPL, receive medical assistance through enrollment in MCOs pursuant to this demonstration. In addition, Delaware's authority for the family planning expansion program under this demonstration expired December 31, 2013 when individuals became eligible for Medicaid expansion or Marketplace coverage options.

The demonstration was amended in 2014 to authorize coverage for enhanced behavioral health services and supports for targeted Medicaid beneficiaries through a voluntary program called PROMISE starting

[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, Section II, pages 6-9 of 166

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.

Technical changes were incorporated into the demonstration in October 2017 and an amendment was approved in December 2017 to add coverage for out-of-state former foster care youth.

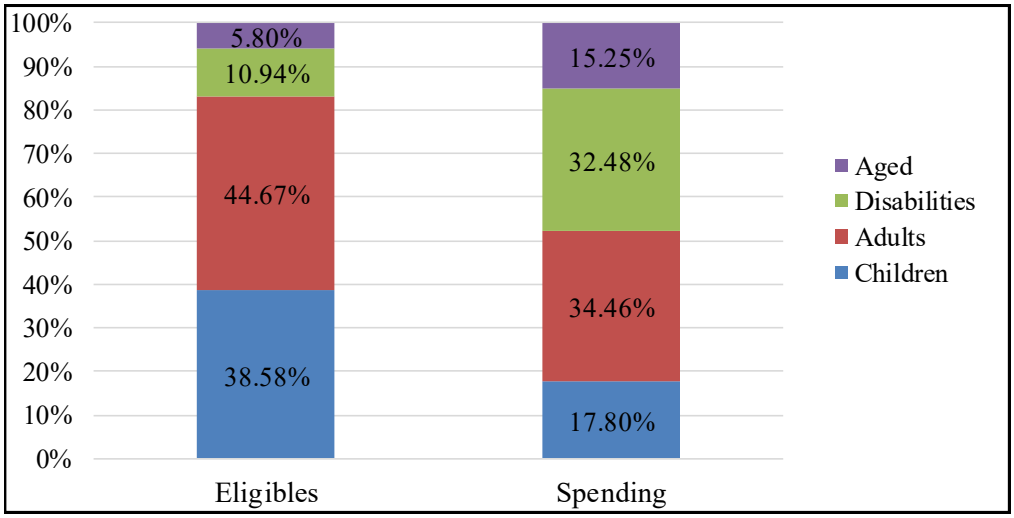
In June 2018, Delaware submitted a five-year demonstration extension and an amendment to provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an IMD. The demonstration was amended effective January 19, 2021 to add adult dental services to the services administered by the state's managed care system.

I.E POPULATION GROUPS IMPACTED

Overview 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. During State Fiscal Year (SFY) 2019, there were 293,091 unduplicated individuals eligible for Delaware's Medicaid program. Children comprise approximately 39 percent of enrollees whereas adults comprise approximately 45 percent. The aged and disabled comprise approximately 16 percent of the enrollees but almost 48 percent of the total Medicaid expenditures.

Exhibit I.1
Medicaid Enrollment and Spending: SFY 2019[4]



Delaware's Medicaid program provides access to healthcare through either a traditional FFS model or managed care. The majority of individuals eligible for Delaware Medicaid are enrolled in the Demonstration and receive services through one of the State's two risk-based managed care plans with either the DSHP or DSHP-Plus benefit plan.

The **Delaware Diamond State Health Plan (DSHP)** began in 1996 with mandatory enrollment in an MCO for eligible populations which includes State Plan Mandatory and Optional Medicaid Eligibility Groups, as well as Demonstration Eligible Groups. Specific populations enrolled in DSHP can be found in Exhibit I.2 on page I-6.

DSHP enrollees are entitled to receive all mandatory and optional state plans services approved under the Medicaid state plan and alternative benefit plan for the Medicaid expansion population. Services are primarily provided through a combination of contracts with MCOs. Some services, however, are delivered through FFS[5]:

[4] Joint Finance Committee Hearing testimony of Director Stephen M. Groff accessed at https://dhss.delaware.gov/dhss/files/dmma2021presentation_02262020.pdf

[5] 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, Section V, page 29 of 166

- Child dental
- Non-emergency medical transportation (NEMT), which is provided one transportation broker
- Day habilitation services authorized by the Division of Developmental Disabilities Services
- Medically necessary behavioral health services for children in excess of the MCO plan benefit coverage (which is 30 visits for children)
- Medically necessary behavioral health services for adults under the PROMISE program
- Prescribed pediatric extended care, and
- Targeted case management (TCM)

Exhibit I.2
Diamond State Health Plan Eligibility and Benefit Plan Groups[6]

Eligibility Group Description	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
State Plan Mandatory Medicaid Eligibility Groups			
Qualified Pregnant Women, Mandatory Poverty Level Related Pregnant Women	X		
Qualified Children, Mandatory Poverty Level Infants, Children Aged 1-5 and Children Aged 6-18	X		
SSI Adults without Medicare	X		
SSI Children without Medicare	X		
Section 4913 Children – lost SSI because of the PRWORA disability definition	X		
Parents and Caretaker Relatives	X		
Extended Medicaid due to Child or Spousal support Collections	X		
Transitional Medical Assistance	X		
Children with Title IV-E Adoption Assistance, Foster Care or Guardianship Care	X		
Continuous eligibility for pregnancy and postpartum period	X		
Deemed newborns	X		
Working disabled under 1619(b)	X		
Disabled Adult Children	X		
Institutionalized Individuals Continuously Eligible Since 1973		X	
Individuals Receiving Mandatory State supplements	X		
Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977 (Pickle amendment)	X		
Disabled widows/widowers ineligible for SSI due to an increase in OASDI	X		
Disabled early widows/widowers ineligible for SSI due to early receipt of Social Security	X		
SSI Adults with Medicare		X	
SSI Children with Medicare	X	X	
Former Foster Care Children	X		
Individuals who lost eligibility for SSI/SSP due to an increase in OASDI benefits in 1972	X		
State Plan Mandatory Medicaid Eligibility Groups			
Optional Infants less than one year old: Optional targeted low-income children Title XXI funding	X		
Adult Group ages 19-64			X
TEFRA Children (Katie Beckett) Qualified Disabled Children under 19	X		
Individuals who would be eligible for SSI/OSS if not for residing in an institutional setting		X	
Children with Non-IV-E Adoption Assistance	X		
Optional State Supplement Recipients – 1634 States, and SSI Criteria States with 1616 Agreements individuals living in an adult residential care facility or assisted living facility	X	X	
Optional State supplement – individuals who lose eligibility for Medicaid due to receipt of SSDI and are not yet eligible for Medicare	X		
Institutionalized individuals in Nursing Facilities who meet the Nursing Facility LOC criteria in place at the time of enrollment into the facility (with and without Medicare) even if they later do not meet the current LOC criteria		X	
Ticket to Work Basic Group	X	X	
Out-of-State Former Foster Care Children	X		
Demonstration Eligible Groups			
TEFRA-Like Children (Katie Beckett) using the "at-risk of NF" LOC criteria in place at time of enrollment	X		
Aged and/or disabled categorically needy individuals over age 18 who meet the Nursing Facility LOC criteria in place at the time of HCBS enrollment and receive HCBS as an alternative (formerly served through an Elderly & Physically Disabled 1915c Waiver)		X	
Individuals with a diagnosis of AIDs or HIV over age 1 who meet the Hospital LOC criteria and who receive HCBS as an alternative (formerly served through an AIDS/HIV 1915c Waiver)		X	
Aged and/or disabled individuals over age 18, who do not meet a NF LOC, but who, in the absence of HCBS, are "at-risk" of institutionalization and meet the "at-risk" for NF LOC criteria in place at the time of enrollment and who need/are receiving HCBS		X	

* Any individual needing Nursing Facility services and is eligible for such services will receive Nursing Facility services through DSHP Plus.

[6] 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, Section IV Table A, pages 16-25 of 166

The **Delaware Diamond State Health Plan Plus (DSHP-Plus)** was created through an amendment approved by CMS in 2012 as Delaware's MLTSS program. In DSHP-Plus, additional state plan populations are required to receive services through MCOs, such as those listed in Exhibit I.2 on the previous page. Members enrolled in DSHP-Plus have more complex medical needs than those enrolled in DSHP. In addition to DSHP services, the DSHP-Plus benefit package includes the services in Exhibit I-3 below. Participants have the option to self-direct some of these HCBS services.

Exhibit I.3
DSHP-Plus HCBS Benefit Plan[7]

Service	Provider Directed	Participant Directed
Adult Day Services	X	
Case Management	X	
Cognitive Services	X	
Community Based Residential Alternatives	X	
Day Habilitation	X	
Home Delivered Meals	X	
Independent Activities of Daily living (Chore)	X	X
Minor Home Modifications	X	
Nutritional Supports	X	
Personal Care/Attendant Care	X	X
Personal Emergency Response System	X	
Respite	X	X
Specialized Medical Equipment & Supplies	X	
Support for Participant Direction	X	

Traditional Medicaid (FFS) is comprised of the remaining Medicaid enrollees who are not enrolled in DSHP or DSHP-Plus. Specifically, the following populations and services are covered under Traditional Medicaid and do not receive benefits through the demonstration[8]:

- Program for All Inclusive Care for the Elderly (PACE)
- Qualified Medicare Beneficiaries (QMB)
- Specified Low Income Medicare Beneficiary (SLMB)
- Qualifying Individuals (QI)
- Qualified and Disabled Working Individuals
- Individuals in a hospital for 30 or more consecutive days
- Presumptive Breast and Cervical Cancer for Uninsured Women
- Breast and Cervical Cancer Program for Women
- Individuals residing in an Intermediate Care Facility for Individuals with Intellectual Disabilities

[7] 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, Section VI, page 30-31 of 166
[8] Ibid, Section IV Table B, page 26-27 of 166

Enrollment at a Glance

Enrollment in Delaware's Medicaid program has experienced a slight decline but overall remains relatively stable near 300,000 unique beneficiaries from SFY 2017 through SFY 2019 (refer to Exhibit I.4).

During this same time period, the majority of Delaware's Medicaid beneficiaries participated in the Demonstration (87-90%). The Demonstration population increased from SFY 2017 to SFY 2019 (refer to Exhibit I.5).

Exhibit I.4 Number of Unique Beneficiaries

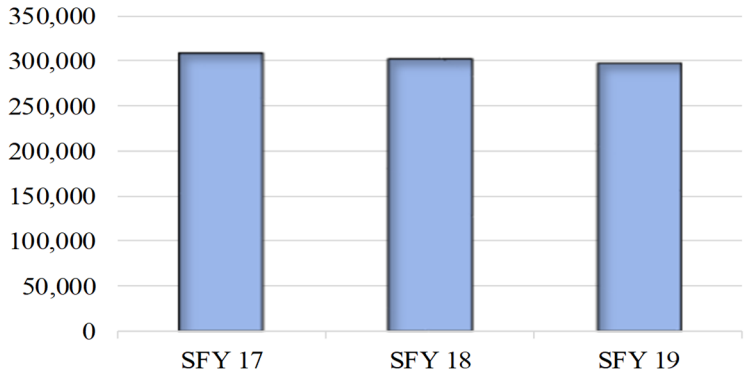
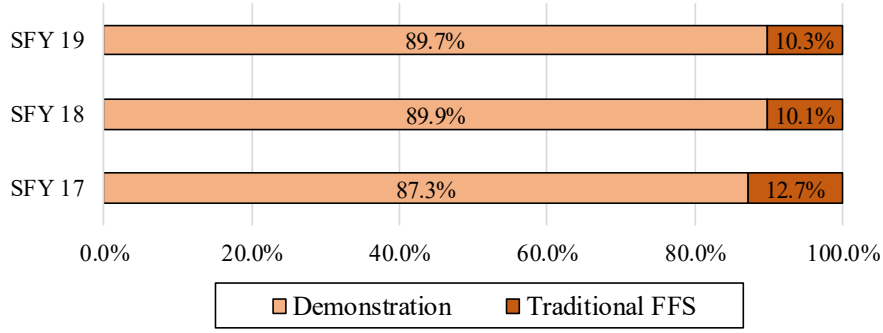


Exhibit I.5 Unique Beneficiaries by Delivery System



Of those members enrolled in the demonstration in SFY 2019, 56.4% were Caucasian, 40.5% were African-American, and 3.1% were other race/ethnicities (refer to Exhibit I.6).

Exhibit I.6 Demonstration Population by Race

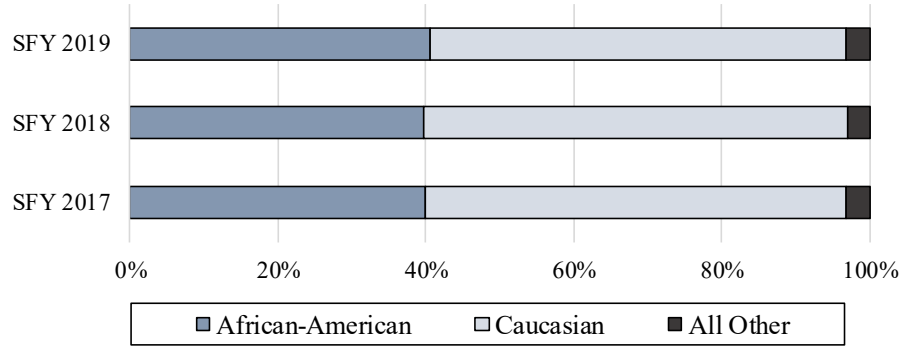
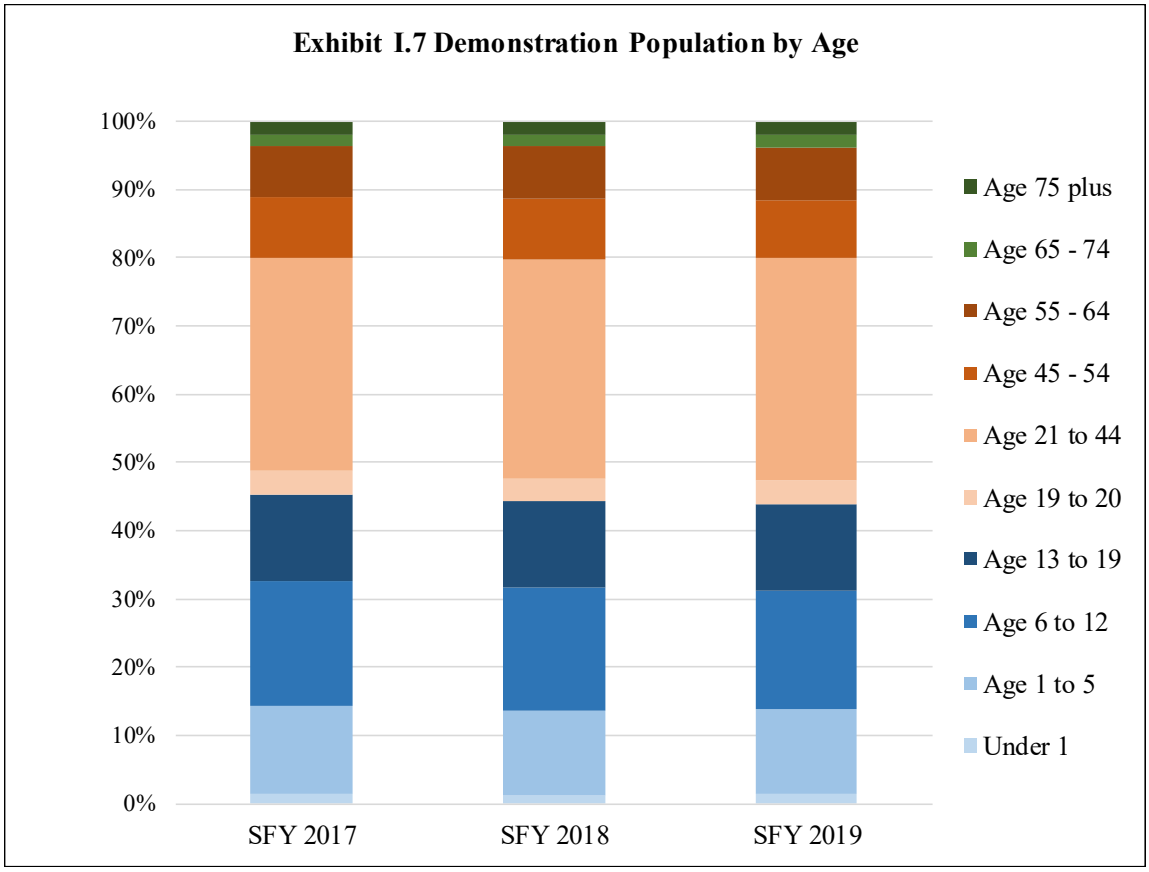


Exhibit I.7 distributes enrollment in the demonstration by the age of the members. In this exhibit, the blue colors represent different age groups among children while the peach/orange colors represent different age groups among adults age 64 and under. The green colors represent adults age 65 and older.



SECTION II: EVALUATION QUESTIONS AND HYPOTHESES

II.A Translating Demonstration Goals into Quantifiable Targets for Improvement

Burns & Associates, a Division of HMA (B&A), the State's Independent Evaluator, examined the relationships between the CMS domains of focus and the Delaware Medicaid demonstration components and goals included in the approved 1115 waiver and special terms and conditions (STCs). To begin development of an evaluation design that is responsive to CMS guidance, each demonstration component was linked to waiver goals and the suggested domains of focus as found in the matrix in Exhibit II.1. Note that demonstration component five and waiver goal eleven will be addressed separately in the 1115 SUD Evaluation Design Plan; therefore, neither is included in this 1115 Demonstration Evaluation Design Plan.

Exhibit II.1
Linking Demonstration Components to Waiver Goals and Domains of Focus

		Demonstration Components				
		C.1	C.2	C.3	C.4	C.5
		Managed Care Delivery System	Managed LTSS	PROMISE	Former Foster Care	SUD IMD
Waiver Goals						
G.1	Access improves and provides increasing options for MLTSS	X	X			
G.2	Rebalancing LTC in favor of HCBS		X			
G.3	Promote early intervention for at risk for LTC		X			
G.4	Increase care coordination and supports	X	X		X	
G.5	Expand consumer choice	X	X		X	
G.6	Improve quality of health services, including LTC	X	X		X	
G.7	Payment structure incentivizes shift from institution to community LTSS		X			
G.8	Duals integration		X			
G.9	PROMISE improves enrollee overall health status and quality of life			X		
G.10	Increase and strengthen coverage for former foster care	X			X	
G.11	Increase access to and appropriate use of SUD services					X
G.12	Increase access to and appropriate use of dental	X				
Domain of Focus						
F.1	Rebalancing LTSS		X			
F.2	Early Intervention cost benefit for LTC		X			
F.3	MLTSS care coordination		X			
F.4	PROMISE care coordination and enhanced BH			X		
F.5	PROMISE enrollee health status and quality improvements			X		
F.6	Former foster care youth gain coverage and improved health outcomes	X			X	X
F.7	Impact of waiving retroactive eligibility and enrollment	X				X
F.8	Impact of adult dental on access and health outcomes	X				

II.B Defining Relationships: Waiver Policy, Short-term and Longer-term Outcomes

As part of the examination of the relationships between demonstration components, waiver goals, and the domains of focus, and due to the maturity of evaluating a long term demonstration, B&A constructed logic models delineating short-term and longer-term outcomes associated with the four principle policy objectives of the demonstration.

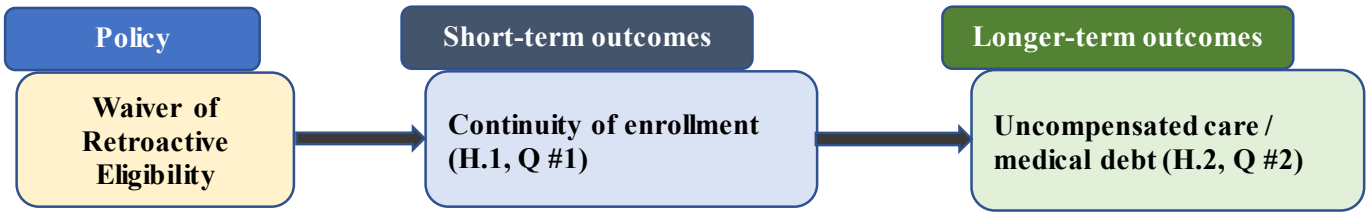
1. Maintain Continuity of Enrollment
2. Maintain Access to Care,
3. Maintain or Improve Health Outcomes, and
4. Rebalance Long-term Care Services and Supports (LTSS) in favor of Home and Community-based Services (HCBS).

The determination of whether an outcome is short-term or longer-term is dependent on the measure specifications including measurement period, and data needed to adequately assess trends with the waiver policy. For example, because national outcome measures tend to have annual measurement periods, they are considered in this evaluation to be longer-term indicators of policy outcomes. Each of the four principle policy objectives are described in detail and include logic models to illustrate both short-term and longer-term outcomes. Each logic model also provides a reference to specific hypotheses and research questions that will be described in Section II.C.

Maintain Continuity of Enrollment

B&A chose Maintain Continuity of Enrollment as the first policy objective as it is responsive to Waiver Goals #1 and #10 and Domain of Focus #7 which focus on access and an assessment of the impact of the waiver of retroactive eligibility. Exhibit II.2 illustrates the baseline assumption is that continuing the policy of waiving retroactive eligibility for specified Medicaid eligibility groups will not have an adverse impact on trends in continuity of Medicaid enrollment in the short term. On a longer-term basis, the assumption is that trends in uncompensated care and medical debt will not worsen over the course of the demonstration. Both process and outcome measures are proposed to assess impact.

Exhibit II.2
Logic Model 1: Maintain Continuity of Enrollment

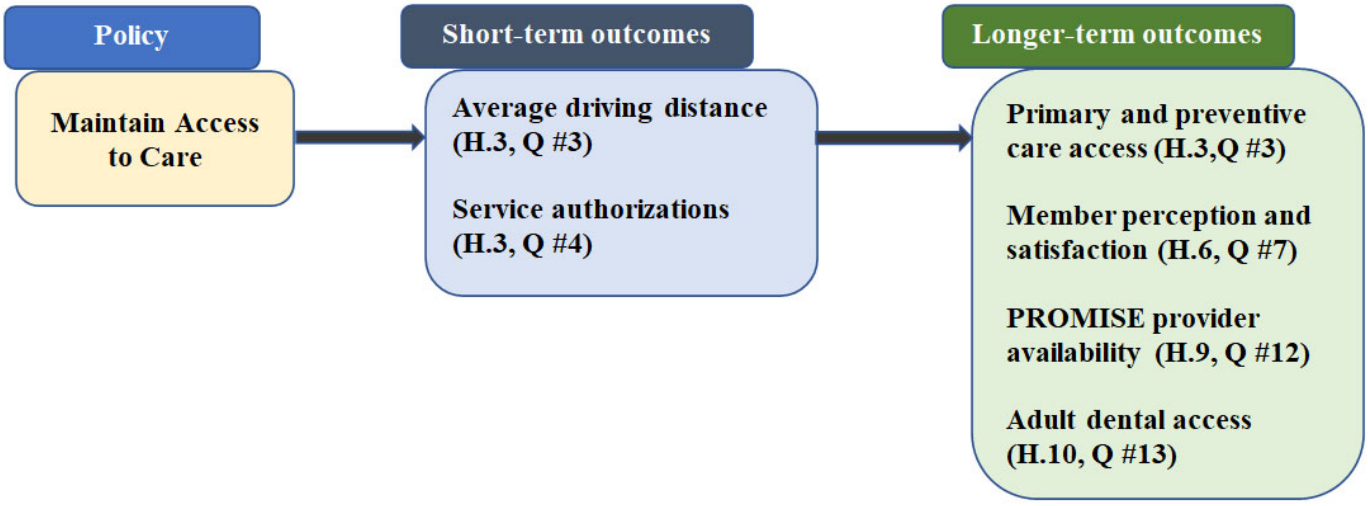


Maintain Access to Care

Maintain Access to Care is the second policy objective and it is based on Waiver Goal #1. Exhibit II.3 on the following page illustrates the assumption that trends in access to care continue or do not worsen. In the short term, a mix of outcome and process measures will be used to assess trends in access to care by focusing on average driving distance and service authorizations. To evaluate access to care on a longer-

term basis, B&A is proposing to use established outcome measures of access, measures of member perceptions, utilization and provider availability.

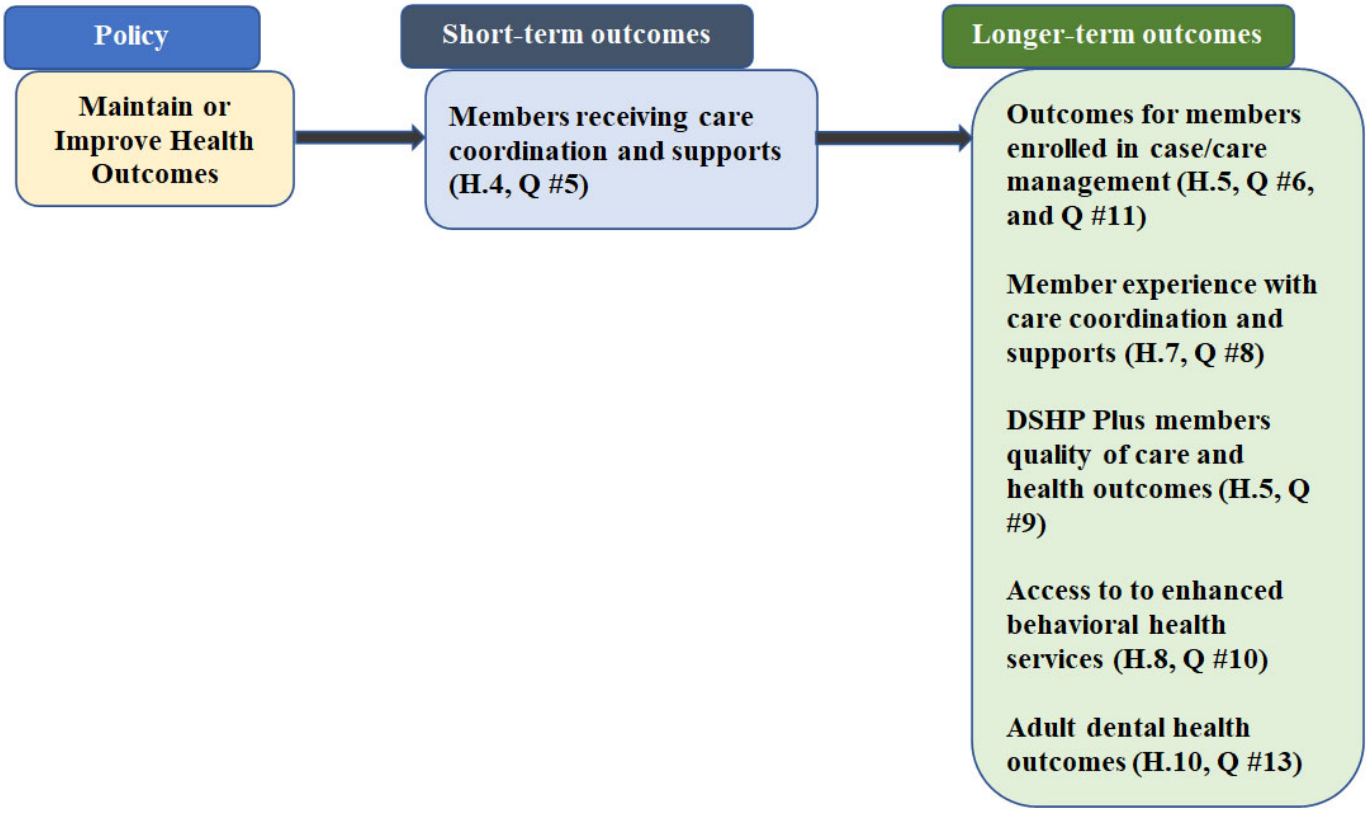
Exhibit II.3
Logic Model 2: Maintain or Improve Access



Maintain or Improve Health Outcomes

The third policy objective is Maintain or Improve Health Outcomes and it encompasses Waiver Goals #3, 4, 6, 9 and 12. Domains of Focus #3, 4, 5 and 8 which all focus on some of the most vulnerable Delaware Medicaid beneficiaries. Exhibit II.4 on the following page illustrates the assumption that Medicaid beneficiaries enrolled in the demonstration will maintain or improve health outcomes. In the short term, process measures will measure access to care coordination and supports. On a longer-term basis, national health outcome metrics and B&A customized process measures focusing on care coordination will complete the assessment of the third principle policy objective.

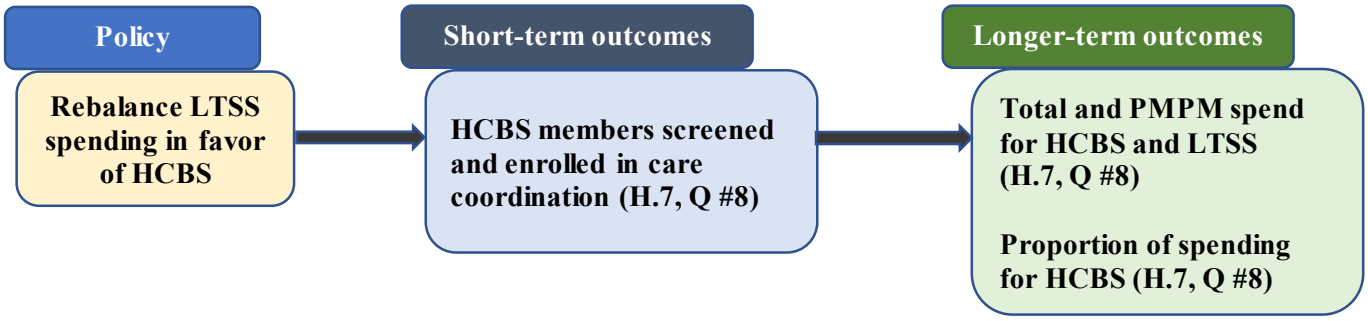
Exhibit II.4
Logic Model 3: Maintain or Improve Health Outcomes



Rebalance LTSS in favor of HCBS

Rebalance LTSS in favor of HCBS is the fourth policy objective and is based on Waiver Goals #2 and 7, and Domains of Focus #1 and #2. As depicted in Exhibit 5, the assumption is that over the course of the demonstration, rebalancing efforts will continue to maintain or increase utilization of HCBS services where appropriate. Member rates of screening and enrollment will be used to assess short-term impact. Longer-term impact will be assessed using a combination of utilization and expenditure metrics, and member satisfaction with their care coordination experiences.

Exhibit II.5
Logic Model 4: Rebalance LTSS spending in favor of HCBS



B&A found that there are existing, nationally-recognized outcome measures associated with principle policy objectives two and three, and the specifications and data sources for many of these measures were already described as part of Delaware Medicaid's Quality Strategy and are required to be reported by the managed care organizations. In addition to using nationally recognized outcome measures, B&A will fill gaps with custom measures developed by us where needed.

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

II.C Hypotheses and Research Questions

The four principle policy areas depicted in the logic models in Section II.B were converted into ten hypotheses (H) and thirteen research questions (Q); and the latter each assigned measures and targeted analytic methodology, described in detail in Section III. Methodology. As described in Section II.B, the evaluation has been constructed to measure trends in each of the demonstration's four long standing policy objectives and assess outcomes both on a short- or longer-term basis. Exhibit II.6 on the following page provides a high-level overview of each hypothesis and the associated research question. In most cases, the research question assesses impact either on a short- or longer-term basis, except for Q #3 and Q #8 which have measures that assess both short- and long-term impact.

Exhibit II.6
Hypotheses and Research Questions

Hypothesis	Research Question	Outcomes: Short-term	Outcomes: Longer-term
H.1: Trends in continuity of enrollment continue (or does not worsen) for Medicaid populations subject to the waiver of retroactive eligibility in the current waiver period.			
	Q #1: ***Does the waiver of retroactive eligibility continue (or does not worsen) the continuity of enrollment in Medicaid in the current waiver period?***	**X**	
H.2: The waiver of retroactive eligibility will continue or not worsen trends in uncompensated care or medical debt in the current waiver period.			
	Q #2: ***Does the waiver of retroactive eligibility continue or not worsen trends in the incidence of uncompensated care or not seeing a doctor because of cost in the current waiver period?***		**X**
H.3: Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.			
	Q #3: ***Does the level and trend of access to primary and preventive care continue (or not worsen) in the current waiver period?***	**X**	**X**
	Q #4: ***Do service authorizations provide an effective tool in the appropriate utilization of health care services in the current waiver period?***	**X**	
H.4: Trends in coordination of care and supports continues (or does not worsen) in the current waiver period.			
	Q #5: ***Does the proportion of members receiving care coordination and supports continue (or not worsen) in the current waiver period?***	**X**	
H.5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.			
	Q #6: ***Do DSHP members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***		**X**
	Q #9: ***Do DSHP Plus members achieve similar or improved quality of care and health outcomes in the current waiver period?***		**X**
	Q #11: ***Do PROMISE members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***		**X**
H.6: Trends in consumer satisfaction will continue (or not worsen) in the current waiver period.			
	Q #7: ***Does the level of satisfaction among DSHP members continue (or not worsen) in the current waiver period?***		**X**
H.7: Creating a delivery system that provides incentives for resources to shift from institutions to community-based LTSS has maintained or increased utilization of HCBS services where appropriate in the current waiver period.			
	Q #8: ***Has the rebalancing of long-term care services and supports maintained or moved more toward home- and community-based services and away from institutional services in the current waiver period?***	**X**	**X**
H.8: Trends in health outcomes will continue or improve in the current waiver period for individuals enrolled in the PROMISE program.			
	Q #10: ***Does the level and trend of access to enhanced behavioral health services continue (or not worsen) in the current waiver period?***		**X**
H.9: The PROMISE program network capacity will continue (or not worsen) in the current waiver period.			
	Q #12: ***Does the availability of PROMISE providers continue (or not worsen) in the current waiver period?***		**X**
H.10: The availability of the adult dental benefit will improve access to dental services and will continue (or not worsen) health outcomes in the current waiver period.			
	Q #13: ***Does the availability of the adult dental benefit increase access to dental services and lead to continued (or not worsen) health outcomes in the current waiver period?***		**X**

II.D Alignment with Demonstration Goals

As described in Section II.B, the demonstration components have been linked to the waiver goals and domains of focus. Building upon the matrix shown in Section II.B, each hypothesis was cross-referenced to demonstration goals and domains of focus. This was to ensure that the evaluation hypotheses and research questions are responsive to the CMS guidance in the approved waiver STCs. As demonstrated in Exhibit II.7, each hypothesis addresses at least one demonstration goal and, in many cases, cross multiple goals. Further, the evaluation design ensures that the domains of focus suggested by CMS in the approved waiver STCs are also addressed in this Evaluation Design Plan.

Exhibit II.7
Alignment of Hypotheses with Demonstration Goals and Domains of Focus

		Hypotheses									
		H.1	H.2	H.3	H.4	H.5	H.6	H.7	H.8	H.9	H.10
		Continuity of Enrollment	Uncomp. Care Medical Debt	Acces to Health Care	Coordination of Care & Supports	Coordination of Care & Supports Maintains Outcomes	Consumer Satisfaction	Resources Shift From LTSS to HCBS	Health Outcomes for PROMISE	PROMISE Network Capacity	Adult Dental Access and Outcomes
Waiver Goals											
G.1	Access improves and provides increasing options for MLTSS	X	X	X				X		X	
G.2	Rebalancing LTC in favor of HCBS							X			
G.3	Promote early intervention for at risk for LTC					X					
G.4	Increase care coordination and supports				X	X					
G.5	Expand consumer choice						X				
G.6	Improve quality of health services, including LTC					X					
G.7	Payment structure incentivizes shift from institution to community LTSS							X			
G.8	Duals integration				X						
G.9	PROMISE improves enrollee overall health status and quality of					X			X		
G.10	Increase and strengthen coverage for former foster care	X	X								X
G.11	Increase access to and appropriate use of SUD services	Addressed in SUD Evaluation Design Plan									
G.12	Increase access to and appropriate use of dental services										X
Domain of Focus											
F.1	Rebalancing LTSS							X			
F.2	Early Intervention cost benefit for LTC							X			
F.3	MLTSS care coordination				X						
F.4	PROMISE care coordination and enhanced BH services				X						
F.5	PROMISE enrollee health status and quality improves								X	X	
F.6	Former foster care youth gain coverage and improved health			X							X
F.7	Impact of waiving retroactive eligibility and enrollment	X	X								
F.8	Impact of adult dental on access and health outcomes										X

II.E How Hypotheses and Research Questions Promote Objectives of Titles XIX and XXI

The Evaluation Design Plan hypotheses were also cross referenced with the objectives of the Medicaid program[9] to ensure that the plan promotes the objectives of Titles XIX and XXI of the Social Security Act as required in Attachment F of the approved waiver STCs. As demonstrated in Exhibit II.8, each hypothesis addresses at least one objective and, in some cases, multiple objectives of the Medicaid and Children's Health Insurance Program (CHIP).

Exhibit II.8
Alignment of Hypotheses with Medicaid and CHIP Program Objectives

		Hypotheses									
		H.1	H.2	H.3	H.4	H.5	H.6	H.7	H.8	H.9	H.10
		Continuity of Enrollment	Uncomp. Care Medical Debt	Acces to Health Care	Coordination of Care & Supports	Coordination of Care & Supports Maintains Outcomes	Consumer Satisfaction	Resources Shift From LTSS to HCBS	Health Outcomes for PROMISE	PROMISE Network Capacity	Adult Dental Access and Outcomes
Objectives of Medicaid and Children's Health Insurance Program											
O.1	Improve access to services that produce positive health outcomes	X	X	X		X	X				X
O.2	Promote efficiencies							X			
O.3	Support coordinated strategies to address certain health determinants				X	X			X		X
O.4	Strengthen beneficiary engagement	X	X		X	X	X	X			
O.5	Enhance alignment between Medicaid policies and commercial health insurance	X						X			X
O.6	Advance innovative delivery system and payment models							X		X	

[9]Accessed at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html

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 thirteen 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 five analytic methods included in the evaluation design.

The five analytic methods proposed for use across the ten hypotheses and thirteen 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.

As described in Section II.B, the majority of the hypotheses and associated research questions focus on whether the 1115 Demonstration made an impact on key DMMA waiver goals (i.e., short-term and longer-term outcomes). In order to facilitate evaluation on whether a statistically significant difference between the pre-waiver and current waiver period can be detected, the data, measures and methods for these research questions will be tested using healthcare claims, member enrollment data, MCO report submissions and provider enrollment data. The proposed metrics blend nationally-recognized measure specifications with custom metrics developed by B&A (where national metrics are unavailable). Analytic methods include ITS and descriptive statistics using chi-square tests or t-tests as applicable.

The focus shifts to assessing member perception to measure consumer satisfaction, choice, and quality. Given that these require information beyond what is available in claims or other public data sets, this section draws upon a set of mixed methods to evaluate progress. Where possible, measures will be incorporated into a reporting dashboard that tracks results from the pre-waiver period and the waiver-to-date period. Wherever possible, data will be tracked and reported on a quarterly basis.

Exhibit III.1
Summary of Five Analytic Methods by Hypotheses

	Hypothesis Description	Method					Analytic Method Examples
		DS	ST	OR	DR	FI	
1	Trends in continuity of enrollment continue (or does not worsen) for Medicaid populations subject to the waiver of retroactive eligibility in the current waiver period.	X		X	X	X	**DS**: trends in frequencies and percentages of time span from application to enrollment stratified by aid category, assignment plan, delivery system). **OR**: Eligibility Process Review (2 rounds). Data sources: enrollment data.
2	The waiver of retroactive eligibility will continue or not worsen trends in uncompensated care or medical debt in the current waiver period.	X		X	X	X	**DS**: trends in DE-reported percentages over the demonstration period; comparison to baseline period and available national and regional values. Data sources: reports submitted by hospitals, BRFSS Health Care Access Module, interviews with members.
3	Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.	X	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests of significance; ITS. **OR**: Eligibility Process Review and Service Authorizations focus studies (2 rounds for each). Data sources: claims and enrollment data, reports submitted by MCOs (validated by B&A).
4	Trends in coordination of care and supports continues (or does not worsen) in the current waiver period.	X		X	X	X	**DS**: trends tracked separately for (1) PROMISE enrollees, (2) DSHP Plus eligibles, (3) selected special health care need categories. **OR**: Care Coordination and Transitions to Care focus studies (2 rounds for each). Data sources: claims, reports submitted by MCOs
5	Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.	X	X	X	X	X	**DS**: trends in frequencies and percentages. **ST**: chi square or t-tests comparing target population to baseline, with stratification to sub-population based on metric; ITS. Data sources: claims, reports submitted by MCOs
6	Trends in consumer satisfaction will continue (or not worsen) in the current waiver period.	X	X		X	X	**ST**: chi square or t-tests of significance comparing target population to baseline, stratified by MCO, adults and children; ITS. **OR**: Critical Incidents, Appeals and Grievances focus study (2 rounds). Data sources: CAHPS survey results, reports submitted by MCOs quarterly to DMMA, ad hoc reports for sub-population reporting, as needed.
7	Creating a delivery system that provides incentives for resources to shift from institutions to community-based LTSS has maintained or increased utilization of HCBS services where appropriate in the current waiver period.	X	X	X	X	X	**ST**: chi square or t-tests of significance comparing target population to baseline; ITS. **OR**: Care Coordination and Transitions to Care focus studies (2 rounds of each). Data sources: claims, reports submitted by the MCOs (validated by B&A), a targeted member survey.
8	Trends in health outcomes will continue or improve in the current waiver period for individuals enrolled in the PROMISE program.	X	X		X		**ST**: chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline; ITS. Data sources: claims, reports submitted by MCOs quarterly to DMMA.
9	The PROMISE program network capacity will continue (or not worsen) in the current waiver period.	X	X		X		**DS**: trends rates stratified by MCO and region. **ST**: chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline. Data sources: claims, provider enrollment data.
10	The availability of the adult dental benefit will improve access to dental services and will continue (or not worsen) health outcomes in the current waiver period.	X	X	X	X	X	**DS**: trends rates stratified by MCO and region. **ST**: chi square or t-tests of significance comparing target population to baseline; ITS. **OR**: Baseline Access to Dental Care focus studies (two rounds), with Dental Transitions to Care (in round two). Data sources: claims, provider enrollment data, reports submitted by MCOs.

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 enrolled in the demonstration in the study period. B&A will use Section IV, Table A in the approved waiver STCs as the basis for identification of beneficiaries enrolled in the demonstration. B&A will create flags to identify Medicaid members and providers that will be part of the analytics. Flags will be assigned to attribute individuals to each sub-population group which includes, but is not limited to:

- MCO enrolled with
- DSHP and DSHP Plus enrollment
- Member enrolled in PROMISE
- Native American status
- Member former foster care status
- Member age (for specified age groups)
- Member home location (e.g., city/county/region)
- Member dual eligible status
- New member enrollment due to COVID

There will also be flags assigned to providers. The provider type and specialty will be tracked. B&A will use these indicators and create other flags that may require the joining of existing variables to assign providers by:

- Regional location
- Level of care
- Newly-enrolled and long-standing enrolled providers

The matrices included in Section III.G identify the target population and stratification proposed for each hypothesis and research question.

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.[10] Specifically, a Medicaid population with similar demographics but 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 Medicaid privacy concerns as it relates to data sharing is not feasible; therefore, it is outside the scope of this evaluation. 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.

Available results from CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP and the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults will be used as a benchmark comparator for those nationally-recognized metrics included in the evaluation design. Results of these measures are reported at a statewide level by Medicaid program. In this case, comparator states will be identified and included within the Summative Evaluation. Comparator states will be chosen in consultation with the State, CMS and other stakeholders.

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

III.C Evaluation Period

A pre-waiver and current wavier period will be defined as three calendar years before and five calendar years after waiver implementation. The pre-waiver period is defined as enrollment or dates of service from January 1, 2016 through December 31, 2018. The current waiver period is defined as enrollment or dates of service from August 1, 2019 through December 31, 2023. In support of the analytic methods described in Section III.F, the calendar year data will be further defined into both monthly and quarterly segments such that both the pre-periods will include 12 quarters or 36 months from the pre-waiver period, and 20 quarters or 60 months from the current waiver period.

To simplify the analytic plan, B&A is making an assumption about the first seven months of 2019 prior to the waiver being approved. For annual measures in which a national steward has defined measure specifications, B&A will consider the entire 12 months of CY 2019 in the period prior to the current approved demonstration that became effective August 1, 2019. Although CMS approved Delaware's 1115 waiver in July 2019, waiver-related activities were moving forward in anticipation of approval of the extension. For ease of conducting and describing the analysis, the evaluation period will include the seven months in the calendar year prior to July 2019 approval as the current waiver period for monthly and quarterly metrics. For annual metrics, January 1, 2020 through December 31, 2023 will be considered the demonstration period.

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 Design Plan directly relate to the four principle policy objectives and short-term and longer-term outcomes described in Section II. The measures fall into three primary domains: quality, access and financial. Exhibit III.2 on the following page summarizes the list of measures included in the evaluation plan. A comprehensive summary of measures, which includes measure stewards as well as a description of numerators and denominators, can be found in the detailed matrices in Section III.G.

Exhibit III.2 Evaluation Measures by Domain

Quality

- Rate of DSHP members with special health care needs screened for care coordination
- Of those members with special health care needs screened, the number enrolled in care coordination
- Duration of enrollment within case/care management
- Prenatal care for pregnant women (PPC), control groups those in/not in case/care management
- Follow-Up After Hospitalization for Mental Illness (FUH)
- Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)
- Follow-Up After Emergency Department Visit for People With Multiple High-Risk Chronic Conditions (FMC)
- Getting Needed Care Composite
- Getting Care Quickly Composite
- How Well Doctors Communicate Composite
- Rating of Personal Doctor
- Rating of Health Plan
- Grievances per 1000 members
- Total number of grievances by category
- Appeals per 1000 members
- Total number of appeals by category
- Critical incidents per 1000 members
- Rate of members needing HCBS services screened for care coordination
- Of those members needing HCBS services screened, the number enrolled in care coordination
- Member experience with care coordination and supports
- Annual Monitoring for Patients on Persistent Medications
- Medication Adherence Rates - Percent of Days Covered (PDC)
- Comprehensive Diabetes Care (CDC)
- Plan All-Cause Readmissions (PCR)*
- Rate of identified members who enroll in PROMISE
- Follow-Up After Hospitalization for Mental Illness (FUH)
- Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)
- Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence*
- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment*
- Antidepressant Medication Management (AMM)
- Ambulatory Care Sensitive Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDV-A-A)
- Follow-up after Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDF-A-A)
- Adults with Diabetes – Oral Evaluation (DOE-A-A)

Access

- Well-Child Visits in the First 15 Months of Life (W15)
- Well-Child Visits in the Third, Fourth, Fifth and Sixth Years of Life (W34)
- Adolescent Well-Care Visits (AWC)
- Adults' Access to Preventive/Ambulatory Health Services (AAP)
- Breast Cancer Screening (BCS)
- Proportion of enrollees continuously enrolled in Medicaid by aid category, delivery system, MCO
- Enrollment duration by aid category
- Medicaid enrollment counts by month and aid category
- Time span from application to enrollment in Medicaid
- Average turnaround time for authorization decisions
- Could Not See Doctor Because of Cost
- Self-identified trends in medical debt
- Rate of approved and denied authorizations
- Frequency and percentage of denial reason codes
- Utilization of HCBS services per 1000 members
- Emergency Department (ED) visits per 1000
- Emergency Department (ED) Frequent Flyer rate
- Average driving distance to primary care services
- Behavioral health providers per 1000 members by geographical region
- HCBS providers per 1000 members by region
- Utilization of dental services per 1000 members
- Dental providers per 1000 members by region
- Average driving distance to dental care services

Financial

- Spending in total and on a per member month basis for HCBS services
- Spending in total and on a per member month basis for institutional LTSS services
- Proportion of spending for HCBS services
- Rate of hospital reported uncompensated care

* Denotes metric that is also part of the SUD Evaluation.

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 will include data created by desk review and facilitated interview instruments. A brief description of these data and their strengths and weaknesses follow.

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 current demonstration time 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.

Survey and Facilitated Interview Data

CAHPS® Health Plan Survey 5.0 (Medicaid)[11]

The Consumer Assessment of Healthcare Providers & Systems (CAHPS)® Health Plan Survey is a survey of Medicaid beneficiaries enrolled in managed care used to identify their experiences with health plans and services. It is used to assess performance of health plans which provide access to health care for Delaware's demonstration enrollees. Data is reported for adults, children, and at the MCO level and will be used to review for descriptive trends over time using chi square tests of significance.

Facilitated Interview Guides

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 are identified at the metric level in Section III. G. Respondents will include the MCOs, non-SUD providers, non-SUD beneficiaries, PROMISE providers and PROMISE 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.

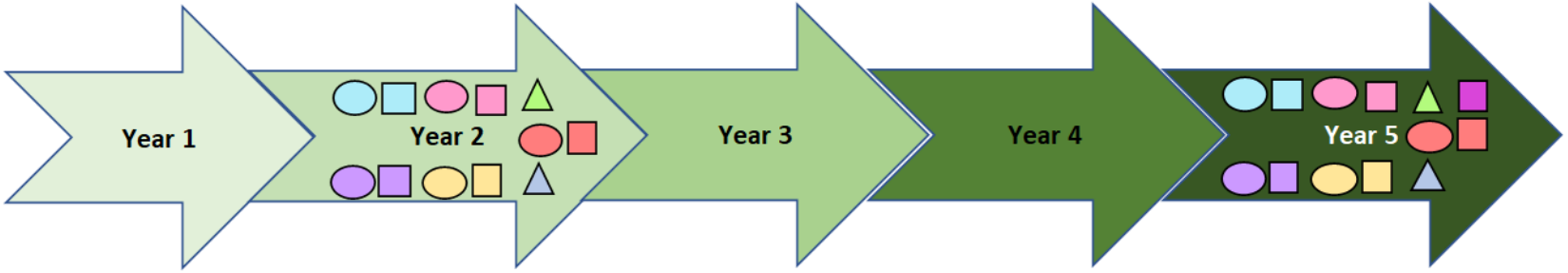
Whereas the Delaware Medicaid administrative data will be collected and used on a monthly basis throughout the waiver period and after the waiver concludes to produce the Summative Evaluation, B&A anticipates that data from our sources will be collected in CY 2021 and CY 2024 for use in evaluation activities. Exhibit III.3 that appears on page III-8 contains the proposed primary data collection activities by source, year, and hypotheses. Exhibit III.4 that appears on page III-9 demonstrates the proposed primary data collection timeline by type, year, and hypotheses.

[11] Accessed at https://www.ahrq.gov/cahps/surveys-guidance/hp/index.html

Exhibit III.3
Proposed Primary Data Collection Activities, by Source, Year and Hypotheses

		Desk / Onsite Review			Facilitated Interviews / Focus Groups			
	Source	**MCOs**	**Other State Partners**	**State Agencies**	**Members**	**Other State Partners**	**State Agencies**	**MCOs**
Hypotheses	**Contract Year 1, CY 2020**							
	All Hypotheses			X				
	Contract Year 2, CY 2021							
	1 Continuity of Enrollment		X	X				
	2 Uncompensated Care/Medical Debt			X	X			
	3 Trends in Access to Care	X	X	X		X	X	X
	4 Trends in Coordination of Care and Supports	X	X	X		X	X	X
	5 Coordination of Care and Supports Maintains Outcomes	X	X	X		X	X	X
	6 Trends in Consumer Satisfaction	X	X	X		X	X	X
	7 Resources Shift From LTCF to HCBS				X			
	8 Trends in Health Outcomes for PROMISE							
	9 PROMISE Network Capacity							
	10 Adult Dental Access and Outcomes							
	Contract Year 3, CY 2022							
	All Hypotheses			X				
	Contract Year 4, CY 2023							
	All Hypotheses			X				
	Contract Year 5, CY 2024							
	1 Continuity of Enrollment		X	X				
	2 Uncompensated Care/Medical Debt			X	X			
	3 Trends in Access to Care	X	X	X		X	X	X
	4 Trends in Coordination of Care and Supports	X	X	X		X	X	X
	5 Coordination of Care and Supports Maintains Outcomes	X	X	X		X	X	X
	6 Trends in Consumer Satisfaction	X	X	X		X	X	X
	7 Resources Shift From LTCF to HCBS				X			
	8 Trends in Health Outcomes for PROMISE							
	9 PROMISE Network Capacity							
	10 Adult Dental Access and Outcomes	X						X

Exhibit III.4
Proposed Primary Data Collection Timeline, by Type, Year and Hypotheses



Hypotheses

1 Continuity of Enrollment
2 Uncompensated Care/Medical Debt
3 Trends in Access to Care
4 Trends in Coordination of Care and Supports
5 Coordination of Care and Supports Maintains Outcomes
6 Trends in Consumer Satisfaction
7 Resources Shift From LTCF to HCBS
8 Trends in Health Outcomes for PROMISE
9 PROMISE Network Capacity
10 Adult Dental Access and Outcomes

Desk Review/Onsite Review
Member Survey
Facilitated Interview/Focus Group

* Years correspond to Independent Evaluator contract years, with Year 1 beginning in 2020. Note: 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.

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 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 small population size 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 non-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:[12]

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.
- 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.

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

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.[13,14,15] As it would not be ethical or consistent with Medicaid policy to withhold services resulting from waiver changes from

[13] 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.
[14] Victora CG , Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. Am J Public Health 2004;94:400–05.
[15] 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.

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.[16,17,18]

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.[19] 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.

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.

[16] 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.
[17] 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.
[18] 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
[19] 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/dyw09 8

Regression Analysis

Wagner et al. described the single segmented regression equation as[20]:

$$\hat{Y}_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time\_after\_intervention_t + e_t$$

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

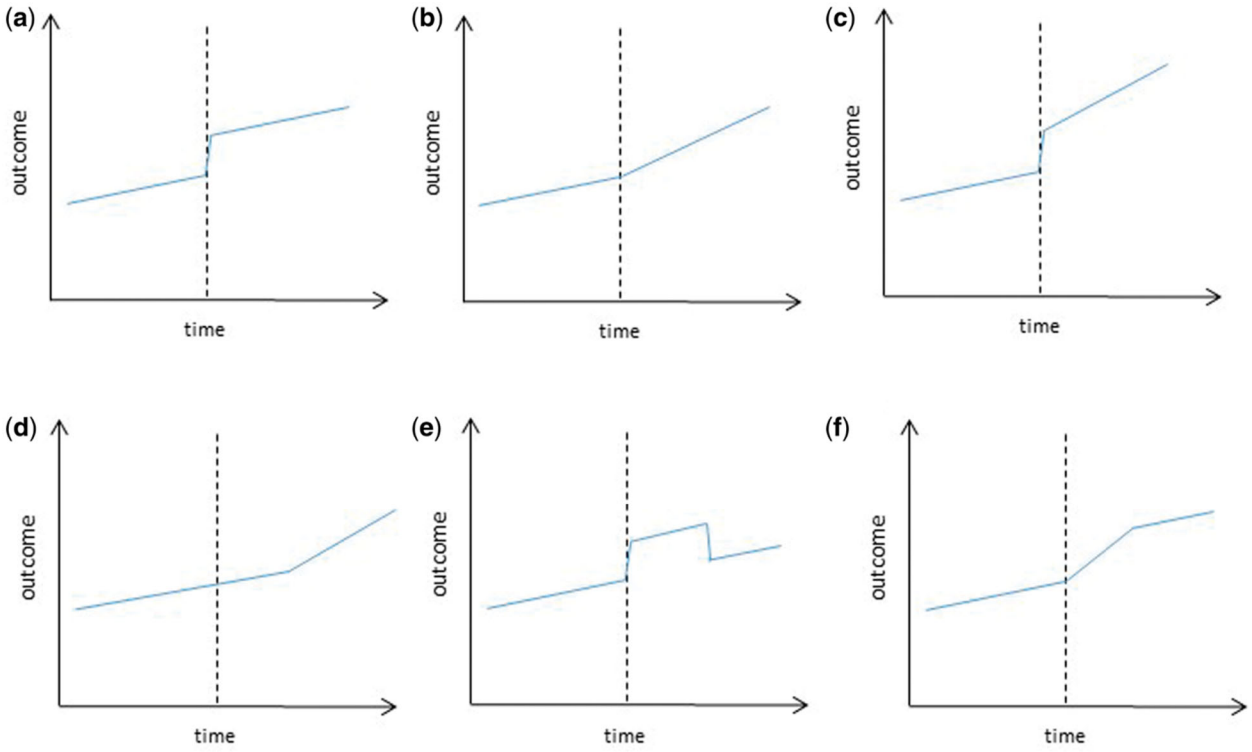
β_3 estimates the change in trend in the post-intervention segment

e_t estimates the error

Visualization and interpretation will be done as depicted in the Exhibit III.5. 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.

[20] 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.5 Illustration of Potential ITS Relationships[21]



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.

[21] 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.

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. 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 non-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 non-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).

<u>Method #3: Onsite Reviews</u>

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
- Critical Incidents, Appeals and Grievances
- Eligibility Process Review
- Service Authorization

- Quality/Outcome Focused Study – topic to be finalized with DMMA

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, non-SUD providers, non-SUD beneficiaries, PROMISE providers and PROMISE 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 research question and hypothesis is presented. Attachment D contains the detailed evaluation matrix which presents the demonstration components and domains of focus for each research question and hypothesis.

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Does the waiver of retroactive eligibility continue (or does not worsen) the continuity of enrollment in Medicaid in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Evaluation Hypothesis #1: Trends in continuity of enrollment continue (or does not worsen) for Medicaid populations subject to the waiver of retroactive eligibility in the current waiver period.						
Short Term (Continuity of Enrollment)	Time span from application to enrollment in Medicaid	Burns & Associates, Inc.	Frequency distribution of enrollees by number of days from application to enrollment during the measurement period.		Enrollment data	Descriptive statistics (trends in frequencies and percentages of time span from application to enrollment stratified by aid category)
	Medicaid enrollment counts by month and aid category	Burns & Associates, Inc.	Count of enrollees by month and aid category during the measurement period.		Enrollment data	Descriptive statistics (trends in enrollment counts over time stratified by aid category)
	Medicaid Enrollment duration by aid category and assignment plan	Burns & Associates, Inc.	Frequency distribution of enrollees by the number of months of eligibility in the measurement period, stratified by aid category and assignment		Enrollment data	Descriptive statistics (trends in enrollment duration by aid category and assignment plan)
	Proportion of enrollees continuously enrolled in Medicaid by aid category, assignment plan and delivery system	Burns & Associates, Inc.	Frequency distribution of enrollees continuously enrolled 9 or more months in the measurement period, stratified by aid category, assignment plan and delivery system.	Total number of enrollees during the measurement period.	Enrollment data	Descriptive statistics (trends in the proportion of enrollees continuously enrolled by aid category, assignment plan and delivery system)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the waiver of retroactive eligibility continue or not worsen trends in the incidence of uncompensated care or not seeing a doctor because of cost in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Evaluation Hypothesis #2: The waiver of retroactive eligibility will continue or not worsen trends in uncompensated care or medical debt in the current waiver period.						
Long Term (Uncompensated Care)	Rate of hospital reported uncompensated care	Burns & Associates, Inc.	Hospital reported uninsured uncompensated care	Number of Delawareans expressed as per 1,000	DMMA Form DSH-1, Line 21	Descriptive statistics (trends in frequencies and percentages over the demonstration period) with comparison to baseline period
	Could Not See Doctor Because of Cost	CDC, BRFSS	Weighted percentage of respondents who reported there was a time over the past 12 months when they needed to see a doctor but could not because of cost (MEDCOST)		Health Care Access Module	Descriptive statistics (trends in Delaware reported percentages over the demonstration period); comparison to baseline period and available national and regional values
	Self-identified trends in medical debt for DSHP enrollees	Burns & Associates, Inc.	Number of respondents reporting if medical debt has improved, stayed the same or not worsened over the past twelve months	Total number of respondents.	Focus Group	Descriptive statistics (trends in frequencies and percentages over the demonstration period) with comparison to baseline period

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Does the level and trend of access to primary and preventive care continue (or not worsen) in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Evaluation Hypothesis #3: Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.						
Long Term (Access to Care)	Well-Child Visits in the First 15 Months of Life (W15)	NCQA	Number of children who turned 15 months old during the measurement year who had 6 or more well-child visits with a PCP	Number of children who turned 15 months old during the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Well-Child Visits in the Third, Fourth, Fifth and Sixth Years of Life (W34)	NCQA	Number of children who are 3 to 6 years old as of December 31 and had one or more visits with a PCP during the measurement year.	Number of children who are 3 to 6 years old as of December 31 of the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adolescent Well-Care Visits (AWC)	NCQA	Number of enrolled members age 12 to 21 years, as of December 31,who had at least one comprehensive well-care visit with a PCP or OB/GYN during the measurement year.	Number of enrolled members age 12 to 21 years as of December 31 of the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Breast Cancer Screening (BCS)	NCQA	Number of women age 50-54 years who had a screening mammogram as of December 31 in the measurement year.	Number of women age 50-54 years as of December 31 in the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adults' Access to Preventive/Ambulatory Health Services (AAP)	NCQA	Number of members who had an ambulatory or preventive care visit as of December 31 in the measurement year, reported using three age stratifications: 22-44 years; 45-64 years; 65+	Number of members as of December 31 in the measurement year, with counts for each of the three age stratifications: 22-44 years; 45-64 years; 65+ years.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
Short Term (Access to Care)	Average driving distance to primary care services	Burns & Associates, Inc.	Sum of the driving distances traveled from member home to their primary care provider	Sum of the unique trips to the member's primary care provider in the year	Claims data	Descriptive statistics (trends in average driving distance stratified by MCO and region)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #4: ***Do service authorizations provide an effective tool in the appropriate utilization of health care services in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS.						
Evaluation Hypothesis #3: Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.						
Short Term (Access to Care)	Average turnaround time for authorization decisions	Burns & Associates, Inc.	Total number of days turnaround time for monthly authorization requests	Total number of monthly authorizations requests (approved and denied)	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)
	Rate of approved and denied authorizations	Burns & Associates, Inc.	Number of monthly (1) approvals and (2) denials for authorization requests	Total number of monthly authorization requests	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)
	Frequency and percentage of denial reason codes	Burns & Associates, Inc.	Count of monthly denied authorization requests, by denial reason code	Total number of monthly denied authorizations requests	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #5: ***Does the proportion of members receiving care coordination and supports continue (or not worsen) in the current waiver period?***						
Demonstration Goal: G.4 Increasing coordination of care and supports; and G.8 Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles.						
Evaluation Hypothesis #4: Trends in coordination of care and supports continues (or does not worsen) in the current waiver period.						
Short Term (Improved Outcomes)	Rate of DSHP members with selected special health care needs screened for care coordination	Burns & Associates, Inc.	Number of DSHP members with selected special health care needs screened for care coordination.	Number of DSHP members with selected special health care needs	MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)
	Of those members with selected special health care needs screened, the number enrolled in care coordination	Burns & Associates, Inc.	Number of DSHP members with selected special health care needs screened for and enrolled in care coordination	Number of DSHP members with selected special health care needs screened for care coordination	MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)
	Duration of enrollment w/in case/care management	Burns & Associates, Inc.	Frequency distribution by days of enrollment in case/care management		MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #6: ***Do DSHP members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Goal: G.4 Increasing coordination of care and supports; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Prenatal care for pregnant women (PPC), control groups those in/not in case/care management.	NCQA	1. Timeliness of Prenatal Care. Number of women having a prenatal care visit as a member of the organization in the first trimester, on the enrollment start date or w/in 42 days of enrollment in the organization.	1. Timeliness of Prenatal Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
		NCQA	2. Postpartum Care. Number of women having a postpartum visit on or between 21 and 56 days after delivery.	2. Postpartum Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Hospitalization for Mental Illness (FUH)	NCQA	Discharges for members age 6 and older who were hospitalized for treatment of mental illness or intentional self-harm and who had a follow-up visit with a MH practitioner w/in 30 days after discharge.	1. Discharges for members age 6 and older who were hospitalized for treatment of mental illness.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)	NCQA	ED visits for members age 6 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit w/ MH practitioner w/in 30 days of ED visit.	1. ED visits for members age 6 and older who had a principal diagnosis of mental illness or intentional self-harm.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Emergency Department Visit for People With Multiple High-Risk Chronic Conditions (FMC)	NCQA	Number of ED visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service w/in 7 days of the ED visit.	Number of members 18 years and older who have multiple high-risk chronic conditions.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline. Report for age stratifications (18-64, 65 and older), and total for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #7: ***Does the level of satisfaction among DSHP members continue (or not worsen) in the current waiver period?***						
Demonstration Goal: G.5 Expanding consumer choices.						
Evaluation Hypothesis #6: Trends in consumer satisfaction will continue (or not worsen) in the current waiver period.						
Long Term (Access to Care)	Getting Needed Care Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline. Stratify by adults and children and MCO for Interim Evaluation; ITS for Summative Evaluation
	Getting Care Quickly Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	How Well Doctors Communicate Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Rating of Personal Doctor	CAHPS	Number of respondents reporting a rating of 8 to 10 out of a maximum score of 10.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Rating of Health Plan	CAHPS	Number of respondents reporting a rating of 8 to 10 out of a maximum score of 10.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Grievances per 1000 members	DMMA	Count of grievances during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR	Descriptive statistics (frequencies and percentages).
	Total number of grievances by category	DMMA	Count of grievances during the reporting period by category.		QCMMR	Descriptive statistics (frequencies and percentages). Stratify by category and MCO.
	Appeals per 1000 members	Burns & Associates, Inc.	Count of appeals during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR	Descriptive statistics (frequencies and percentages).
	Total number of appeals by category	Burns & Associates, Inc.	Count of grievances during the reporting period by category.		QCMMR	Descriptive statistics (frequencies and percentages). Stratify by category and MCO.
	Critical incidents per 1000 members	Burns & Associates, Inc.	Count of critical incidents during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR DSHP Plus	Descriptive statistics (frequencies and percentages).

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #8: ***Has the rebalancing of long-term care services and supports maintained or moved more toward home- and community-based services and away from institutional services in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; G.2 Rebalancing Delaware's LTC system in favor of HCBS; and G.7 Creating a payment structure that provides incentives for resources to shift from institutions to community-based LTSS services where appropriate.						
Evaluation Hypothesis #7: Creating a delivery system that provides incentives for resources to shift from institutions to community-based LTSS has maintained or increased utilization of HCBS services where appropriate in the current waiver period.						
Long Term (LTSS Rebalancing)	Utilization of HCBS services per 1000 members	Burns & Associates, Inc.	Count of HCBS services by category. Categories are: (1) personal care/attendant care/chore services, (2) home-delivered meals, (3) specialized medical equipment/supplies, home modifications, personal emergency response system	Total number of DSHP member months in a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims data	Descriptive statistics (frequencies and percentages) reported at HCBS service category
	Spending in total and on a per member month basis for HCBS services	Burns & Associates, Inc.	Total spend for HCBS services	Total DSHP Plus member months in a 12-month study period	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
	Spending in total and on a per member month basis for institutional LTSS services	Burns & Associates, Inc.	Total spend for institutional MLTSS	Total DSHP Plus member months in a 12-month study period	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
	Proportion of spending for HCBS services	Burns & Associates, Inc.	Total spend for HCBS services	Total spend for all MLTSS services	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
Short Term (Improved Outcomes)	Rate of members needing HCBS services screened for care coordination	Burns & Associates, Inc.	Number of members utilizing HCBS screened for care coordination	Number of members utilizing HCBS	MCO-submitted report	Descriptive statistics (trends rates stratified by MCO and region)
	Of those members needing HCBS services screened, the number enrolled in care coordination	Burns & Associates, Inc.	Number of members utilizing HCBS screened for and enrolled in care coordination	Number of members utilizing HCBS screened for care coordination	MCO-submitted report	Descriptive statistics (trends rates stratified by MCO and region)
	Member experience with care coordination and supports	Burns & Associates, Inc.	Member experience with care coordination and supports, and the extent to which it has facilitated transition to the next appropriate level of care		Member survey	Descriptive statistics (frequencies and percentages)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #9: ***Do DSHP Plus members achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Goal: G.3 Promoting early intervention for individuals with, or at-risk, for having, LTC needs; G.4 Increasing coordination of care and supports; and G.8 Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles.						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Plan All-Cause Readmissions (PCR)[a]	NCQA	At least one acute unplanned readmission for any diagnosis w/in 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	DSHP Plus Medicaid beneficiaries age 18 and older with a discharge from an acute IP stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group for Interim Evaluation; ITS for Summative Evaluation
	Comprehensive Diabetes Care (CDC)	NCQA	Members 18–75 years of age with diabetes (type 1 and type 2) who had a Hemoglobin A1c (HbA1c) testing	Total members 18-75 years of age with diabetes (type 1 and type 2).	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Annual Monitoring for Patients on Persistent Medications (MPM)	NCQA	Members 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. Metric #1: ACE inhibitor or angiotensin receptive blocker (ARB). Metric #2: Members on diuretics. Metric #3: Sum of the two.	Members on persistent medications (i.e., members who received at least 180 treatment days of ambulatory medication in the measurement year).	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Medication Adherence Rates - Percent of Days Covered (PDC)	PQA	Number of Days in Period covered by the same or another drug in its therapeutic class for Asthma, COPD and Diabetes	Number of Days in Period	Claims data	Descriptive statistics (trend over time for conditions of interest with stratification by cohort population and by MCO

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #10: ***Does the level and trend of access to enhanced behavioral health services continue (or not worsen) in the current waiver period?***						
Demonstration Goal: G.9 Improving overall health status and quality of life of individuals enrolled in PROMISE.						
Evaluation Hypothesis #8: Trends in health outcomes will continue or improve in the current waiver period for individuals enrolled in the PROMISE program.						
Long Term (Improved Outcomes)	Rate of identified members who enroll in PROMISE	Burns & Associates, Inc.	Members identified for and referred to that enroll in PROMISE	Members identified or referred to PROMISE	QCMMR	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Hospitalization for Mental Illness (FUH)	NCQA	Discharges for members age 6+ who were hospitalized for treatment of MI or intentional self-harm and who had a f/u visit with a MH practitioner w/in 30 days after discharge.	1. Discharges for members age 6 and older who were hospitalized for treatment of mental illness.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative
	Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)	NCQA	ED visits for members age 6+ with a principal diagnosis of MI or intentional self-harm and who had a follow-up visit w/ MH practitioner w/in 30 days of ED visit.	1. ED visits for members age 6 and older who had a principal diagnosis of mental illness or intentional self-harm.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative
	Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence[a]	NCQA	Members who had a follow-up visit to and ED visit w/ SUD indicator w/in 30 days of discharge w/in the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) w/in the previous rolling 12 months	Claims data	Descriptive statistics; chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline and comparison group for Interim
	Initiation and engagement of alcohol and other drug dependence treatment[a]	NQF #0004	Initiation: Number of patients who began initiation of treatment through IP admission, OP visits, IOP encounter or partial hosp. w/in 14 days of 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	Descriptive statistics; chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Initiation and engagement of alcohol and other drug dependence treatment[a]	NQF #0004	Engagement: Initiation of treatment and two or more IP admissions, OP visits, IOP encounters or partial hosp. with any alcohol/drug diagnosis w/in 30 days after date of 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	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #11: ***Do PROMISE members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Goal: G.4 Increase care coordination and supports; and G.9 Improving overall health status and quality of life of individuals enrolled in PROMISE						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Plan All-Cause Readmissions (PCR)[a]	NCQA	At least one acute unplanned readmission for any diagnosis w/in 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	DSHP Plus Medicaid beneficiaries age 18 and older with a discharge from an acute IP stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics; chi square tests of significance comparing target population (PROMISE enrollees) to baseline and to the comparison group for Interim Evaluation; ITS for Summative Evaluation
	Emergency Department (ED) visits per 1000	Burns & Associates, Inc.	Count of ED visits for DSHP Plus members enrolled in PROMISE in the measurement period	Total DSHP Plus PROMISE enrollee member months	Claims data	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Emergency Department (ED) Frequent Flyer rate	Burns & Associates, Inc.	Frequency distribution of DSHP Plus members enrolled in PROMISE by count of ED visits in the measurement period		Claims data	
	Antidepressant Medication Management (AMM)	NCQA	1. Members 18 years and older treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment for at least 84 days (12 weeks).	1. Members 18 years of age and older who had a diagnosis of major depression.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
		NCQA	2. Members 18 years and older treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment for at least 180 days (6 months).	2. Members 18 years of age and older who had a diagnosis of major depression.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #12: ***Does the availability of PROMISE providers continue (or not worsen) in the current waiver period?***						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS						
Evaluation Hypothesis #9: The PROMISE program network capacity will continue (or not worsen) in the current waiver period.						
Long Term (Access to Care)	Behavioral health providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of behavioral health providers	Total PROMISE enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)
	HCBS providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of HCBS providers	Total PROMISE enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #13: ***Does the availability of the adult dental benefit increase access to dental services and lead to continued (or not worsen) health outcomes in the current waiver period?***						
Demonstration Goal: G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population; and G.12 Increasing access to dental services; decrease the percent of emergency department visits for non-traumatic dental conditions in adults; increase follow up with dentists after an emergency department visit for non-traumatic dental conditions in adults; and increase the number of adults with diabetes who receive an oral exam annually.						
Evaluation Hypothesis #10: The availability of the adult dental benefit will improve access to dental services and will continue (or not worsen) health outcomes in the current waiver period.						
Long Term (Access to Care)	Utilization of dental services per 1000	Burns & Associates, Inc.	Count of dental services in the measurement period for DSHP and DSHP Plus enrollees	Total DSHP and DSHP Plus enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims data	Descriptive statistics (frequencies and percentages) stratified by age, MCO and region; chi square tests of significance comparing target population (adult enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Dental providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of dental providers	Total DSHP and DSHP Plus enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)
	Average driving distance to dental care services	Burns & Associates, Inc.	Sum of the driving distances traveled from member home to their dental care provider	Sum of the unique trips to the member's dental care provider in the year	Claims data	Descriptive statistics (trends in average driving distance stratified by age, MCO and region)
Long Term (Improved Outcomes)	Ambulatory Care Sensitive Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDV-A-A)	Dental Quality Alliance	Number of ED visits with an ambulatory care sensitive non-traumatic dental condition diagnosis code among individuals 18 years and older	All member months for individuals 18 years and older during the reporting year (result of this formula expressed per 100,000 member months for adults)	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-up after Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDF-A-A)	Dental Quality Alliance	Number of ambulatory care sensitive non-traumatic dental condition ED visits in the reporting period for which the member visited a dentist within (a) 7 days (NUM1) and (b) 30 days (NUM2) of the ED visit	Number of ambulatory care sensitive non-traumatic dental condition ED visits in the reporting period	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adults with Diabetes – Oral Evaluation (DOE-A-A)	Dental Quality Alliance	Unduplicated number of adults with diabetes who received a comprehensive or periodic oral evaluation or a comprehensive periodontal evaluation	Unduplicated number of adults with diabetes	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation

[a] Denotes metric that is also part of SUD Evaluation Design Plan

SECTION IV: METHODOLOGICAL LIMITATIONS

There are inherent limitations to both the study design and its specific application to the 1115 waiver evaluation. That being said, the proposed design is feasible and is a rational explanatory framework for evaluating the impact of the 1115 waiver on the demonstration population. Moreover, to fill gaps left by the limitations of this study design, a limited number of onsite reviews, desk reviews, and facilitated interviews/focus groups are proposed to provide a more holistic and comprehensive evaluation. Some known limitations are addressed below.

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. This would be true in the case of former foster care youth. 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 prefers a true comparator group from another state, this would require significantly more resources and cooperation with another state on sharing data. Therefore, B&A is recommending the use of ITS and descriptive statistics including the use of chi square or t-tests as the starting point in development of the evaluation design. One exception to this would be to use available results from CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP and the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults as a benchmark comparator for nationally recognized metrics included in the evaluation design. In this scenario, B&A would compare these trends to two other states if desired and if the data is available. The determination of the states to compare to would be done in consultation with the State, CMS and other stakeholders

The fact that most of the 1115 waiver components have been in place during what would be considered the pre-waiver period for evaluation purposes will make identifying any changes in outcomes directly attributable to waiver implementation difficult. Therefore, it is expected that not all outcomes or process measures included in the study will show a demonstrable change descriptively.

Equally, observed changes in outcome metrics in the current waiver period will be difficult, if not impossible, to attribute to one specific demonstration component given the interrelationship of the components themselves and the longstanding nature of the demonstration. Therefore, it will be important to use statistical tests of significance so that findings are properly put into context.

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, such as housing, employment, and previous incarcerations.

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.

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 related to 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 1115 Diamond State Health Plan Waiver Demonstration Project. 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 Diamond State Health Plan Waiver Demonstration Project serves as the independent evaluator of Indiana's 1115 Substance Use Disorder 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 two Independent Assessments of Indiana's 1915(c) waiver and has 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 Diamond State Health Plan. 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 1115 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 1115 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 1115 Demonstration Waiver Diamond State Health Plan is $1,335,660 to complete all deliverables through June 30, 2025.

	PROPOSED HOURS FOR 1115 WAIVER EVALUATION						
	Mark Podrazik	Debbie Saxe	Ryan Sandhaus	Shawn Stack	Akhilesh Pasupulati	Barry Smith	TOTAL
	Project Director	Project Manager	Statistician	Senior Consultant	SAS Programmer	Consultant	
	817	1,388	362	540	2,154	708	5,961
SECTION A: PROJECT MANAGEMENT	**104**	**165**	**0**	**46**	**223**	**8**	**546**
1 Kickoff Meeting	8	10	0	4	4	0	26
2 Project Management	70	114	0	42	18	0	244
3 Obtain and Read in Data for Project	26	41	0	0	201	8	276
SECTION B: MONITORING ACTIVITIES	**88**	**326**	**32**	**0**	**1200**	**170**	**1816**
4 Build and Maintain Data Warehouse, Compute Metrics	24	70	0	0	176	42	312
5 Ongoing activities each quarter - compute and validate metrics	64	256	32	0	1024	128	1504
SECTION C: EVALUATION DESIGN	**36**	**128**	**0**	**20**	**30**	**8**	**222**
6 Develop Evaluation Design	36	128	0	20	30	8	222
SECTION D: INTERIM EVALUATION ACTIVITIES	**341**	**407**	**148**	**288**	**351**	**276**	**1803**
7 Focus Study: Care Coordination/Transitions to Care	85	0	0	62	64	44	255
8 Focus Study: Critical Incidents (CI), Grievances and Appeals (G&A)	8	60	0	40	4	20	124
9 Focus Study: Review Retroactive Eligibility Process	0	60	0	34	28	14	136
10 Focus Study: Review Authorization Process	76	0	0	44	20	44	184
11 Focus Study: Baseline Access to Dental Care	84	0	0	50	88	50	272
12 Prepare Interim Evaluation	88	287	148	58	147	104	832
SECTION E: SUMMATIVE EVALUATION ACTIVITIES	**248**	**362**	**182**	**186**	**350**	**246**	**1574**
7 Focus Study: Care Coordination/Transitions to Care	56	0	0	36	60	36	188
8 Focus Study: Critical Incidents (CI), Grievances and Appeals (G&A)	6	38	0	20	4	16	84
9 Focus Study: Review Retroactive Eligibility Process	0	32	0	16	28	14	90
10 Focus Study: Review Authorization Process	46	0	0	26	20	44	136
11 Focus Study: Baseline Access to Dental Care + Transitions to Care	40	0	0	16	64	36	156
13 Prepare Summative Evaluation	100	292	182	72	174	100	920

	PROPOSED COSTS FOR 1115 WAIVER EVALUATION						
	Mark Podrazik	Debbie Saxe	Ryan Sandhaus	Shawn Stack	Akhilesh Pasupulati	Barry Smith	TOTAL
	Project Director	Project Manager	Statistician	Senior Consultant	SAS Programmer	Consultant	
	$250.00	$230.00	$230.00	$230.00	$215.00	$200.00	
	$204,250	$319,240	$83,260	$124,200	$463,110	$141,600	$1,335,660
SECTION A: PROJECT MANAGEMENT	**$26,000**	**$37,950**	**$0**	**$10,580**	**$47,945**	**$1,600**	**$124,075**
1 Kickoff Meeting	$2,000	$2,300	$0	$920	$860	$0	$6,080
2 Project Management	$17,500	$26,220	$0	$9,660	$3,870	$0	$57,250
3 Obtain and Read in Data for Project	$6,500	$9,430	$0	$0	$43,215	$1,600	$60,745
SECTION B: MONITORING ACTIVITIES	**$22,000**	**$74,980**	**$7,360**	**$0**	**$258,000**	**$34,000**	**$396,340**
4 Build and Maintain Data Warehouse, Compute Metrics	$6,000	$16,100	$0	$0	$37,840	$8,400	$68,340
5 Ongoing activities each quarter - compute and validate metrics	$16,000	$58,880	$7,360	$0	$220,160	$25,600	$328,000
SECTION C: EVALUATION DESIGN	**$9,000**	**$29,440**	**$0**	**$4,600**	**$6,450**	**$1,600**	**$51,090**
6 Develop Evaluation Design	$9,000	$29,440	$0	$4,600	$6,450	$1,600	$51,090
SECTION D: INTERIM EVALUATION ACTIVITIES	**$85,250**	**$93,610**	**$34,040**	**$66,240**	**$75,465**	**$55,200**	**$409,805**
7 Focus Study: Care Coordination/Transitions to Care	$21,250	$0	$0	$14,260	$13,760	$8,800	$58,070
8 Focus Study: Critical Incidents (CI), Grievances and Appeals (G&A)	$2,000	$13,800	$0	$9,200	$860	$4,000	$29,860
9 Focus Study: Review Retroactive Eligibility Process	$0	$13,800	$0	$7,820	$6,020	$2,800	$30,440
10 Focus Study: Review Authorization Process	$19,000	$0	$0	$10,120	$4,300	$8,800	$42,220
11 Focus Study: Baseline Access to Dental Care	$21,000	$0	$0	$11,500	$18,920	$10,000	$61,420
12 Prepare Interim Evaluation	$22,000	$66,010	$34,040	$13,340	$31,605	$20,800	$187,795
SECTION E: SUMMATIVE EVALUATION ACTIVITIES	**$62,000**	**$83,260**	**$41,860**	**$42,780**	**$75,250**	**$49,200**	**$354,350**
7 Focus Study: Care Coordination/Transitions to Care	$14,000	$0	$0	$8,280	$12,900	$7,200	$42,380
8 Focus Study: Critical Incidents (CI), Grievances and Appeals (G&A)	$1,500	$8,740	$0	$4,600	$860	$3,200	$18,900
9 Focus Study: Review Retroactive Eligibility Process	$0	$7,360	$0	$3,680	$6,020	$2,800	$19,860
10 Focus Study: Review Authorization Process	$11,500	$0	$0	$5,980	$4,300	$8,800	$30,580
11 Focus Study: Baseline Access to Dental Care + Transitions to Care	$10,000	$0	$0	$3,680	$13,760	$7,200	$34,640
13 Prepare Summative Evaluation	$25,000	$67,160	$41,860	$16,560	$37,410	$20,000	$207,990

ATTACHMENT C: TIMELINE AND MILESTONES

As part of the procurement process, Burns & Associates, a Division of HMA (B&A) was required to submit a work plan, including major tasks and milestones to complete the 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.

B&A has built a work plan for the independent evaluation of Delaware's 1115 Demonstration Waiver Diamond State Health 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 tasks in this work plan scheduled out by month appears at the end of this section.

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 DMES

- Section B, ***Monitoring Activities***, includes Tasks 4 and 5. It is anticipated that the work in this section will start immediately upon contract execution and continue until March 31, 2024.
    - Deliverables in this section:
        - Creation and maintenance of the analytic data warehouse specific to the Evaluation Design Plan and associated focus studies
        - Compute and validate metrics specific to the Evaluation Design Plan on a quarterly basis (6 quarters Q4 2020 – Q1 2022, and then 10 additional quarters after this time period)

- Section C, ***Evaluation Activities***, includes Tasks 6 through 11. It is expected that the work in this section will start immediately upon contract execution and continue until August 31, 2022.
    - Deliverables in this section:
        - Draft Evaluation Design to CMS (May 31, 2020)
        - Final Evaluation Design approved by CMS (August 31, 2020)

- Section D, ***Interim Evaluation Activities,*** includes Tasks 7 through 12. It is expected that the work in this section will start in Q1 of CY 2021 and continue until March 31, 2023. Tasks 7 through 11 represent five different focus studies. Each will include an internal report to DMMA. Results from each study will also be included in the Interim Evaluation to CMS. Task 12 represents work to produce the Interim Evaluation report itself.
    - Deliverables in this section:
        - Conduct Four Focus Studies (June 30, 2021 – February 28, 2022) – Interim reports for each focus study delivered intermittently during this 13-month period
        - Conduct a Fifth Focus Study if a contract extension is authorized (July 31, 2022)
        - Detailed outline of the Interim Evaluation (May 31, 2022)
        - Draft Version of Interim Evaluation (November 30, 2022)
        - Final Version of Interim Evaluation (December 31, 2022)

- Section E, Summative Evaluation Deliverables, includes Tasks 7 and 11 again and Task 13. Tasks 7 through 11 are repeated because a follow-up on each focus study reported on in the Interim Evaluation is proposed so that updates can be reported in the Summative Evaluation. It is expected that the work in this section will start in Q1 of CY 2024 and continue until June 30, 2025.
    - Deliverables in this section:
        - Conduct Five Focus Studies (May 31, 2024 – December 31, 2024) – Interim reports for each focus study delivered intermittently during this 8-month time period
        - Detailed outline of the Summative Evaluation (November 30, 2024)
        - Draft Version of Summative Evaluation (May 15, 2025)
        - Final Version of Summative Evaluation (June 30, 2025)

CONTRACT YEAR 1

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
		2020								
SECTION A: PROJECT MANAGEMENT										
1	Kickoff Meeting									
2	Project Management									
3	Obtain and Read in Data for Project									
SECTION B: MONITORING ACTIVITIES										
4	Build and Maintain Data Warehouse, Develop and Compute Metrics									
5	Ongoing Activities Each Quarter - Compute and Validate Metrics									
SECTION C: EVALUATION DESIGN										
6	Develop Evaluation Design									
SECTION D: INTERIM EVALUATION ACTIVITIES										
7	Focus Study: Care Coordination/Transitions to Care									
8	Focus Study: Critical Incidents (CI), Grievances and Appeals									
9	Focus Study: Review Retroactive Eligibility Process									
10	Focus Study: Review Authorization Process									
11	Focus Study: Baseline Access to Dental Care									
12	Prepare Interim Evaluation									
SECTION E: SUMMATIVE EVALUATION ACTIVITIES										
7	Focus Study: Care Coordination/Transitions to Care									
8	Focus Study: Critical Incidents (CI), Grievances and Appeals									
9	Focus Study: Review Retroactive Eligibility Process									
10	Focus Study: Review Authorization Process									
11	Focus Study: Baseline Access to Dental Care + Transitions to Care									
13	Prepare Summative Evaluation									

CONTRACT YEAR 2

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
		2021											
SECTION A: PROJECT MANAGEMENT													
1	Kickoff Meeting												
2	Project Management												
3	Obtain and Read in Data for Project												
SECTION B: MONITORING ACTIVITIES													
4	Build and Maintain Data Warehouse, Develop and Compute Metrics												
5	Ongoing Activities Each Quarter - Compute and Validate Metrics												
SECTION C: EVALUATION DESIGN													
6	Develop Evaluation Design												
SECTION D: INTERIM EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care												
12	Prepare Interim Evaluation												
SECTION E: SUMMATIVE EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care + Transitions to Care												
13	Prepare Summative Evaluation												

CONTRACT YEAR 3

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
		2022											
SECTION A: PROJECT MANAGEMENT													
1	Kickoff Meeting												
2	Project Management												
3	Obtain and Read in Data for Project												
SECTION B: MONITORING ACTIVITIES													
4	Build and Maintain Data Warehouse, Develop and Compute Metrics												
5	Ongoing Activities Each Quarter - Compute and Validate Metrics												
SECTION C: EVALUATION DESIGN													
6	Develop Evaluation Design												
SECTION D: INTERIM EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care												
12	Prepare Interim Evaluation												
SECTION E: SUMMATIVE EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care + Transitions to Care												
13	Prepare Summative Evaluation												

CONTRACT YEAR 4

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan 2023	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
SECTION A: PROJECT MANAGEMENT													
1	Kickoff Meeting												
2	Project Management												
3	Obtain and Read in Data for Project												
SECTION B: MONITORING ACTIVITIES													
4	Build and Maintain Data Warehouse, Develop and Compute Metrics												
5	Ongoing Activities Each Quarter - Compute and Validate Metrics												
SECTION C: EVALUATION DESIGN													
6	Develop Evaluation Design												
SECTION D: INTERIM EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care												
12	Prepare Interim Evaluation												
SECTION E: SUMMATIVE EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care + Transitions to Care												
13	Prepare Summative Evaluation												

CONTRACT YEAR 5

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan 2024	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
SECTION A: PROJECT MANAGEMENT													
1	Kickoff Meeting												
2	Project Management												
3	Obtain and Read in Data for Project												
SECTION B: MONITORING ACTIVITIES													
4	Build and Maintain Data Warehouse, Develop and Compute Metrics												
5	Ongoing Activities Each Quarter - Compute and Validate Metrics												
SECTION C: EVALUATION DESIGN													
6	Develop Evaluation Design												
SECTION D: INTERIM EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care												
12	Prepare Interim Evaluation												
SECTION E: SUMMATIVE EVALUATION ACTIVITIES													
7	Focus Study: Care Coordination/Transitions to Care												
8	Focus Study: Critical Incidents (CI), Grievances and Appeals												
9	Focus Study: Review Retroactive Eligibility Process												
10	Focus Study: Review Authorization Process												
11	Focus Study: Baseline Access to Dental Care + Transitions to Care												
13	Prepare Summative Evaluation												

CONTRACT YEAR 6

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan 2025	Feb	Mar	Apr	May	June
SECTION A: PROJECT MANAGEMENT							
1	Kickoff Meeting						
2	Project Management						
3	Obtain and Read in Data for Project						
SECTION B: MONITORING ACTIVITIES							
4	Build and Maintain Data Warehouse, Develop and Compute Metrics						
5	Ongoing Activities Each Quarter - Compute and Validate Metrics						
SECTION C: EVALUATION DESIGN							
6	Develop Evaluation Design						
SECTION D: INTERIM EVALUATION ACTIVITIES							
7	Focus Study: Care Coordination/Transitions to Care						
8	Focus Study: Critical Incidents (CI), Grievances and Appeals						
9	Focus Study: Review Retroactive Eligibility Process						
10	Focus Study: Review Authorization Process						
11	Focus Study: Baseline Access to Dental Care						
12	Prepare Interim Evaluation						
SECTION E: SUMMATIVE EVALUATION ACTIVITIES							
7	Focus Study: Care Coordination/Transitions to Care						
8	Focus Study: Critical Incidents (CI), Grievances and Appeals						
9	Focus Study: Review Retroactive Eligibility Process						
10	Focus Study: Review Authorization Process						
11	Focus Study: Baseline Access to Dental Care + Transitions to Care						
13	Prepare Summative Evaluation						

ATTACHMENT D: DETAILED EVALUATION DESIGN PLAN TABLE

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #1: ***Does the waiver of retroactive eligibility continue (or does not worsen) the continuity of enrollment in Medicaid in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Domain of Focus: F.7 Hypotheses for the waiver of retroactive eligibility will include (but not be limited to): the effects of the waiver on enrollment and eligibility continuity (including for different subgroups of individuals, such as individuals who are healthy, individuals with complex medical needs, prospective applicants, and existing beneficiaries in different care settings.						
Evaluation Hypothesis #1: Trends in continuity of enrollment continue (or does not worsen) for Medicaid populations subject to the waiver of retroactive eligibility in the current waiver period.						
Short Term (Continuity of Enrollment)	Time span from application to enrollment in Medicaid	Burns & Associates, Inc.	Frequency distribution of enrollees by number of days from application to enrollment during the measurement period.		Enrollment data	Descriptive statistics (trends in frequencies and percentages of time span from application to enrollment stratified by aid category)
	Medicaid enrollment counts by month and aid category	Burns & Associates, Inc.	Count of enrollees by month and aid category during the measurement period.		Enrollment data	Descriptive statistics (trends in enrollment counts over time stratified by aid category)
	Medicaid Enrollment duration by aid category and assignment plan	Burns & Associates, Inc.	Frequency distribution of enrollees by the number of months of eligibility in the measurement period, stratified by aid category and assignment plan.		Enrollment data	Descriptive statistics (trends in enrollment duration by aid category and assignment plan)
	Proportion of enrollees continuously enrolled in Medicaid by aid category, assignment plan and delivery system	Burns & Associates, Inc.	Frequency distribution of enrollees continuously enrolled 9 or more months in the measurement period, stratified by aid category, assignment plan and delivery system.	Total number of enrollees during the measurement period.	Enrollment data	Descriptive statistics (trends in the proportion of enrollees continuously enrolled by aid category, assignment plan and delivery system)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #2: ***Does the waiver of retroactive eligibility continue or not worsen trends in the incidence of uncompensated care or not seeing a doctor because of cost in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Domain of Focus: F.7 Hypotheses for the waiver of retroactive eligibility will include (but not be limited to): the effects of the waiver on enrollment and eligibility continuity (including for						
Evaluation Hypothesis #2: The waiver of retroactive eligibility will continue or not worsen trends in uncompensated care or medical debt in the current waiver period.						
Long Term (Uncompensated Care)	Rate of hospital reported uncompensated care	Burns & Associates, Inc.	Hospital reported uninsured uncompensated care	Number of Delawareans expressed as per 1,000	DMMA Form DSH-1, Line 21	Descriptive statistics (trends in frequencies and percentages over the demonstration period) with comparison to baseline period
	Could Not See Doctor Because of Cost	CDC, BRFSS	Weighted percentage of respondents who reported there was a time over the past 12 months when they needed to see a doctor but could not because of cost (MEDCOST)		Health Care Access Module	Descriptive statistics (trends in Delaware reported percentages over the demonstration period); comparison to baseline period and available national and regional values
	Self-identified trends in medical debt for DSHP enrollees	Burns & Associates, Inc.	Number of respondents reporting if medical debt has improved, stayed the same or not worsened over the past twelve months	Total number of respondents.	Focus Group	Descriptive statistics (trends in frequencies and percentages over the demonstration period) with comparison to baseline period

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #3: ***Does the level and trend of access to primary and preventive care continue (or not worsen) in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Domain of Focus: F.6 The extent to which including former foster care youth who "aged out" of foster care in a different state increases and strengthens overall coverage for former foster care youth and improves health outcomes for these youth.						
Evaluation Hypothesis #3: Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.						
Long Term (Access to Care)	Well-Child Visits in the First 15 Months of Life (W15)	NCQA	Number of children who turned 15 months old during the measurement year who had 6 or more well-child visits with a PCP	Number of children who turned 15 months old during the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Well-Child Visits in the Third, Fourth, Fifth and Sixth Years of Life (W34)	NCQA	Number of children who are 3 to 6 years old as of December 31 and had one or more visits with a PCP during the measurement year.	Number of children who are 3 to 6 years old as of December 31 of the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adolescent Well-Care Visits (AWC)	NCQA	Number of enrolled members age 12 to 21 years, as of December 31,who had at least one comprehensive well-care visit with a PCP or OB/GYN during the measurement year.	Number of enrolled members age 12 to 21 years as of December 31 of the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Breast Cancer Screening (BCS)	NCQA	Number of women age 50-54 years who had a screening mammogram as of December 31 in the measurement year.	Number of women age 50-54 years as of December 31 in the measurement year.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adults' Access to Preventive/Ambulatory Health Services (AAP)	NCQA	Number of members who had an ambulatory or preventive care visit as of December 31 in the measurement year, reported using three age stratifications: 22-44 years; 45-64 years; 65+ years.	Number of members as of December 31 in the measurement year, with counts for each of the three age stratifications: 22-44 years; 45-64 years; 65+ years.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
Short Term (Access to Care)	Average driving distance to primary care services	Burns & Associates, Inc.	Sum of the driving distances traveled from member home to their primary care provider	Sum of the unique trips to the member's primary care provider in the year	Claims data	Descriptive statistics (trends in average driving distance stratified by MCO and region)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #4: ***Do service authorizations provide an effective tool in the appropriate utilization of health care services in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #2: The DSHP Plus program provides long-term care services and supports (LTSS) to certain individuals under the State Plan, and to certain demonstration						
Demonstration Component #3: The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS.						
Domain of Focus: F.3 The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion.						
Evaluation Hypothesis #3: Trends observed in access to health care through the DSHP for the Medicaid population continues (or does not worsen) in the current waiver period.						
Short Term (Access to Care)	Average turnaround time for authorization decisions	Burns & Associates, Inc.	Total number of days turnaround time for monthly authorization requests	Total number of monthly authorizations requests (approved and denied)	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)
	Rate of approved and denied authorizations	Burns & Associates, Inc.	Number of monthly (1) approvals and (2) denials for authorization requests	Total number of monthly authorization requests	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)
	Frequency and percentage of denial reason codes	Burns & Associates, Inc.	Count of monthly denied authorization requests, by denial reason code	Total number of monthly denied authorizations requests	MCO-submitted report	Descriptive statistics (will be stratified by MCO and by subpopulations PROMISE and All Other)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #5: ***Does the proportion of members receiving care coordination and supports continue (or not worsen) in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #2: The DSHP Plus program provides long-term care services and supports (LTSS) to certain individuals under the State Plan, and to certain demonstration						
Demonstration Component #3: The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.4 Increasing coordination of care and supports; and G.8 Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles.						
Domains of Focus: F2 The costs and benefits of providing early intervention for individuals with, or at-risk, for having LTC needs; F.3 The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion; and F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE.						
Evaluation Hypothesis #4: Trends in coordination of care and supports continues (or does not worsen) in the current waiver period.						
Short Term (Improved Outcomes)	Rate of DSHP members with selected special health care needs screened for care coordination	Burns & Associates, Inc.	Number of DSHP members with selected special health care needs screened for care coordination.	Number of DSHP members with selected special health care needs	MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)
	Of those members with selected special health care needs screened, the number enrolled in care coordination	Burns & Associates, Inc.	Number of DSHP members with selected special health care needs screened for and enrolled in care coordination	Number of DSHP members with selected special health care needs screened for care coordination	MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)
	Duration of enrollment w/in case/care management	Burns & Associates, Inc.	Frequency distribution by days of enrollment in case/care management		MCO-submitted report	Descriptive statistics (trends tracked separately for three populations: (1) enrolled in PROMISE, (2) DSHP Plus eligible, (3) other selected special health care need categories in State Quality Strategy Plan)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #6: ***Do DSHP members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.4 Increasing coordination of care and supports; and G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.						
Domain of Focus: F.3 The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion; and F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE.						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Prenatal care for pregnant women (PPC), control groups those in/not in case/care management.	NCQA	1. Timeliness of Prenatal Care. Number of women having a prenatal care visit as a member of the organization in the first trimester, on the enrollment start date or w/in 42 days of enrollment in the organization.	1. Timeliness of Prenatal Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
		NCQA	2. Postpartum Care. Number of women having a postpartum visit on or between 21 and 56 days after delivery.	2. Postpartum Care. Number of deliveries of live births.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Hospitalization for Mental Illness (FUH)	NCQA	Discharges for members age 6 and older who were hospitalized for treatment of mental illness or intentional self-harm and who had a follow-up visit with a MH practitioner w/in 30 days after discharge.	1. Discharges for members age 6 and older who were hospitalized for treatment of mental illness.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)	NCQA	ED visits for members age 6 and older with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit w/ MH practitioner w/in 30 days of ED visit.	1. ED visits for members age 6 and older who had a principal diagnosis of mental illness or intentional self-harm.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-Up After Emergency Department Visit for People With Multiple High-Risk Chronic Conditions (FMC)	NCQA	Number of ED visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service w/in 7 days of the ED visit.	Number of members 18 years and older who have multiple high-risk chronic conditions.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline. Report for age stratifications (18-64, 65 and older), and total for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #7: ***Does the level of satisfaction among DSHP members continue (or not worsen) in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Component #4: Coverage for former foster care youth under age 26 who were in foster care under the responsibility of another state or tribe when they "aged out" of foster care at age 18 (or such higher age as elected by the state), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.						
Demonstration Goal: G.5 Expanding consumer choices.						
Domain of Focus: F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE; and F.5 The extent to which the PROMISE services improve the overall health status and quality of life of the individuals enrolled in PROMISE.						
Evaluation Hypothesis #6: Trends in consumer satisfaction will continue (or not worsen) in the current waiver period.						
Long Term (Access to Care)	Getting Needed Care Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline. Stratify by adults and children and MCO for Interim Evaluation; ITS for Summative Evaluation
	Getting Care Quickly Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	How Well Doctors Communicate Composite	CAHPS	Number of respondents reporting always or usually.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Rating of Personal Doctor	CAHPS	Number of respondents reporting a rating of 8 to 10 out of a maximum score of 10.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Rating of Health Plan	CAHPS	Number of respondents reporting a rating of 8 to 10 out of a maximum score of 10.	Total number of respondents.	CAHPS® 5.0 Health Plan	
	Grievances per 1000 members	DMMA	Count of grievances during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR	Descriptive statistics (frequencies and percentages).
	Total number of grievances by category	DMMA	Count of grievances during the reporting period by category.		QCMMR	Descriptive statistics (frequencies and percentages). Stratify by category and MCO.
	Appeals per 1000 members	Burns & Associates, Inc.	Count of appeals during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR	Descriptive statistics (frequencies and percentages).
	Total number of appeals by category	Burns & Associates, Inc.	Count of grievances during the reporting period by category.		QCMMR	Descriptive statistics (frequencies and percentages). Stratify by category and MCO.
	Critical incidents per 1000 members	Burns & Associates, Inc.	Count of critical incidents during the reporting period.	Total number of DSHP member months in 12-month study period (result of this formula expressed as per 1,000 member months)	QCMMR DSHP Plus	Descriptive statistics (frequencies and percentages).

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #8: ***Has the rebalancing of long-term care services and supports maintained or moved more toward home- and community-based services and away from institutional services in the current waiver period?***						
Demonstration Component #2: The DSHP Plus program provides long-term care services and supports (LTSS) to certain individuals under the State Plan, and to certain demonstration						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS; G.2 Rebalancing Delaware's LTC system in favor of HCBS; and G.7 Creating a payment structure that provides incentives for resources to shift from institutions to community-based LTSS services where appropriate.						
Domain of Focus: F.1 The impact of rebalancing the LTC system in favor of HCBS; F.2 The costs and benefits of providing early intervention for individuals with, or at-risk, for having LTC needs; and F.3 The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion.						
Evaluation Hypothesis #7: Creating a delivery system that provides incentives for resources to shift from institutions to community-based LTSS has maintained or increased utilization of HCBS services where appropriate in the current waiver period.						
Long Term (LTSS Rebalancing)	Utilization of HCBS services per 1000 members	Burns & Associates, Inc.	Count of HCBS services by category. Categories are: (1) personal care/attendant care/chore services, (2) home-delivered meals, (3) specialized medical equipment/supplies, home modifications, personal emergency response system	Total number of DSHP member months in a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims data	Descriptive statistics (frequencies and percentages) reported at HCBS service category
	Spending in total and on a per member month basis for HCBS services	Burns & Associates, Inc.	Total spend for HCBS services	Total DSHP Plus member months in a 12-month study period	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
	Spending in total and on a per member month basis for institutional LTSS services	Burns & Associates, Inc.	Total spend for institutional MLTSS	Total DSHP Plus member months in a 12-month study period	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
	Proportion of spending for HCBS services	Burns & Associates, Inc.	Total spend for HCBS services	Total spend for all MLTSS services	Claims data	Descriptive statistics (frequencies and percentages) for Interim Evaluation; ITS for Summative Evaluation
Short Term (Improved Outcomes)	Rate of members needing HCBS services screened for care coordination	Burns & Associates, Inc.	Number of members utilizing HCBS screened for care coordination	Number of members utilizing HCBS	MCO-submitted report	Descriptive statistics (trends rates stratified by MCO and region)
	Of those members needing HCBS services screened, the number enrolled in care coordination	Burns & Associates, Inc.	Number of members utilizing HCBS screened for and enrolled in care coordination	Number of members utilizing HCBS screened for care coordination	MCO-submitted report	Descriptive statistics (trends rates stratified by MCO and region)
	Member experience with care coordination and supports	Burns & Associates, Inc.	Member experience with care coordination and supports, and the extent to which it has facilitated transition to the next appropriate level of care		Member survey	Descriptive statistics (frequencies and percentages)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #9: ***Do DSHP Plus members achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Component #2: The DSHP Plus program provides long-term care services and supports (LTSS) to certain individuals under the State Plan, and to certain demonstration						
Demonstration Goal: G.3 Promoting early intervention for individuals with, or at-risk, for having, LTC needs; G.4 Increasing coordination of care and supports; and G.8 Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles.						
Domain of Focus: F.2 The costs and benefits of providing early intervention for individuals with, or at-risk, for having LTC needs; and F.3 The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion.						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Plan All-Cause Readmissions (PCR)[a]	NCQA	At least one acute unplanned readmission for any diagnosis w/in 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	DSHP Plus Medicaid beneficiaries age 18 and older with a discharge from an acute IP stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics; chi square tests of significance comparing target population to baseline and to the comparison group for Interim Evaluation; ITS for Summative Evaluation
	Comprehensive Diabetes Care (CDC)	NCQA	Members 18–75 years of age with diabetes (type 1 and type 2) who had a Hemoglobin A1c (HbA1c) testing	Total members 18-75 years of age with diabetes (type 1 and type 2).	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Annual Monitoring for Patients on Persistent Medications (MPM)	NCQA	Members 18 years of age and older who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. Metric #1: ACE inhibitor or angiotensin receptive blocker (ARB). Metric #2: Members on diuretics. Metric #3: Sum of the two.	Members on persistent medications (i.e., members who received at least 180 treatment days of ambulatory medication in the measurement year).	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Medication Adherence Rates - Percent of Days Covered (PDC)	PQA	Number of Days in Period covered by the same or another drug in its therapeutic class for Asthma, COPD and Diabetes	Number of Days in Period	Claims data	Descriptive statistics (trend over time for conditions of interest with stratification by cohort population and by MCO

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #10: ***Does the level and trend of access to enhanced behavioral health services continue (or not worsen) in the current waiver period?***						
Demonstration Component #3: The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.						
Demonstration Goal: G.9 Improving overall health status and quality of life of individuals enrolled in PROMISE.						
Domain of Focus: F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE.; and F.5 The extent to which the PROMISE services improve the overall health status and quality of life of the individuals enrolled in PROMISE.						
Evaluation Hypothesis #8: Trends in health outcomes will continue or improve in the current waiver period for individuals enrolled in the PROMISE program.						
Long Term (Improved Outcomes)	Rate of identified members who enroll in PROMISE	Burns & Associates, Inc.	Members identified for and referred to that enroll in PROMISE	Members identified or referred to PROMISE	QCMMR	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative
	Follow-Up After Hospitalization for Mental Illness (FUH)	NCQA	Discharges for members age 6+ who were hospitalized for treatment of MI or intentional self-harm and who had a f/u visit with a MH practitioner w/in 30 days after discharge.	1. Discharges for members age 6 and older who were hospitalized for treatment of mental illness.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative
	Follow-Up After Emergency Department (ED) Visit for Mental Illness (FUM)	NCQA	ED visits for members age 6+ with a principal diagnosis of MI or intentional self-harm and who had a follow-up visit w/ MH practitioner w/in 30 days of ED visit.	1. ED visits for members age 6 and older who had a principal diagnosis of mental illness or intentional self-harm.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative
	Follow-Up After Discharge from the Emergency Department for Alcohol or Other Drug (AOD) Dependence[a]	NCQA	Members who had a follow-up visit to and ED visit w/ SUD indicator w/in 30 days of discharge w/in the previous rolling 12 months.	Individuals with an ED visit (with SUD indicator) w/in the previous rolling 12 months	Claims data	Descriptive statistics; chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline and comparison group for Interim Evaluation; ITS for Summative
	Initiation and engagement of alcohol and other drug dependence treatment[a]	NQF #0004	Initiation: Number of patients who began initiation of treatment through IP admission, OP visits, IOP encounter or partial hosp. w/in 14 days of 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	Descriptive statistics; chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Initiation and engagement of alcohol and other drug dependence treatment[a]	NQF #0004	Engagement: Initiation of treatment and two or more IP admissions, OP visits, IOP encounters or partial hosp. with any alcohol/drug diagnosis w/in 30 days after date of 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	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #11: ***Do PROMISE members enrolled in case/care management achieve similar or improved quality of care and health outcomes in the current waiver period?***						
Demonstration Component #3: The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.						
Demonstration Goal: G.4 Increase care coordination and supports; and G.9 Improving overall health status and quality of life of individuals enrolled in PROMISE						
Domain of Focus: F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE; and F.5 The extent to which the PROMISE services improve the overall health status and quality of life of the individuals enrolled in PROMISE.						
Evaluation Hypothesis #5: Coordination of care and supports maintains or improves quality of care and health outcomes in the current waiver period.						
Long Term (Improved Outcomes)	Plan All-Cause Readmissions (PCR)[a]	NCQA	At least one acute unplanned readmission for any diagnosis w/in 30 days of the date of discharge from the index hospital stay, that is on or between the second day of the measurement year and the end of the measurement year	DSHP Plus Medicaid beneficiaries age 18 and older with a discharge from an acute IP stay (index hospital stay) on or between January 1 and December 1 of the measurement year	Claims data	Descriptive statistics; chi square tests of significance comparing target population (PROMISE enrollees) to baseline and to the comparison group for Interim Evaluation; ITS for Summative Evaluation
	Emergency Department (ED) visits per 1000	Burns & Associates, Inc.	Count of ED visits for DSHP Plus members enrolled in PROMISE in the measurement period	Total DSHP Plus PROMISE enrollee member months	Claims data	Descriptive statistics (frequencies and percentages); chi square tests of significance comparing target population (PROMISE enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Emergency Department (ED) Frequent Flyer rate	Burns & Associates, Inc.	Frequency distribution of DSHP Plus members enrolled in PROMISE by count of ED visits in the measurement period		Claims data	
	Antidepressant Medication Management (AMM)	NCQA	1. Members 18 years and older treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment for at least 84 days (12 weeks).	1. Members 18 years of age and older who had a diagnosis of major depression.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
		NCQA	2. Members 18 years and older treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment for at least 180 days (6 months).	2. Members 18 years of age and older who had a diagnosis of major depression.	Claims data	Descriptive statistics (frequencies and percentages); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #12: ***Does the availability of PROMISE providers continue (or not worsen) in the current waiver period?***						
Demonstration Component #3: The PROMISE program provides enhanced behavioral health services fee-for-service (FFS) to Medicaid beneficiaries with a higher level of behavioral health needs and functional limitations who need HCBS to live and work in integrated settings.						
Demonstration Goal: G.1 Improving access to health care for the Medicaid population, including increasing options for those who need long-term care (LTC) by expanding access to HCBS						
Domain of Focus: F.4 Effectiveness of the coordination of the MCO and DSAMH case managers, as well as the services provided by the MCO with the enhanced behavioral health services provided by PROMISE; and F.5 The extent to which the PROMISE services improve the overall health status and quality of life of the individuals enrolled in PROMISE.						
Evaluation Hypothesis #9: The PROMISE program network capacity will continue (or not worsen) in the current waiver period.						
Long Term (Access to Care)	Behavioral health providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of behavioral health providers	Total PROMISE enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)
	HCBS providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of HCBS providers	Total PROMISE enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)

Outcome	Measure description	Measure steward, endorsement	Numerator	Denominator	Data source	Analytic approach
Evaluation Question #13: ***Does the availability of the adult dental benefit increase access to dental services and lead to continued (or not worsen) health outcomes in the current waiver period?***						
Demonstration Component #1: The DSHP Medicaid managed care program provides Medicaid state plan benefits through a comprehensive managed care delivery system to most recipients eligible under the state plan.						
Demonstration Goal: G.10 Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population; and G.12 Increasing access to dental services; decrease the percent of emergency department visits for non-traumatic dental conditions in adults; increase follow up with dentists after an emergency department visit for non-traumatic dental conditions in adults; and increase the number of adults with diabetes who receive an oral exam annually.						
Domain of Focus: F.6 The extent to which including former foster care youth who "aged out" of foster care in a different state increases and strengthens overall coverage for former foster care youth and improves health outcomes for these youth; and F.8 If the addition of adult dental benefits increases access to dental services and ultimately improved health outcomes for adults in Delaware.						
Evaluation Hypothesis #10: The availability of the adult dental benefit will improve access to dental services and will continue (or not worsen) health outcomes in the current waiver period.						
Long Term (Access to Care)	Utilization of dental services per 1000	Burns & Associates, Inc.	Count of dental services in the measurement period for DSHP and DSHP Plus enrollees	Total DSHP and DSHP Plus enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims data	Descriptive statistics (frequencies and percentages) stratified by age, MCO and region; chi square tests of significance comparing target population (adult enrollees) to baseline for Interim Evaluation; ITS for Summative Evaluation
	Dental providers per 1000 members by geographical region	Burns & Associates, Inc.	Unique count of dental providers	Total DSHP and DSHP Plus enrollee member months for a 12-month study period (result of this formula expressed as per 1,000 member months)	Claims and Provider Enrollment data	Descriptive statistics (trends rates stratified by MCO and region)
	Average driving distance to dental care services	Burns & Associates, Inc.	Sum of the driving distances traveled from member home to their dental care provider	Sum of the unique trips to the member's dental care provider in the year	Claims data	Descriptive statistics (trends in average driving distance stratified by age, MCO and region)
Long Term (Improved Outcomes)	Ambulatory Care Sensitive Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDV-A-A)	Dental Quality Alliance	Number of ED visits with an ambulatory care sensitive non-traumatic dental condition diagnosis code among individuals 18 years and older	All member months for individuals 18 years and older during the reporting year (result of this formula expressed per 100,000 member months for adults)	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Follow-up after Emergency Department Visits for Non-Traumatic Dental Conditions in Adults (EDF-A-A)	Dental Quality Alliance	Number of ambulatory care sensitive non-traumatic dental condition ED visits in the reporting period for which the member visited a dentist within (a) 7 days (NUM1) and (b) 30 days (NUM2) of the ED visit	Number of ambulatory care sensitive non-traumatic dental condition ED visits in the reporting period	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative Evaluation
	Adults with Diabetes – Oral Evaluation (DOE-A-A)	Dental Quality Alliance	Unduplicated number of adults with diabetes who received a comprehensive or periodic oral evaluation or a comprehensive periodontal evaluation	Unduplicated number of adults with diabetes	Claims data	Descriptive statistics (trends in percentage); chi square or t-tests of significance comparing target population to baseline for Interim Evaluation; ITS for Summative

[a] Denotes metric that is also part of SUD Evaluation Design Plan

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

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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.

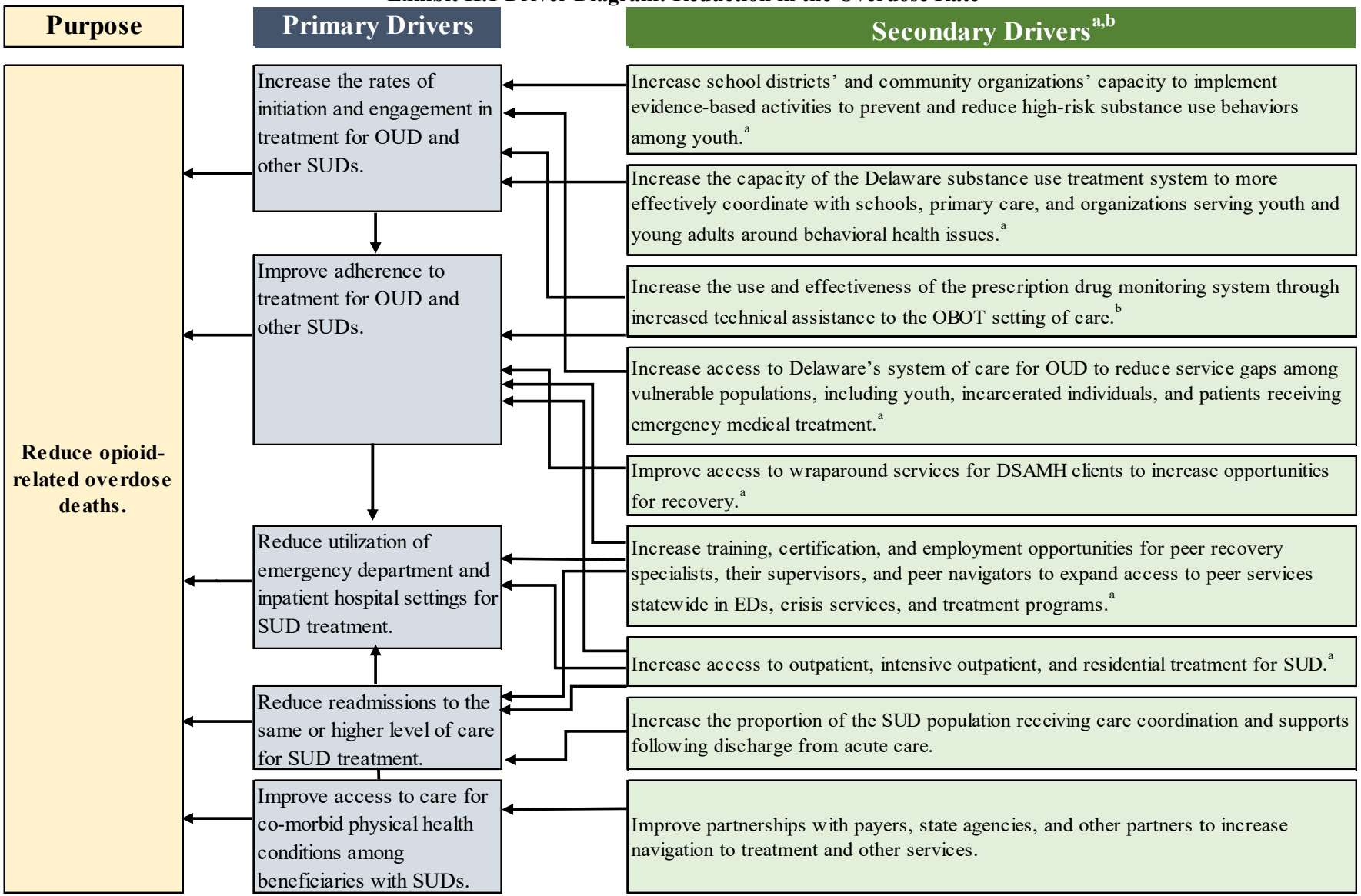
Overdose deaths is an important measurable health outcome of interest and, therefore, is the aim of the driver diagram. CMS's goals represent primary drivers all of which identified as having the potential to contribute to a reduction in overdose deaths. The specific actions described in the concurrent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

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[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

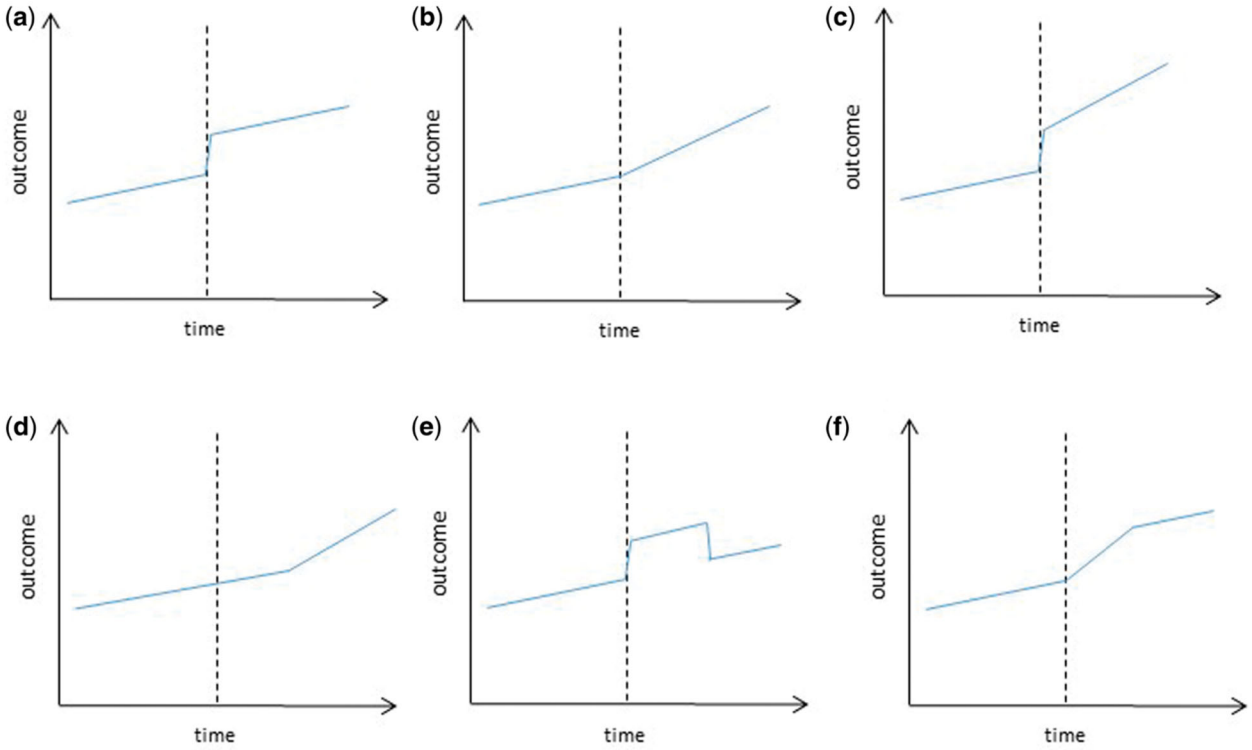
β_3 estimates the change in trend in the post-intervention segment

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)