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
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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

CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **11-W-00036/4**

TITLE: **Delaware Diamond State Health Plan**

AWARDEE: **Delaware Department of Health & Social Services**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Delaware for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period of this demonstration extension, beginning August 1, 2019 through December 31, 2023, be regarded as expenditures under the state's title XIX plan. All previously approved expenditure authorities for this demonstration are superseded by those set forth below for the state's expenditures relating to dates of service during this demonstration extension.

The following expenditure authorities to provide coverage to the below list of demonstration populations may only be implemented consistent with the approved Special Terms and Conditions (STCs) and shall enable Delaware to implement the Delaware Diamond State Health Plan (DSHP) Medicaid section 1115 demonstration as outlined in the approved STCs:

1. **217-Like Elderly and Disabled Home and Community Based Services (HCBS) Group**. Expenditures for medical assistance for disabled individuals over age 18 who meet the Nursing Facility (NF) level of care (LOC) criteria and who would otherwise be Medicaid-eligible if the state had elected the group described in section 1902(a)(10)(A)(ii)(VI) of the Act and 42 CFR 435.217 in conjunction with section 1902(a)(10)(A)(ii)(V) of the Act, if enrolled and receiving services under a 1915(c) HCBS waiver program.

2. **217-Like HIV/AIDS HCBS Group**. Expenditures for medical assistance for individuals over age 1, who have a diagnosis of AIDS or HIV, who meet the hospital LOC criteria, and who would otherwise be Medicaid-eligible if the state had elected the eligibility group described in section 1902(a)(10)(A)(ii)(VI) of the Act and 42 CFR 435.217 in conjunction with section 1902(a)(10)(A)(ii)(V) of the Act, and they were enrolled and receiving services under a 1915(c) HCBS waiver program.

3. **"At-risk" for Nursing Facility Group**. Expenditures for medical assistance

for disabled individuals over age 18 with incomes at or below 250 percent of the Supplemental Security Income (SSI) Federal Benefit Rate who do not meet the NF LOC, but are "at-risk" for institutionalization.

4. **TEFRA-Like Group.** Expenditures for medical assistance for disabled children under age 18 with incomes at or below 250 percent of the SSI who do not meet the NF LOC, but are "at-risk" of institutionalization absent the provision of DSHP services. The state will use financial institutional eligibility rules for individuals who would not be eligible in the community because of community deeming rules (in the same manner that would be used if the group were eligible under the state plan.

5. **Continuing Receipt of Nursing Facility Care.** Expenditures for medical assistance for nursing facility residents, who do not currently meet the NF LOC criteria, but continue to meet the NF level of care criteria in place at the time of admission/enrollment.

6. **Continuing Receipt of Home and Community-Based Services.** Expenditures for medical assistance for individuals receiving HCBS for the disabled and elderly, who do not meet the NF LOC criteria, but continue to meet the LOC criteria in place at the time of enrollment, including HCBS furnished under a terminated 1915(c) waiver.

7. **Continuing Receipt of Medicaid State Plan Services.** Expenditures for medical assistance for disabled children with incomes at or below 250 percent of the SSI, who do not meet the NF or hospital LOC criteria, but continue to meet the LOC criteria in place at the time of their enrollment.

8. **PROMISE Services.** Expenditures for behavioral health services beyond the services described in the approved state plan for otherwise eligible individuals enrolled in the Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE) program.

9. **HCBS for Medicaid State Plan Eligibles.** Expenditures to provide HCBS not included in the Medicaid State Plan to individuals who are eligible for Medicaid as described in the STCs.

10. **Residential and Inpatient Treatment for Individuals with a Substance Use Disorder (SUD).** Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and

withdrawal management services for SUD who are short-term residents in facilities that meet the definition of an Institution for Mental Diseases (IMD).

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly identified as not applicable or that are explicitly waived under the Waiver List, shall apply to demonstration populations.

CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER AUTHORITY

NUMBER: **11-W-00036/4**

TITLE: **Delaware Diamond State Health Plan**

AWARDEE: **Delaware Department of Health & Social Services**

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the demonstration project beginning August 1, 2019 through December 31, 2023, unless otherwise specified. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs). All previously approved waivers for this demonstration are superseded by those set forth below for the state's expenditures relating to dates of service during this demonstration extension.

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of the state plan requirements contained in section 1902 of the Act are granted in order to enable Delaware to implement the Delaware Diamond State Health Plan (DSHP) Medicaid section 1115 demonstration.

1. Amount, Duration, and Scope of Services **Section 1902(a)(10)(B) and 1902(a)(17)**

To the extent necessary to enable Delaware to offer a different benefit package to DSHP and DSHP-Plus participants than is being offered to the traditional Medicaid population. To the extent necessary to enable Delaware to provide additional services to enrollees in the Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE) program.

2. Provision of Medical Assistance **Section 1902(a)(8) and 1902(a)(10)**

To the extent necessary to enable Delaware to limit the provision of medical assistance (and treatment as eligible) for individuals described in the eligibility group under section 1902(a)(10)(A)(ii)(XX) of the Act and the Medicaid State Plan to only former foster care youth who are under 26 years of age, were in foster care under the responsibility of another state or tribe on the date of attaining 18 years of age (or such higher age as the state has elected), were enrolled in Medicaid on that date, and are

now residents in Delaware applying for Medicaid.

3. Freedom of Choice **Section 1902(a)(23)(A)**

To the extent necessary to enable Delaware to restrict freedom-of-choice of provider through the use of mandatory enrollment into managed care plans for DSHP and DSHP- Plus participants. To the extent necessary to enable the state to use selective contracted fee-for-service (FFS) providers, including for Home and Community Based Services (HCBS) and a transportation broker for non- medical transportation. No waiver of freedom of choice is authorized for family planning providers.

4. Retroactive Eligibility **Section 1902(a)(34)**

To the extent necessary to enable Delaware to not extend eligibility to DSHP and DSHP- Plus participants prior to the date that an application for assistance is made, with the exception of institutionalized individuals in nursing facilities and qualified disabled working individuals (QDWIs), as outlined in Table A of the STCs. The waiver of retroactive eligibility does not apply to pregnant women (including during the 60-day postpartum period beginning on the last day of the pregnancy), infants under age 1, or individuals under age 19.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS (STCs)

NUMBER: **11-W-00036/4**

TITLE: **Delaware Diamond State Health Plan 1115(a) Demonstration**

AWARDEE: **Delaware Department of Health & Social Services**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for Delaware's Diamond State Health Plan (DSHP) section 1115(a) Medicaid demonstration (hereinafter "demonstration") to enable the Delaware Department of Health & Social Services (hereinafter "state") to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted waivers of requirements under section 1902(a) of the Social Security Act (Act), and expenditure authorities authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The STCs are effective as of the date of the approval letter, unless otherwise specified.

These STCs related to the programs for those state plan and waiver populations affected by the demonstration are effective August 1, 2019 through December 31, 2023. The state submitted an amendment to this demonstration on August 11, 2020, to revise its budget neutrality expenditures to reflect the costs associated with the adult dental benefits that were recently added to the Medicaid state plan. The state requested this amendment because although the dental services are authorized under state plan authority, they will be administered by the state's managed care delivery system, which is authorized by this demonstration. The amendment was approved effective January 19, 2021.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Eligibility
V. DSHP Benefits

II. PROGRAM DESCRIPTION AND OBJECTIVES

Delaware's Diamond State Health Plan (DSHP) 1115 Demonstration Waiver was initially approved in 1995, and implemented beginning on January 1, 1996. The original goal of the demonstration was to improve the health status of low-income Delawareans by expanding access to healthcare to more individuals throughout the State; creating and maintaining a managed care delivery system with an emphasis on primary care; and controlling the growth of healthcare expenditures for the Medicaid population. The DSHP 1115 Demonstration was designed to mandatorily enroll eligible Medicaid recipients into managed care organizations (MCOs) and 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% 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 was previously 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 create the Diamond State Health Plan Plus (DSHP-Plus), Delaware's managed long term services and supports (MLTSS) program, and require additional state plan populations to receive services through MCOs, including: (1) individuals receiving care at nursing facilities (NF) other than intermediate care facilities for the mentally retarded (ICF/MR); (2) children in pediatric nursing facilities; (3) individuals who receive benefits from both Medicaid and Medicare (dual eligibles); and (4) workers with disabilities who buy-in for coverage. This amendment also added eligibility for the following new demonstration populations: (1) individuals who would previously have been enrolled through the 1915(c) home and community based services (HCBS) waiver program for the Elderly and Disabled - including those receiving services under the Money Follows the Person demonstration; (2) individuals who would previously have been enrolled though the 1915(c) HCBS waiver for Individuals with Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV/AIDS) Related Diseases; (3) individuals residing in NF who no longer meet the current medical necessity criteria for NF services; and (4) adults and children with incomes below 250 percent of the Supplemental Security Income Federal Benefit Rate who are at risk for institutionalization. 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 Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE) starting in 2015. PROMISE enrollees include Medicaid beneficiaries who have a

severe and persistent mental illness (SPMI) and/or a substance use disorder (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 Institution for Mental Diseases (IMD).

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

- 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;
- Rebalancing Delaware's LTC system in favor of HCBS;
- Promoting early intervention for individuals with, or at-risk, for having, LTC needs;
- Increasing coordination of care and supports;
- Expanding consumer choices;
- Improving the quality of health services, including LTC services, delivered to all Delawareans;
- Creating a payment structure that provides incentives for resources to shift from institutions to community-based LTSS services where appropriate;
- Improving coordination and integration of Medicare and Medicaid benefits for full-benefit dual eligibles;
- Improving overall health status and quality of life of individuals enrolled in PROMISE;
- Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population; and
- 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.
    - 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 DSHP demonstration includes five distinct 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 long-term care services and supports (LTSS) to certain individuals under the State Plan, and to certain demonstration populations. Further details on these programs are provided in Table A, Sections V through X of the STCs; 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; and (5) Coverage for high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as IMDs.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Laws.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act (Section 1557).

2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid program and CHIP, expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), must apply to the demonstration.

3. **Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in federal law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operational nature without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state 30 calendar days, in writing, in advance of the expected approval date of the amended STCs, to allow the state time to provide comments and establish a reasonable timeframe for implementation of the change. Changes will be considered effective upon issuance of the approval letter by CMS, subject to agreement on an implementation timeframe. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. Further, the state may seek an amendment to the demonstration (as per STC 7 of this section) as a result of the change in FFP.
    b. If mandated changes in the federal law, regulation, or policy require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under federal law, whichever is sooner.

5. **State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan may be required, except as otherwise noted in these STCs. In all such instances, the Medicaid and CHIP state plan governs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.

7. **Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 calendar days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit reports required in the approved STCs and other deliverables in a timely fashion according to the

deadlines specified herein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
c. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
d. An up-to-date CHIP allotment worksheet, if necessary;
e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. Extension of the Demonstration. States that intend to request a demonstration extension under sections 1115(e) or 1115(f) of the Act must submit extension applications in accordance with the timelines contained in statute. Otherwise, no later than twelve (12) months prior to the expiration date of the demonstration, the Governor or Chief Executive Officer of the state must submit to CMS either a demonstration extension request that meets federal requirements at CFR 431.412(c) or a phase-out plan consistent with the requirements of STC 9.

9. Demonstration Phase Out. The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements:

a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a 30-day public comment period. In

addition, the state must conduct tribal consultation in accordance with STC 13, if applicable. Once the 30-day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its transition and phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.

c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than 14 calendar days after CMS approval of the transition and phase-out plan.

d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210, 431.211, and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR. 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).

e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).

f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.

g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of dis-enrolling beneficiaries.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. Adequacy of Infrastructure. The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The state must comply with the state notice procedures as required in 42 CFR 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the public notice procedures set forth in 42 CFR section 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. Federal Financial Participation (FFP). No federal matching for state expenditures under this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. **Administrative Authority.** When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. **Common Rule Exemption.** The state shall ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program -including procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. The Secretary has determined that this demonstration as represented in these approved STCs meets the requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.101(b)(5).

IV. ELIGIBILITY

16. **State Plan Eligibility Groups Affected By the Demonstration.** Mandatory and optional state plan groups described below derive their eligibility through the Medicaid State Plan, and are subject to all applicable Medicaid laws and regulations in accordance with the Medicaid State Plan, except as expressly waived in this demonstration and as described in these STCs. These state plan eligible beneficiaries are included in the demonstration for use of the managed care network and access to additional benefits not described in the state plan.

Table A. Overview of Eligibility for DSHP and DSHP Plus

Note: All eligibility groups outlined in the below chart are mandatorily enrolled into managed care. The eligibility groups receive DSHP and/or DSHP Plus benefit package as outlined in sections V and VI based on the eligibility criteria. Retroactive eligibility is provided to all pregnant women and children under the age of 19 in all applicable eligibility groups for 3 months prior to the application month, subject to STC #22. Retroactive eligibility is also provided to Institutionalized individuals in nursing facilities and the Ticket to Work Basic Group.

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
Qualified Pregnant Women, Mandatory Poverty Level Related Pregnant Women	§1902(a)(10)(A)(i)(III) and (IV) §1902(aa)(10)(A)(ii)(I), (IV) and (IX) §1931(b) and (d) 42 CFR 435.116 §1905(n)	If age 20 and under: DSHP TANF Children If age 21 and over: DSHP TANF Adults	X		
Qualified Children, Mandatory Poverty Level Infants, Children Aged 1-5 and Children Aged 6-18	§1902(a)(10)(A)(i)(III), (IV),), (VI) and (VII) §1902(a)(10)(A)(ii)(I), (IV) and (IX) §1931(b) and (d) 42 CFR 435.118	DSHP TANF Children	X		

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
SSI Adults without Medicare	§1902(a)(10)(A)(i)(I)(aa) 42 CFR 435.120	DSHP SSI Adults	X		
SSI Children without Medicare	§1902(a)(10)(A)(i)(I)	DSHP SSI Children	X		
Section 4913 Children – lost SSI because of the PRWORA disability definition	§1902(a)(10)(A)(i)(II)	DSHP SSI Children	X		
Parents and Caretaker Relatives	§1931(b) and (d) 42 CFR 435.110	If age 20 and under: DSHP TANF Children If age 21 and over: DSHP TANF Adult	X		
Extended Medicaid due to Child or Spousal support Collections	§408(a)(11)(B) §1931(c)(1) 42 CFR 435.115	If age 20 and under: DSHP TANF	X		

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
		Children If age 21 and over: DSHP TANF Adults			
Transitional Medical Assistance	§408(a)(11)(A) §1902(a)(52) §1902(e)(1) §1925 §1931(c)(2)	If age 20 and under: DSHP TANF Children If age 21 and over: DSHP TANF Adult	X		
Children with Title IV-E Adoption Assistance, Foster Care or Guardianship Care	§1902(a)(10)(A)(I) §473(b)(3) 42 CFR 435.145	DSHP TANF Children	X		
Continuous eligibility for pregnancy and postpartum period	§1902(e)(5) and (e)(6) 42 CFR 435.170	If age 20 and under: DSHP TANF Children If age 21 and over: DSHP TANF Adult	X		

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
Deemed newborns	§1902(e)(4) 42 CFR 435.117	DSHP TANF Children	X		
Working disabled under 1619(b)	§1902(a)(10)(A)(i)(II) §1905(q) §1619(b)	If age 20 and under: DSHP SSI Children If age 21 and over: DSHP SSI Adults	X		
Disabled Adult Children	§1634(c)	If age 20 and under: DSHP SSI Children If age 21 and over: DSHP SSI Adults	X		
Institutionalized Individuals Continuously Eligible Since 1973		DSHP Plus State Plan		X	
Individuals Receiving Mandatory State supplements	42 CFR 435.130	If age 20 and under: DSHP SSI Children	X		

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
		If age 21 and over: DSHP SSI Adults			
Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977 (Pickle amendment)	P.L. 94-566 Sec. 503 42 CFR 435.135	If age 20 and under: DSHP SSI Children If age 21 and over: DSHP SSI Adults	X		
Disabled widows/widowers ineligible for SSI due to an increase in OASDI	§1634(b) 42 CFR 435.137	DSHP SSI Adults	X		
Disabled early widows/widowers ineligible for SSI due to early receipt of Social Security	§1634(d) 42 CFR 435.138	DSHP SSI Adults	X		
SSI Adults with Medicare	§1902(a)(10)(A)(i)(I)	DSHP PLUS State Plan		X	
SSI Children with Medicare	§1902(a)(10)(A)(i)(I)	DSHP PLUS +State Plan	X	X	
Former Foster Care Children	§1902(a)(10)(A)(i)(IX) 42 CFR 435.150	If age 20 and under: DSHP TANF Children	X		

State Plan Mandatory Medicaid Eligibility Groups	Description and Citation	Medicaid Eligibility Group (MEG)	DSHP Benefit Package	DSHP Plus Benefit Package*	Alternative Benefits Plan Package
		If age 21 and over: DSHP TANF Adults			
Individuals who lost eligibility for SSI/SSP due to an increase in OASDI benefits in 1972	42 CFR 435.134	DSHP SSI Adults	X		

State Plan Optional Medicaid Eligibility Groups	Description and Citation	MEG	DSHP Benefit Package	DSHP Plus Benefit Package	Alternative Benefit Plan Package
Optional Infants less than one year old: Optional targeted low-income children Title XXI funding	§1902(a)(10)(A)(ii)(IX) 42 CFR 435.118	DSHP MCHP	X		
Adult Group ages 19-64	§1902(a)(10)(A)(i)(VIII) 42 CFR 435.119	DSHP Adult Group			X
TEFRA Children (Katie Beckett) Qualified Disabled Children under 19	§1902(e)(3)	DSHP SSI Children	X		

State Plan Optional Medicaid Eligibility Groups	Description and Citation	MEG	DSHP Benefit Package	DSHP Plus Benefit Package	Alternative Benefit Plan Package
Individuals who would be eligible for SSI/OSS if not for residing in an institutional setting	§1902(a)(10)(A)(ii)(IV) 42 CFR 435.211	If age 21 and over: DSHP SSI Adults		X	
Children with Non-IV-E Adoption Assistance	§1902(a)(10)(A)(ii)(VIII) 42 CFR 435.227	DSHP TANF Children	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	§1902(a)(10)(A)(ii)(IV) 42 CFR 435.232	If age 20 and under: DSHP SSI Children If age 21 and over: DSHP SSI Adults	X	X	
Optional State supplement – individuals who lose eligibility for Medicaid due to receipt of SSDI and are not yet eligible for Medicare Medical Assistance in Transition to Medicare (MAT)	§1902(a)(10)(A)(ii)(IV) 42 CFR 435.232	If age 20 and under: DSHP SSI Children If age 21 and over: DSHP SSI Adults	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	§1902(a)(10)(A)(ii)(V) 42 CFR 435.236 1905(a)	DSHP PLUS State Plan		X	

State Plan Optional Medicaid Eligibility Groups	Description and Citation	MEG	DSHP Benefit Package	DSHP Plus Benefit Package	Alternative Benefit Plan Package
Medicare) even if they later do not meet the current LOC criteria					
Ticket to Work Basic Group	§1902(a)(10)(A)(ii)(XV)	DSHP PLUS State Plan	X	X	
Out-of-State Former Foster Care Children	Optional Group of Individuals above 133 percent of the FPL §1902(a)(10)(A)(ii)(XX) 42 CFR 435.218	DSHP FFCY	X		

Demonstration Eligible Groups	Description and Citation	Income Standard	Resource Standard	MEG	DSHP Benefit Package	DSHP Plus Benefit Package
TEFRA-Like Children (Katie Beckett) using the "at-risk of NF" LOC criteria in place at time of enrollment	§1902(e)(3) Children, ages 18 or younger, who are disabled as described in section 1614(a) of the Social Security Act, who do not meet the NF LOC, but who in the absence of receiving care are "at-risk" of institutionalization and meet an "at-risk of NF" LOC. Use financial institutional eligibility rules for individuals who would not be eligible in the community because of community deeming rules.	Up to 250% of SSI Standard	$2,000	DSHP TEFRA-Like	X	

Demonstration Eligible Groups	Description and Citation	Income Standard	Resource Standard	MEG	DSHP Benefit Package	DSHP Plus Benefit Package
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)	Use institutional eligibility and post eligibility rules for individuals who would not be eligible in the community because of community deeming rules in the same manner as specified under 42 CFR 453.217, 435.236, and 435.726 of the Federal regulations and 1924 of the Social Security Act, if the State had a 1915(c) waiver program.	Up to 250% of SSI Standard	$2,000 individual $3,000 couple	DSHP PLUS HCBS		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)	Use institutional eligibility and post eligibility rules for individuals who would not be eligible in the community because of community deeming rules in the same manner as specified under 42 CFR 453.217, 435.236, and 435.726 of the Federal regulations and 1924 of the Social Security Act, if the State had a 1915(c) waiver program.	Up to 250% of SSI Standard	$2,000 individual $3,000 couple	DSHP PLUS HCBS		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	§1115 Use financial institutional eligibility and post-eligibility rules for individuals who would not be eligible in the community because of community	Up to 250% of SSI Standard	$2,000 individual $3,000 couple	DSHP PLUS +HCBS		X

Demonstration Eligible Groups	Description and Citation	Income Standard	Resource Standard	MEG	DSHP Benefit Package	DSHP Plus Benefit Package
institutionalization and meet the "at-risk" for NF LOC criteria in place at the time of enrollment and who need/are receiving HCBS	deeming rules in the same manner that would be used if the State had a 1915(c) program.					

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

17. Eligibility Exclusions. Notwithstanding Table A, the following persons are excluded from this demonstration.

Table B. Eligibility Exclusions

Exclusions from DSHP and DSHP Plus	Description and Citation
Individuals participating in a PACE Program	§1934
Qualified Medicare Beneficiaries (QMB)	§1902(a)(10)(E)(i) §1902(r)(2) used to disregard all resources
Specified Low Income Medicare Beneficiary (SLMB)	§1902(a)(10)(E)(iii) §1902(r)(2) used to disregard all resources
Qualifying Individuals (QI)	§1902(a)(10)(E)(iv) §1902(r)(2) used to disregard all resources
Qualified and Disabled Working Individuals	§1902(a)(10)(E)(ii) §1902(r)(2) used to disregard all resources
Individuals in a hospital for 30 consecutive days* (acute care)	§1902(a)(10)(A)(ii)(V)
Presumptive Breast and Cervical Cancer for Uninsured Women	§1920B

Exclusions from DSHP and DSHP Plus	Description and Citation
Breast and Cervical Cancer Program for women	§1902(a)(10)(A)(ii)(XVIII)
Institutionalized individuals in an ICF/MR facility	§1902(a)(10)(A)(ii)(V)

* Individuals who are eligible for Medicaid under 42 CFR 435.236 by virtue of the fact that they are in the hospital for period of not less than 30 consecutive days will be excluded from enrollment in DSHP or DSHP Plus during the period of continuous hospitalization. When this population is ready for discharge, the state will determine whether they meet income and resource criteria under any other Medicaid eligibility categories and their need for continued services such as out of state rehabilitation facilities or LTC services in the community. Their eligibility category determined at that point would determine whether they would be enrolled in the demonstration per the attached eligibility matrix. During the period when the client may not enroll in the demonstration, their hospital stay will be covered fee for service.

18. Eligibility and Post Eligibility Treatment of Income for DSHP Plus Individuals who are Institutionalized. The state must follow the rules specified in the currently approved State plan for institutionalized DSHP Plus participants. All individuals receiving institutional services must be subject to post eligibility treatment of income rules set forth in section 1924 of the Social Security Act (for DSHP Plus individuals who are "institutionalized spouses" under section 1924(h)(1) of the Act) and 42 CFR 435.725 of the federal regulations.

19. Maintenance Needs Allowances and Patient Liability. For HCBS participants who are determined to be "217-like" (i.e., individuals who would not otherwise be eligible under an eligibility group covered under the state plan but who would be financially eligible if institutionalized), the state will apply the post-eligibility treatment-of-income calculation described in section 1924 of the Act (for such married HCBS participants) and 42 CFR 435.726. For such individuals who do not receive services in an Assisted Living Facility, the state will provide a maintenance needs allowance that is equal to the individuals' total income as determined under the post eligibility process, which includes income that is placed in a Miller Trust. For those HCBS participants

that elect to receive services in an Assisted Living Facility, the state will provide a maintenance needs allowance set at the Adult Foster Care Rate, which is the SSI standard plus the Optional State Supplement amount.

For HCBS participants residing in Assisted Living Facilities, the state must provide the MCOs the set of unique taxonomies and procedure codes that the state currently uses to identify HCBS services. The MCOs will instruct HCBS providers to use this set of codes when billing them for HCBS so that they can identify HCBS in their claims processing systems. This way MCOs can ensure that the patient liability amount assessed for each Assisted Living client is only applied toward the cost of HCBS and not to regular state plan services. The state must also include language in the MCO contract specifying the requirement that patient liability only be applied to the cost of HCBS.

20. **Eligibility for the PROMISE Program.** DSHP and DSHP Plus eligible beneficiaries and enrollees applying for services must be screened by the Division of Substance Abuse and Mental Health (DSAMH) using a standardized clinical and functional assessment developed for Delaware and based on national standards. See Attachment D for a detailed explanation of clinical and functional assessments that are used in the screening process.

21. **Eligibility for Former Foster Care Youth (FFCY).** Individuals eligible as "former foster care youth" are defined as individuals under age 26 who were in foster care in another state or tribe when they turned 18 (or such higher age as the state has elected for termination of federal foster care assistance under title IV-E of the Social Security Act (the Act)), were enrolled in Medicaid at that time, and are now residents in Delaware applying for Medicaid.

22. **Retroactive Eligibility.** Delaware has informed CMS that due to technical and administrative issues, it will not be able to implement retroactive eligibility for individuals in the groups specified in section 1902(l)(4) of the Act as of August 1, 2019. The state must complete determinations and provide retroactive eligibility for individuals in the groups specified in section 1902(l)(4) of the Act who apply on or after August 1, 2019 as soon as possible, but no later than July 1, 2020. The state must promptly complete determinations and provide retroactive eligibility for individuals in the groups specified in section 1902(l)(4) of the Act who apply on or after July 1, 2020. The state must conduct outreach and education activities regarding how to apply for and receive Medicaid coverage to the public and to Medicaid providers, particularly those who serve vulnerable populations that may be impacted by the retroactive eligibility waiver.

V. DSHP BENEFITS

23. DSHP Benefits. Benefits provided through this demonstration for the Medicaid managed care program are described below:

a. **DSHP Benefits.** As outlined in Table A, all mandatory and optional state plan and demonstration-eligible populations are entitled to receive all mandatory and optional services under the approved Medicaid state plan. These Medicaid state plan benefits are provided through a combination of contracts with managed care organizations or managed care delivery systems, as well as FFS, for specific services noted below.

b. **DSHP FFS Benefits.** The following state plan services are carved out from the Medicaid MCO benefit package and are paid on a FFS basis:
   i. Child dental;
   ii. Non-emergency transportation, except for emergency ambulance transportation (NEMT transportation broker);
   iii. Day services authorized by the Division of Developmental Disabilities Services Medically necessary behavioral health services for children in excess of MCO plan benefit coverage, which is 30 visits for children;
   iv. Medically necessary behavioral health services for adults under the PROMISE program;
   v. Prescribed pediatric extended care; and
   vi. Targeted case management (TCM).

24. Alternative benefit plan. The Newly Eligible Group, made eligible under the state plan effective January 1, 2014, will receive benefits described in the state's approved alternative benefit plan (ABP) state plan amendment (SPA).

25. Self-Referral. Demonstration beneficiaries may self-refer for the following services:
a. Emergency care;
b. Family planning services, including obstetrics and gynecology services; and
c. For female participants, the MCOs must allow direct access to women's health specialists within the health plan's network for covered care related to women's routine and preventive care.

26. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT). The MCOs must fulfill the state's responsibilities for coverage, outreach, and assistance with respect to EPSDT services that are described in the requirements of sections 1905(a)(4)(b) (services), 1902(a)(43) (administrative requirements), and 1905(r) (definitions).

VI. DSHP PLUS BENEFITS

27. Eligibility for DSHP Plus HCBS Benefits. DSHP Plus provides HCBS LTSS as identified in Table C to eligible individuals as outlined in Table A. Medical and/or functional needs are assessed according to LOC criteria for NFs, hospitals and "at-risk of NF" criteria published in the state rules. These criteria must be based on accepted medical standards. These LOC criteria must be used in assessing eligibility for DSHP Plus HCBS benefits at the time of an individual's initial HCBS enrollment. Attachment E outlines the LOC criteria for NFs and hospitals in effect prior to implementation of DSHP Plus within the demonstration and the LOC criteria for NFs, hospitals, and "at-risk of NF" criteria for initial implementation of DSHP Plus. The state is required to notify CMS 60 days in advance of any changes to these LOC criteria and provide an update to this attachment.

28. DSHP Plus HCBS Benefit Package. The following Table C describes the additional benefits available to HCBS participants, that are provider-directed and, if the participant elects the option, self-directed. The services are further defined in Attachment C.

Table C. DSHP Plus HCBS

Service	Provider Directed	Participant Directed
Case Management	X	
Community Based Residential Alternatives	X	
Personal Care/Attendant Care	X	X
Respite	X	X
Adult Day Services	X	

Service	Provider Directed	Participant Directed
Day Habilitation	X	
Cognitive Services	X	
Personal Emergency Response System	X	
Support for Participant Direction	X	
Independent Activities of Daily living (Chore)	X	X
Nutritional Supports	X	
Specialized Medical Equipment &Supplies	X	
Minor Home Modifications	X	
Home Delivered Meals	X	

29. Option for Participant Direction of DSHP Plus HCBS Services. DSHP Plus participants who elect self-directed care must have the opportunity to have choice and control over how self-directed DSHP Plus HCBS services are provided and who provides the service. Member participation in participant direction is voluntary, and members may participate in or withdraw from participant direction at any time.

a. **Information and Assistance in Support of Participant Direction.** The state/MCO shall have a support system that provides participants with information, training, counseling, and assistance, as needed or desired by each participant, to assist the participant to effectively direct and manage their self-directed services and budgets. Participants shall be informed about self-directed care, including feasible alternatives, before electing the self-direction option. Participants shall also have access to the support system throughout the time that they are self-directing their care. Support activities must include, but is not limited to Support for Participant Direction service which includes two components: Financial Management Services and Support Brokerage and Providers of Support for Participant. Direction must carry out activities associated with both components. The Support for Participant Direction service provides assistance to participants who elect to self-direct their DSHP Plus HCBS services.

b. **Participant Direction by Representative.** The participant who self-directs the DSHP Plus HCBS service may appoint a volunteer designated representative to assist with or perform employer responsibilities to the extent approved by the participant. DSHP Plus HCBS services may be directed by a legal representative of the participant. DSHP Plus HCBS services may be directed by a non-legal representative freely chosen by an adult participant. A person who serves as a representative of a participant for the purpose of directing DSHP Plus HCBS services cannot serve as a provider of DSHP Plus HCBS services for that participant.

c. **Participant Employer Authority.** The participant (or the participant's representative) must have decision-making authority over workers who provide DSHP Plus HCBS.

    i. Participant/Common Law Employer. The participant (or the participant's representative) is the common law employer of workers who provide DSHP Plus HCBS. An IRS-Approved Fiscal/Employer Agent functions as the participant's agent in performing payroll and other employer responsibilities that are required by federal and state law. Supports are available to assist the participant in conducting employer-related functions.

    ii. Decision Making Authorities. The participant exercises the following decision making authorities: Recruit staff, select staff from worker registry, hire staff as common law employer, verify staff qualifications, obtain criminal history and/or background investigation of staff, specify additional staff qualifications based on participant needs and preferences, evaluate staff performance, verify time worked by staff and approve time sheets, and discharge staff.

d. **Disenrollment from Participant-Direction.** A participant may voluntarily disenroll from the self-directed option at any time and return to a traditional service delivery system through the DSHP Plus MCOs. To the extent possible, the member shall provide his/her DSHP Plus HCBS provider ten (10) days advance notice regarding his/her intent to withdraw from participant direction. A participant may also be involuntarily dis-enrolled from the self-directed option for cause, if continued participation in the participant-directed services option would not permit the participant's health, safety, or welfare needs to be met, or the participant demonstrates the inability to self-direct by consistently demonstrating a lack of ability to carry out the tasks needed to self-direct personal care services, or if there is fraudulent use of funds such as substantial evidence that a participant has falsified documents related to participant directed services. If a participant is terminated voluntarily or involuntarily from the self-directed service delivery option, the MCO must transition the participant to the traditional agency direction option and must have safeguards in place to ensure continuity of services.

VII. Substance Use Disorder (SUD) Program

30. <u>Substance Use Disorder Program.</u> Effective upon CMS' approval of the SUD Implementation Protocol, the demonstration benefit package for Delaware Medicaid recipients will include SUD treatment services, including short term residential services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Delaware Medicaid recipients who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including SUD benefits that would otherwise be matchable if the beneficiary were not residing in an IMD. Delaware will must aim for a statewide average length of stay of 30 days in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol J as outlined in STC 31(b) below, to ensure short-term residential treatment stays. Under this demonstration, beneficiaries will have access to high quality, evidence-based SUD treatment services ranging from medically supervised withdrawal management to on-going chronic care for these conditions in cost-effective settings while also improving care coordination and care for comorbid physical and mental health conditions.

The coverage of SUD treatment services and withdrawal management during short term residential and inpatient stays in IMDs will expand Delaware's current SUD benefit package available to all Delaware Medicaid recipients as outlined in Table D. Room and board costs are not considered allowable costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

<u>Table D: Delaware SUD Benefits Coverage with Expenditure Authority</u>

SUD Benefit	Medicaid Authority	Expenditure Authority
Outpatient Services	State plan (Individual services covered)	
Intensive Outpatient Services	State plan (Individual services covered)	

Residential Treatment	State plan (Individual services covered)	Services provided to individuals in IMDs
Medically Supervised Withdrawal Management	State plan	Services provided to individuals in IMDs
Medication-Assisted Treatment (MAT)	State plan	Services provided to individuals in IMDs

The state attests that the services indicated in Table D, above, as being covered under the Medicaid state plan authority are currently covered in the Delaware Medicaid state plan.

31. Substance Use Disorder (SUD) Monitoring and Evaluation

a. **SUD Implementation Plan.** The state must submit an SUD Implementation Plan within 90 calendar days after approval of the SUD program under this demonstration. The state may not claim FFP for services provided in IMDs until CMS has approved the Implementation Plan. Once approved, the Implementation Plan will be incorporated into the STCs, as Attachment I, and once incorporated, may be altered only with CMS approval. After approval of the SUD Implementation Plan, FFP will be available prospectively, not retrospectively. Failure to submit an Implementation Protocol will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral.

At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives of the SUD component of this demonstration program:

i. **Access to Critical Levels of Care for Opioid Use Disorder and other SUDs:** Service delivery for new benefits, including residential treatment and withdrawal management, within 12-24 months of SUD program demonstration approval;

ii. **Use of Evidence-based SUD-specific Patient Placement Criteria:** Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of SUD program demonstration approval;

iii. **Patient Placement:** Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of SUD program demonstration approval;

iv. **Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities:** Currently, residential treatment service providers must be a licensed organization, pursuant to the residential service provider qualifications described in Title 16 Delaware Health and Social Services, Delaware Administrative Code, Section 6001, 4.1. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

v. **Standards of Care:** Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of SUD program demonstration approval;

vi. **Standards of Care:** Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of SUD program demonstration approval;

vii. **Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD:** An assessment of the availability of providers in the key levels of care throughout the state, or in the regions of the

state participating under this demonstration, including those that offer MAT within 12 months of SUD program demonstration approval;

viii. **Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD:** Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;

ix. **SUD Health IT Plan:** Implementation of the milestones and metrics as detailed in STC 31(g) [or Attachment I, if included as attachment]; and

x. **Improved Care Coordination and Transitions between levels of care:** Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of SUD program demonstration approval.

b. SUD Monitoring Protocol. The state must submit a SUD Monitoring Protocol within 150 calendar days after approval of the the SUD implementation plan. The SUD Monitoring Protocol must be developed in cooperation with CMS and is subject to CMS approval. The state must submit the revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS's comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment J. The Monitoring Protocol will describe the quantitative and qualitative elements on which the state will report through quarterly and annual monitoring reports. At a minimum, the SUD Monitoring Protocol must include reporting relevant to each of the program implementation areas listed in STC 31(a). The SUD Monitoring Protocol mustspecify the methods of data collection and timeframes for reporting on the state's progress on required measures as part of the general reporting requirements described in STC 55 of the demonstration. In addition, the SUD Monitoring Protocol must identify a baseline and a target to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings. CMS will closely monitor demonstration spending on services in IMDs to ensure adherence to budget neutrality requirements. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports.

c. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by December 31, 2021. The state must require that the assessor must collaborate with key stakeholders, including representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners in the design, planning and conducting of the mid-point assessment. The state must require that the assessment will include an examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Protocol, and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol. The state must also require that the assessment will also include a determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date, and a determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and about the risk of possibly missing those milestones and performance targets. The state must require that the mid-point assessment will also provide a status update of budget neutrality requirements. For each milestone or measure target at medium to high risk of not being met, the state must require that the assessor will provide, for consideration by the state, recommendations for adjustments in the state's implementation plan or to pertinent factors that the state can influence that will support improvement. The state must require that the assessor will provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report will be provided to CMS. The state must brief CMS will be briefed on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Protocol and SUD Monitoring Plan Protocols for ameliorating these risks subject to CMS approval.

d. SUD Evaluation. The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as listed in sections XII General Reporting Requirements and XVI Evaluation of the Demonstration of the STCs.

e. SUD Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment F (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a revision to the Evaluation Design to include the SUD program with implementation timeline, no later than one hundred eighty (180) days after the effective date of these amended STCs. Any modifications to an existing approved Evaluation Design will not

affect previously established requirements and timelines for report submission for the demonstration, if applicable. The state must use an independent evaluator to develop the draft Evaluation Design.

i. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Quarterly and Annual Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation design, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

ii. **Evaluation Questions and Hypotheses Specific to SUD Program.** Consistent with Attachments F and G (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

f. SUD Health Information Technology (Health IT). The state must provide CMS with an assurance that it has a sufficient health IT infrastructure/"ecosystem" at every appropriate level (i.e. state, delivery system, health plan/MCO and individual provider) to achieve the goals of the demonstration-or it will submit to CMS a plan to develop the infrastructure/capabilities. This "SUD Health IT Plan," or assurance, must be included as a section of the state's "Implementation Plan" (see STC 31(a)) to be approved by CMS. The SUD Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The SUD Health IT Plan must also be used to identify areas of SUD health IT ecosystem improvement.

i. The SUD Health IT section of the SUD Implementation Protocol must include implementation milestones and dates for achieving them (see Attachment I).

ii. The SUD Health IT Plan must be aligned with the state's broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state's Behavioral Health (BH) "Health IT" Plan.

iii. The SUD Health IT Plan must describe the state's goals, each DY, to enhance the state's prescription drug monitoring program's (PDMP)[1]

iv. The SUD Health IT Plan must address how the state's PDMP will enhance ease of use for prescribers and other state and federal stakeholders.[2] This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients' history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.

v. The SUD Health IT Plan must, as applicable, describe the state's capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the SUD Health IT Plan must describe current and future capabilities regarding PDMP queries-and the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will must also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.

vi. The SUD Health IT Plan must describe how the activities described in (a) through (e) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.[3]

vii. In developing the SUD Health IT Plan, states should use the following resources.

1. States may use resources at Health IT.Gov (https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/) in "Section 4: Opioid Epidemic and Health IT."

[1] Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the "opioid" epidemic and facilitate a nimble and targeted response.
[2] *Ibid*.
[3] Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morbidity and Mortality Weekly Rep 2017; 66.

2. States may also use the CMS 1115 Health IT resources available on "Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability" at https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html. States should review the "1115 Health IT Toolkit" for health IT considerations in conducting an assessment and developing their Health IT Plans.
3. States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP plans and, more generally, to meet the goals of the demonstration

g. The state must include in its Monitoring Plan (see STC 31(b)) an approach to monitoring its SUD Health IT Plan which will include performance metrics to be approved in advance by CMS.

h. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines-and report on its progress to CMS in in an addendum to its Annual Reports (see STC 55).

i. As applicable, the state should advance the standards identified in the 'Interoperability Standards Advisory-Best Available Standards and Implementation Specifications' (ISA) in developing and implementing the state's SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.

i. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the state must use the federally-recognized standards, barring another compelling state interest.
ii. Where there are opportunities at the state-and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state must use the federally-recognized ISA standards, barring no other compelling state interest.

VIII. PROMISE BENEFITS

32. PROMISE Enrollee Access to DSHP and DSHP Plus Benefits. Individuals enrolled in PROMISE will receive all of their

DSHP or DSHP Plus state plan benefits through the MCOs, just as the individuals had before enrollment in PROMISE. However, DSHP beneficiaries who are enrolled in PROMISE, will have a Department of Substance Abuse and Mental Health (DSAMH) counselor as their primary case manager. DSHP Plus beneficiaries will continue to have the MCO case manager act as their primary; the DSAMH counselor will be the secondary case manager. Individuals enrolled in PROMISE and eligible for DSHP and DSHP Plus but not yet enrolled in an MCO may receive all of their state plan benefits through FFS while awaiting enrollment in the MCO.

33. **PROMISE Benefits.** Beneficiaries enrolled in PROMISE receive all of the following non-state plan benefits through the program (definitions of these services are found in Attachment D):
    a. Benefits counseling
    b. Case management
    c. Community-based residential alternative supports that exclude assisted living
    d. Community transition services
    e. CPST/PSR and other services by non-licensed clinic staff including evidence-based practices, such as assertive community treatment (ACT) and intensive case management (ICM)
    f. Financial coaching
    g. Non-medical transportation
    h. Nursing
    i. Peer supports
    j. Personal care
    k. Respite
    l. Skill-building for individual activities of daily living/chore
    m. Supported employment (both individual and small group)

In addition, the individuals will receive the behavioral health state plan benefits of substance use disorder including medication assisted treatment (MAT) and services by licensed behavioral health practitioners through the PROMISE program.

IX. COST SHARING

34. Co-payments will be charged to all DSHP and DSHP Plus Managed Care enrollees as stipulated in the state plan. Standard Medicaid exemptions from cost-sharing, such as family planning services, as stipulated in 42 CFR. 447.56, apply to the demonstration.

X. ENROLLMENT

35. DSHP and DSHP plus Mandatory Enrollment.

a. **Enrollment.** The state may mandatorily enroll individuals pursuant to 42 CFR 438.54(d) served through this demonstration in managed care programs to receive DSHP and DSHP Plus benefits pursuant to Sections V, VI and VIX of the STCs.

b. **Notice Requirement for a Change in Network.** The state must provide notice to CMS as soon as it becomes aware of (or at least 90 days prior if possible) a potential change in the number of plans available for choice within an area, or any other changes impacting proposed network adequacy.

36. PROMISE Enrollment. DSAMH coordinates enrollment into PROMISE. A DSAMH care manager will arrange to meet the beneficiary and assess the beneficiary's eligibility for the PROMISE program based on the standardized assessment tool in Attachment D. If the individual meets the criteria for enrollment into the program, the individual can choose whether to enroll in the program, as enrollment is strictly voluntary. Individuals enrolled in this program will receive the benefits outlined in Attachment D.

XI. DELIVERY SYSTEMS

37. Managed Care Requirements. The state, its MCOs and any subcontractor delegated to perform activities under the managed care contract must comply with the managed care regulations published at 42 CFR Part 438, except as explicitly waived herein. Capitation rates shall be developed and certified as actuarially sound, in accordance with 42 CFR 438.4 through 438.8.

38. Managed Care Benefit Package. Individuals enrolled in any managed care plan within the state must receive from the managed

care plan the benefits as identified in Sections V and VI of the STCs.

39. **Public Contracts.** Payments under contracts with public agencies, that are not competitively bid in a process involving multiple bidders, must not exceed the documented costs incurred in furnishing covered services to eligible individuals (or a reasonable estimate with an adjustment factor no greater than the annual change in the consumer price index).

40. **Requirements for Quality Measurement and Performance Improvement.** The state must meet all the requirements of 42 CFR Part 438 Subpart E.

41. **Advisory Committee as required in 42 CFR 438.70**. The state must maintain for the duration of the demonstration a managed care advisory group comprised of individuals and interested parties impacted by the demonstration's use of managed care, regarding the impact and effective implementation of these changes to seniors and persons with disabilities. Membership on this group should be periodically updated to ensure adequate representation of individuals receiving LTSS.

42. **PROMISE and MCO Care Coordination.** The state must assure that the MCOs coordinate, to the maximum extent possible, all services provided by the MCO (primary, acute, and any state plan behavioral health services) with the enhanced behavioral health services provided FFS by the PROMISE program.

XII. HCBS SERVICE DELIVERY AND REPORTING REQUIREMENTS

43. **HCBS Electronic Visit Verification System**. The state must demonstrate compliance with the Electronic Visit Verification System (EVV) requirements for personal care services (PCS) by January 1, 2020 and home health services by January 1, 2023 in accordance with section 12006 of the 21st Century CURES Act, unless the state has received a good faith effort exemption for up to one year from CMS.

44. **Integration of HCBS assurances within the State Quality Strategy** - DSHP Plus and PROMISE. The state is required to integrate the Section 1915(c) waiver assurances and program requirements into DSHP Plus (as appropriate for a managed long-term services and supports program, consistent with the 42 CFR Part 438 requirements) and the 1915(i) SPA assurances and

program requirements into PROMISE. The state is expected to implement systems that measure and improve its performance to meet the waiver assurances set forth in 42 CFR 441.301 and 441.302 and the state, or its EQRO, must monitor and annually evaluate the MCO's performance on these assurances as part of its external quality review. Within 120 days of CMS approval of the waiver extension, the state will submit for CMS review an HCBS Assurances Assessment to demonstrate how these assurances are addressed, measured through the State Quality Strategy, and monitored. CMS and the state agree that any gaps identified will be added to the DSHP 1115 demonstration requirements via the process outlined in STC 3.

45. Home and Community-Based Settings. The state must demonstrate compliance with the requirements for HCBS settings as described in the 1915(c) and 1915(i) regulations in accordance with implementation/effective dates as published in the Federal Register and CMS guidance.

46. Quality Improvement Strategy for 1915(c) or 1915(i) approvable HCBS Services either by the state, the MCOs through specific contract provisions, or DSAMH (for PROMISE) as follows**:** For services that could have been authorized to individuals under a 1915(c) waiver or under a 1915(i) HCBS State plan, the state's Quality Assessment and Performance Improvement Plan must encompass LTSS specific measures set forth in the federal managed care rule at 42 CFR 438.330 and should also reflect how the state will assess and improve performance to demonstrate compliance with applicable federal waiver assurances set forth in 42 CFR 441.301 and 441.302 as follows:

a. Level of Care (LOC) and At-Risk Determinations.
    i. Performance measures are required for the following: An evaluation for level of care or at-risk determination must be given to all applicants for whom there is reasonable indication that services may be needed in the future either by the State, or as a contractual requirement, by the MCO or PROMISE program.
    ii. All DSHP Plus and PROMISE enrollees must be reevaluated at least annually or as otherwise specified either by the state, or as a contractual requirement, by the MCO.
    iii. Performance measures are required for the following: The LOC and at-risk process and instruments will be implemented as specified by the state, either through the state's own processes, or as a contractual requirement, by the MCO.

b. Person-Centered Planning and Individual Service Plans.

i. The state must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants. Performance measures are required for choice of waiver services and providers, service plans address all assessed needs and personal goals, and services are delivered in accordance with the service plan including the type, scope, amount, duration, and frequency specified in the service plan.

ii. The MCO contract and PROMISE program shall require the use of a person-centered and directed planning process as required by 42 CFR 441.301(c)(1) (1915(c), and 42 CFR 441.725(c) (1915(i))and intended to identify the strengths, capacities, and preferences of the enrollee as well as to identify an enrollee's long term care needs and the resources available to meet these needs, and to provide access to additional care options as specified by the contract. The person-centered plan is developed by the participant with the assistance of the team and those individuals, such as family, friends and professionals the participant chooses to include. The individual will have informed choices about treatment and service decisions. The plan includes the services and supports that the participant needs to live in the community.

iii. The MCO contract and PROMISE program shall require the written person-centered service plan meets federal requirements at 42 CFR 441.301(c)(2) (1915(c)) or 42 CFR 441.725(b) (1915(i)) so that service plans must address all enrollees' assessed needs (including health and safety risk factors), preferences, choices abilities and personal goals and the strategies to address them.

iv. The MCO contract and PROMISE program shall require that a process is in place that permits participants to request a change to the person-centered plan if the participant's circumstances necessitate a change. The MCO contract and PROMISE program shall require that all service plans are updated collaboratively and/or revised at least annually or when warranted by changes in the enrollee's needs and involve an ongoing commitment to the participant.

v. The MCO contract and PROMISE program shall require development of a back-up plan to ensure that needed assistance will be provided in the event that the regular services and supports identified in the individual service plan are temporarily unavailable. The back-up plan may include other individual assistants or services.

vi. The MCO contract and PROMISE program shall require that services be delivered in accordance with the service plan, including the type, scope, amount, and frequency.

vii. The MCO contract and PROMISE program shall require that enrollees receiving HCBS services have a choice of provider within the MCO's network and PROMISE program, as applicable.

viii. The MCO contract and PROMISE program shall require policies and procedures for the MCO and PROMISE performance improvement process to monitor appropriate implementation of the individual service plans**.**

ix. The MCO contract and PROMISE program shall utilize the state established minimum guidelines as outlined in the approved MCO contracts and PROMISE manuals regarding:

- The individuals who develop the person-centered service plan (and their requisite qualifications);
- The individuals who are expected to participate in the plan development process;
- Types of assessments that are conducted as part of the service plan development process;
- How participants are informed of the services available to them;

c. Qualified Providers.

i. The MCO provider credentialing requirement in 42 CFR 438.214 and HCBS provider qualification requirements in PROMISE shall apply to all HCBS providers. If the state wishes to change provider qualification standards from those that exist under waivers #0136 and #4159, the state must reach agreement with CMS to do so and ensure that the new standards preserve health and welfare. The state is required to report any changes in provider qualification standards as a part of the quarterly monitoring calls and quarterly reports pursuant to STCs 55 and 57.

ii. To the extent that the MCO's credentialing policies and procedures do not address non-licensed non-certified providers, the MCO shall create alternative mechanisms to ensure the health and safety of enrollees.

iii. The state must have performance measures that track that providers meet licensure/certification standards, that non-certified providers are monitored to assure adherence to demonstration requirements, and that the state verifies that training is given to providers in accordance with the demonstration

d. Financial Accountability: The state must demonstrate that it has designed and implemented an adequate system for ensuring financial accountability of the HCBS program. For DSHP Plus, this requires the state to demonstrate actuarial soundness on an annual basis pursuant to 42 CFR Part 438.

e. Health and Welfare. The MCO contract and PROMISE program shall require the MCO and PROMISE staff to, on a

continuous basis, identify, address, and seek to prevent instances of abuse, neglect, exploitation; and unexplained deaths; that an incident management system is in place that effectively resolves incidents and prevents further singular incidents to the extent possible; that state policies and procedures for the use or prohibition of restrictive interventions are followed; and, that the state establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved demonstration.

f. Fair Hearings.
   i. All enrollees must have access to the state fair hearing process as required by 42 CFR 431 Subpart E. In addition, the requirements governing MCO appeals and grievances in 42 CFR 438 Subpart F shall apply for MCO covered benefits.
   ii. The MCO contract shall require the MCO to make whatever reasonable accommodations are necessary to ensure that enrollees have a meaningful opportunity to exercise their appeal and grievance rights.

47. The state will submit a report or reports to CMS which includes evidence on the status of the HCBS quality assurances and measures that adheres to the requirements outlined in the March 12, 2014, CMS Informational Bulletin, Modifications to Quality Measures and Reporting in 1915(c) Home and Community-Based Waivers. (1915(c) and 1915(i) HCBS). NOTE: This information could be captured in the 1115 Summary report detailed in STC 91. If this information is provided via existing reporting (e.g. EQR reports), Delaware will provide to CMS a list of such reports that support each assurance.

The state must report annually the deficiencies found during the monitoring and evaluation of the HCBS waiver assurances, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not reoccur. The state must also report on the number of substantiated instances of abuse, neglect, exploitation and/or death, the actions taken regarding the incidents and how they were resolved. NOTE: This information could be included in the annual reports submitted for 1115 demonstration waivers detailed in STC 55. If this information is provided via existing reporting, Delaware will provide to CMS a list of such reports that support the waiver assurances.

48. Critical Incident Management System. The state must operate a critical incident management system according to the state's established policies, procedures and regulations (as described in Attachment E), including the requirement to report, document,

and investigate incidents of abuse, neglect, exploitation, and any unexplained deaths. The state must notify CMS of any changes to the policies, procedures and regulations. The MCO/state is required to analyze the critical incident data, track and trend, and make necessary changes in order to prevent reoccurrence.

49. State Grievance/Complaint System. The state must operate a grievance/complaint system that affords participants the opportunity to register grievances or complaints concerning the provision of services.

50. Freedom of Choice. The MCO case managers must be required to inform each applicant or member of any alternatives available, including the choice of institutional care versus HCBS, during the assessment process. Documentation of choice must be incorporated into the Service Plan.

51. HCBS Beneficiary Protections: Conflict of Interest: The state agrees that the entity that authorizes the services is external to the agency or agencies that provide the HCB services. The state also agrees that appropriate separation of assessment, treatment planning and service provision functions are incorporated into the state's conflict of interest policies. Nothing in this STC precludes the use of MCOs, operating in accordance with 42 CFR 438, to provide HCBS services under the DSHP Plus Program (MLTSS).

Each beneficiary eligible for long term services and supports will have informed choice on their option to self-direct LTSS, have a designated representative direct LTSS on their behalf, or select traditional agency-based service delivery. Both level of care assessment and person-centered service planning personnel will receive training on these options.

The state, either directly or through its MCO contracts must ensure that participants' engagement and community participation is supported to the fullest extent desired by each participant. Beneficiaries may change managed care plans if their residential or employment support provider is no longer available through their current plan.

52. Medicaid Authorities Transition. During the demonstration period, the state must conduct an evaluation to assess if portions of the demonstration could be transitioned to 1915(c) and 1915(i) authorities and how such transitions are consistent with the state's program goals including (but not limited to) consideration for the impact to services, members, state administrative costs

and burden, state reporting, a waiver allocation process and budget implications. The state will work with CMS to complete and submit this assessment by December 31, 2021.

XIII. GENERAL REPORTING REQUIREMENTS

53. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of $5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as "deliverable(s)") are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement.

The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state's anticipated date of submission. Should CMS agree to the state's request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state's written extension request.
c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next

Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.

d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.
e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

54. Deferral of Federal Financial Participation (FFP) from IMD claiming for Insufficient Progress toward Milestones. Up to $5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the SUD Implementation Protocol and the required performance measures in the SUD Monitoring Protocol agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to $5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made. The state is expected to meet the milestones by the end of the first two years of when the state is first able to claim FFP under the SUD program.

55. Submission of Post-approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

56. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
c. Submit deliverables to the appropriate system as directed by CMS.

XIV. MONITORING

57. Monitoring Reports. The state must submit three (3) Quarterly Reports and one compiled Annual Report each DY. The information for the fourth quarter should be reported as distinct information within the Annual Report. The Quarterly Reports must be submitted in the format specified in Attachment A and are due no later than sixty (60 calendar days) following the end of each demonstration quarter. The compiled Annual Report is due no later than ninety (90 calendar days) following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

a. Operational Updates - Per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.

b. Performance Metrics – Per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.

c. Budget Neutrality and Financial Reporting Requirements - Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements section of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.

d. Evaluation Activities and Interim Findings - Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
e. SUD Health IT Plan - The state must include a summary of progress made in regards to SUD Health IT Plan requirements outlined in STC 31(f).

58. Close-Out Operational Report. Within 120 calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

a. The draft close-out report must comply with the most current guidance from CMS.
b. The state will present to and participate in a discussion with CMS on the close-out report.
c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
d. The final close-out report is due to CMS no later than 30 calendar days after receipt of CMS' comments.
e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 51.

59. Monitoring Calls. CMS will convene periodic conference calls with the state.

a. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, enrollment and access, budget neutrality, and progress on the evaluation.
b. CMS will provide updates on any amendments or concept papers under review, as well as federal policies and issues that may affect any aspect of the demonstration.
c. The state and CMS will jointly develop the agenda for the calls.

60. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least 30 calendar days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the

comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XV. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

61. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS.

62. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this Medicaid section 1115 demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and State and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state shall submit the form CMS-64 Quarterly Medicaid Expenditure Report, showing Medicaid expenditures made in the quarter just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on the form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

63. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the applicable federal matching rate for the demonstration as a whole as outlined for the following, subject to the budget neutrality expenditure limits described in Section XV of the STCs:

a. Administrative costs, including those associated with the administration of the demonstration;
b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and

c. Net medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration.

64. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this section 1115 demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

b. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

c. The state acknowledges that any amendments that impact the financial status of this section 1115 demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

65. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.

b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.

c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
e. Under all circumstances, health care providers must retain 100 percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

66. Monitoring the Demonstration. The state will provide CMS with information to effectively monitor the demonstration, upon request, in a reasonable time frame.

67. Program Integrity. The state must have processes in place to ensure that there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

68. Medicaid Eligibility Group (MEG). MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The following Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table E: Master MEG Chart

MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
DSHP TANF Children	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 1: TANF Children less than 21
DSHP TANF Adult	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 2: TANF Adults aged 21and over
DSHP SSI Children	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 3: Disabled Children less than 21
DSHP SSI Adults	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 4: Aged and Disabled Adults 21and older
DSHP MCHP	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 5: Infants less than one year of age with income levels above 185 percent FPL through 200 percent FPL.
DSHP Plus State Plan	Main Budget Neutrality Test	X		X	Medical assistance expenditures for Demonstration Population 6: DSHP Plus State Plan.
DSHP Adult Group	Hypo 1	X		X	Medical assistance expenditures for Demonstration Population 11: DSHP Adult Group.

SUD IMD	Hypo 2	X		X	All expenditures for costs of medical assistance that could be covered, were it not for the IMD prohibition under the state plan, provided to otherwise eligible individuals during a month in an IMD. Expenditure Authority #9.
DSHP Plus HCBS	Hypo 3	X		X	Medical assistance expenditures for Demonstration Population 9: DSHP Plus HCBS. Expenditure Authorities #1, #2, and #3.
DSHP TEFRA-Like	Hypo 3	X		X	Medical assistance expenditures for Demonstration Population 10: DSHP Plus HCBS. Expenditure Authority #4.
Diamond State Health Plan (PROMISE)	Hypo 4	X		X	Medical assistance expenditures for Demonstration Population 10: PROMISE Services. Expenditure Authority #8.

69. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-00036/4). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in

the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.

b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by demonstration year on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.

c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.

d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the table below, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

e. Member Months. Through its quarterly submission of the Budget Neutrality Monitoring Tool, as described in STC 69, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs indicated in the table entitled MEG Detail for Expenditure and Member Month Reporting. The term “eligible member

months" refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information. To permit full recognition of "in-process" eligibility, reported counts of member months may be revised retrospectively as needed.

f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state's Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

g. Specific Reporting Requirements for Demonstration Population 5.
   i. As outlined in Table A, uninsured children above 185 percent through 200 percent of the FPL are funded with title XXI funds. Insured children above 185 percent through 200 percent of the FPL are funded with title XIX funds. The state is eligible to receive title XXI funds for expenditures for these uninsured children meeting the definition specified in section 2110(b)(1) of the Social Security Act, up to the amount of its title XXI allotment. Expenditures for these children under title XXI must be reported on separate Forms CMS-64.21U and/or 64.21UP in accordance with the instructions in section 2115 of the State Medicaid Manual.
   ii. Title XIX funds for these uninsured children meeting the definition specified in section 2110(b)(1) of the Social Security Act are available under this demonstration if the state exhausts its title XXI allotment once timely notification as described in subparagraph (iii) has been provided.
   iii. If the state exhausts its title XXI allotment prior to the end of a federal fiscal year, title XIX federal matching funds are available for these children. During the period when title XIX funds are used, expenditures related to this demonstration population must be reported as waiver expenditures on the Forms CMS 64.9 Waiver and/or CMS 64.9P Waiver. To initiate this:
      1. The state shall provide CMS with 120 days prior notice before it begins to draw down title XIX

matching funds for this demonstration population;

2. The state shall submit:
    A. An updated budget neutrality assessment that includes a data analysis which identifies the specific "with waiver" impact of the proposed change on the current budget neutrality expenditure cap. Such analysis shall include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current extension approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as result of the proposed change which isolates (by Eligibility Group) the impact of the change;
    B. An updated CHIP allotment neutrality worksheet.

iv. The expenditures attributable to this demonstration population will count toward the budget neutrality expenditure cap calculated under STC 75, using the same per member per month (PMPM) amounts as for TANF Children and will be considered expenditures subject to the budget neutrality cap as defined in STC 75, so that the state is not at risk for claiming title XIX federal matching funds when title XXI funds are exhausted.

Table F: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
DSHP TANF Children	Medical assistance expenditures for DSHP TANF Children, as defined in Table A.	Exclude persons identified in Table B. Exclude DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP TANF Children, as defined in Table A. Exclude months for persons identified in Table B. Exclude SUD IMD months.	1/1/1994	12/31/2023
DSHP TANF Adult	Medical assistance expenditures for DSHP TANF Adult, as defined in Table A.	Exclude spending for persons identified in Table B. Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP TANF Adult, as defined in Table A. Exclude months for persons identified in Table B. Exclude SUD IMD months.	1/1/1994	12/31/2023
DSHP SSI Children	Medical assistance expenditures for DSHP SSI Children, as defined in Table A.	Exclude spending for persons identified in Table B. Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP SSI Children, as defined in Table A. Exclude months for persons identified in Table B. Exclude SUD IMD months.	1/1/1994	12/31/2023

DSHP SSI Adults	Medical assistance expenditures for DSHP SSI Adults, as defined in Table A.	Exclude spending for persons identified in Table B. Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP SSI Adults, as defined in Table A. Exclude months for persons identified in Table B. Exclude SUD IMD months.	1/1/1994	12/31/2023
DSHP MCHP	Medical assistance expenditures for DSHP MCHP, as defined in Table A, when funded with title XIX funds. See STC 67(g).	Exclude spending for persons identified in Table B. Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP MCHP, as defined in Table A, when funded with title XIX funds. See STC 67(g). Exclude months for persons identified in Table B. Exclude SUD IMD months.	7/1/1997	12/31/2023
DSHP PLUS State Plan	Medical assistance expenditures for DSHP Plus State	Exclude spending for persons identified in Table B.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP Plus State Plan, as defined in Table A.	3/22/2012	12/31/2023

	Plan, as defined in Table A.	Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.				Exclude months for persons identified in Table B. Exclude SUD IMD months.		
DSHP Adult Group	Medical assistance expenditures for DSH Adult Group, as defined in Table A.	Exclude spending for persons identified in Table B. Exclude spending for DSHP FFS Benefits. Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP Adult Group, as defined in Table A. Exclude months for persons identified in Table B. Exclude SUD IMD months.	1/1/2014	12/31/2023
SUD IMD	SUD IMD spending: Expenditures for otherwise covered services furnished to otherwise eligible individuals provided	None	Report on customary lines by category of service. Report IMD service expenditures on Line 2A, Mental Health Facility Services - Reg. Payments	Date of service	MAP	Y Report SUD IMD months, which are months of eligibility in which the individual receives treatment for SUD as a short-term resident in an IMD at any point during the month.	7/1/2019	12/31/2023

	during a SUD IMD month. See Expenditure Authority #9.							
DSHP PLUS HCBS	Medical assistance expenditures for DSHP Plus HCBS, as defined in Table A. See Expenditure Authorities #1, #2, and #3.	Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP Plus HCBS, as defined in Table A. Exclude SUD IMD months.	3/22/2012	12/31/2023
DSHP TEFRA-Like	Medical assistance expenditures for DSHP TEFRA-Like, as defined in Table A. See Expenditure	Exclude SUD IMD spending.	Report on customary lines by category of service.	Date of service	MAP	Y Report months of Medicaid eligibility for DSHP TEFRA-Like, as defined in Table A. Exclude SUD IMD months.	3/22/2012	12/31/2023

	Authority #4.							
Diamond State Health Plan (PROMISE)	Expenditures for behavioral health services beyond the services described in the approved state plan for otherwise eligible individuals enrolled in PROMISE. See Expenditure Authority #8.	Exclude SUD IMD spending.	Report PROMISE Services expenditures on Line 49, Other Care Services	Date of service	MAP	Y Report Medicaid months of eligibility for individuals during which they receive PROMISE services at any time in the month. Exclude SUD IMD months.	1/1/2015	12/31/2023

70. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in Table G below.

Table G: Demonstration Years

Demonstration Year 24	August 1, 2019 to December 31, 2019	5 months
Demonstration Year 25	January 1, 2020 to December 31, 2020	12 months
Demonstration Year 26	January 1, 2021 to December 31, 2021	12 months
Demonstration Year 27	January 1, 2022 to December 31, 2022	12 months
Demonstration Year 28	January 1, 2023 to December 31, 2023	12 months

*For the purpose of calculating budget neutrality for the temporary extension period of January 1, 2019 through July, 31, 2019, DY 24 budget neutrality limits will apply.

71. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the performance metrics database and analytics (PMDA) system. The tool incorporates the "Schedule C Report" for comparing demonstration's actual expenditures to the budget neutrality expenditure limits described in section XI. CMS will provide technical assistance, upon request.

72. Future Adjustments to Budget Neutrality. CMS reserves the right to adjust the budget neutrality expenditure limit:

a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments. CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the

change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation. The changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.

c. If, after review and/or audit, the data supplied by the state to set the budget neutrality expenditure limit are if found to be inaccurate. The state certifies that the data it provided are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief.

73. Expenditure Reconciliation and Limitations. Since DY 19 (01/01/14 through 12/31/2014), Delaware has not reported demonstration expenditures consistently to CMS through the CMS-64 reports, leading to significant discrepancies between the expenditures reported on budget neutrality monitoring spreadsheets and the CMS-64.

a. The state must correct and complete reporting of expenditures subject to the budget neutrality limit for DY 19 through DY 23. By December 31, 2019, the state must submit to CMS a draft plan and timeline for remediation that will include the following elements:

i. Completion of the Budget Neutrality Specifications to support reporting of expenditures in compliance with the requirements in these STCs;

ii. A detailed methodology and approach for identifying demonstration relevant expenditures, including any past expenditures that may have been reported on CMS-64.9 Base or CMS-64.9P Base forms instead of CMS 64.9 Waiver and 64.9P Waiver forms;

iii. Submission of appropriate prior period adjustments, consistent with timely filing requirements, to reassign reported expenditures from Base to Waiver (or vice versa). The Budget Neutrality Specifications Manual will address how adjustments will be made for DY 19 through 23.

b. Time Frame and Limitations. The State must complete the reconciliation process by December 31, 2021. Failure to complete the reconciliation process will result in forfeiture by the state of all budget neutrality savings from DY 19 through 23.

XVI. MONITORING BUDGET NEUTRALITY

74. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP

that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

75. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

76. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which projected fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

77. Main Budget Neutrality Test. The Main Budget Neutrality Test allows the state to show that demonstration waivers granted have not resulted in increased costs to Medicaid, and that federal Medicaid "savings" have been achieved sufficient to offset the additional projected federal costs resulting from expenditure authority. The table below identifies the MEGs that are used for the Main Budget Neutrality Test. MEGs designated as "WOW Only" or "Both" are components used to calculate the budget neutrality expenditure limit. MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against the budget neutrality expenditure limit. In addition, any expenditures in excess of limit from Hypothetical Budget Neutrality Tests count as expenditures under the Main Budget Neutrality Test. The Composite Federal Share for this test is calculated based on all MEGs indicated as "Both."

Table H: Main Budget Neutrality Test

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR *[define]*	TREND	DY 24	DY 25	DY 26	DY 27	DY 28
DSHP TANF Children	PC	Both	$	3.7%	$521.61	$540.91	$560.92	$581.67	$603.19
DSHP TANF Adult	PC	Both	$	4.4%	$874.71	$946.39	$987.47	$1030.93	$1,076.29
DSHP SSI Children	PC	Both	$	4.1%	$2,986.78	$3,109.24	$3,236.72	$3,369.43	$3,507.58
DSHP SSI Adults	PC	Both	$	4.1%	$2,984.50	$3,131.85	$3,259.87	$3,393.53	$3,532.66
DSHP MCHP	PC	Both		3.7%	$521.61	$540.91	$560.92	$581.67	$603.19
DSHP PLUS State Plan	PC	Both		2.76%	$2,896.82	$3,000.03	$3,082.59	$3,167.67	$3,255.10

***PC = Per Capita, Agg = Aggregate**

77. **Hypothetical Budget Neutrality.** When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be "hypothetical;" that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS's current view that states should not have to "pay for," with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, during negotiations. If the state's WW hypothetical spending exceeds the supplemental test's expenditure limit, the state agrees (as a condition of CMS approval) to offset that excess spending by savings elsewhere in the demonstration or to refund the FFP to CMS.

78. **Hypothetical Budget Neutrality Test 1: DSHP Adult Group.** Adults eligible for Medicaid as the group defined in section 1902(a)(10)(A)(i)(VIII) of the Act are included in this demonstration, and in the budget neutrality. The state will not be allowed to obtain budget neutrality "savings" from this population. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test. If the state's experience of the take up rate for the DHSP Adult Group and other factors that affect the costs of this population indicates that the PMPM limit described above in paragraph (a) may underestimate the actual costs of medical assistance for the DHSP Adult Group, the state may submit an adjustment to paragraph (a) for CMS review without submitting an amendment pursuant to STC 7. Adjustments to the PMPM limit for a demonstration year must be submitted to CMS by no later than October 1 of the demonstration year for which the adjustment would take effect.

Table I: Hypothetical Budget Neutrality Test 1

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 24	DY 25	DY 26	DY 27	DY 28
DSHP Adult Group	PC	Both	$799.72 DY 23 Actual PMPM Cost	4.7%	$837.31	$909.10	$951.25	$995.95	$1,042.76

79. **Hypothetical Budget Neutrality Test 2: SUD Initiative.** SUD IMD is a "pass-through" or "hypothetical" population, and are included in this demonstration, and in the budget neutrality. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 2. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as

"WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table J: Hypothetical Budget Neutrality Test 2

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 24	DY 25	DY 26	DY 27	DY 28
SUD IMD	PC	Both	$772.14 CY 2017 Actual PMPM Cost	4.5%	$806.89	$874.20	$912.97	$954.00	$996.88

80. Hypothetical Budget Neutrality Test 3: DSHP plus HCBS and DSHP TEFRA-Like. DSHP Plus HCBS and DSHP TEFRA-Like are "pass-through" or "hypothetical" population, and are included in this demonstration, and in the budget neutrality. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 3. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table K: Hypothetical Budget Neutrality Test 3

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 24	DY 25	DY 26	DY 27	DY 28
DSHP Plus HCBS	PC	Both	$6,866.14	2.76%	$7,055.65	$7,274.31	$7,74.83	$7,681.13	$7,893.13

			DY 23 Actual PMPM Cost						
DSHP TEFRA-Like	PC	Both	$2,869.14 DY 23 BN PMPM	4.4%	$2,995.38	$3,127.18	$3,264.78	$3,408.43	$3,558.40

81. Hypothetical Budget Neutrality Test 4: PROMISE. PROMISE is "pass-through" or "hypothetical" expenditure category, and is included in this demonstration, and in the budget neutrality. The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 4. MEGs that are designated "WOW Only" or "Both" are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as "WW Only" or "Both." MEGs that are indicated as "WW Only" or "Both" are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table L: Hypothetical Budget Neutrality Test 4

MEG	PC or Agg*	WOW Only, WW Only, or Both	BASE YEAR	TREND	DY 24	DY 25	DY 26	DY 27	DY 28
Diamond State Health Plan (PROMISE)	PC	Both	$1,432.06 DY 23 BN PMPM	4.4%	$1,495.07	$1,560.85	$1,629.53	$1,701.23	$1,776.08

82. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be

known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Main or Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

83. Transitional Phase-Down of Newly Accrued Savings. Beginning with DY 24, the net variance between the without-waiver cost and actual with-waiver cost will be reduced for selected Medical population based MEGs. The reduced variance, calculated as an applicable percentage times the total variance, will be used in place of the total variance to determine overall budget neutrality for the demonstration. (Equivalently, the difference between the total variance and reduced variance could be subtracted from the without-waiver cost estimate.) The applicable percentages have been determined in accordance with the policy for Transitional Phase-Down of Newly Accrued Savings described in State Medicaid Director Letter # 18-009. This provision only applies to the Main Budget Neutrality Test, and to the MEGs that are designated "Both" without-waiver and with-waiver. The MEGs affected by this provision and the applicable percentages are shown in the table below. If the total variance for an MEG in a DY is negative, the applicable percentage is 100 percent.

Table M: Savings Phase-Down

MEG	DY 24	DY 25	DY 26	DY 27	DY 28
DSHP TANF Children	25%	25%	25%	25%	25%
DSHP TANF Adult	25%	25%	25%	25%	25%
DSHP SSI Children	25%	25%	25%	25%	25%
DSHP SSI Adults	25%	25%	25%	25%	25%
DSHP MCHP	25%	25%	25%	25%	25%
DSHP PLUS State Plan	80%	70%	60%	50%	40%

84. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from January 1, 2019 to December 31, 2023. The Main Budget Neutrality Test may incorporate net savings from

the immediately prior demonstration period of January 1, 2014 through December 31, 2018 (but not from any earlier approval period). If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

85. Mid-Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the table below as a guide for determining when corrective action is required.

Year	Cumulative target definition	Percentage
DY 24	Cumulative budget neutrality limit plus:	2.0 percent
DY 24 & 25	Cumulative budget neutrality limit plus:	1.5 percent
DY 24 through 26	Cumulative budget neutrality limit plus:	1.0 percent
DY 24 through 27	Cumulative budget neutrality limit plus:	0.5 percent
DY 24 through 28	Cumulative budget neutrality limit plus:	0 percent

XVII. EVALUATION OF THE DEMONSTRATION

86. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 51.

87. **Independent Evaluator.** Upon approval of the demonstration, the state must begin arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party must sign an agreement with the state to conduct the demonstration evaluation in an independent manner in accord with the CMS-approved, draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

88. **Evaluation Budget.** A budget for the evaluation must be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluation such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the design is not sufficiently developed, or if the estimates appear to be excessive.

89. **Draft Evaluation Design.** The draft Evaluation Design must be developed in accordance with attachment F (Developing the Evaluation Design including guidance about retroactive eligibility) of these STCs. The state may choose to submit one evaluation design inclusive of the demonstration and SUD, or a separate evaluation design focused on SUD. If the state chooses to submit two evaluation designs, the SUD evaluation design is subject to the same terms and conditions listed below which apply to the overall demonstration evaluation. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the effective date of these STCs. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable.

90. **Evaluation Design Approval and Updates.** The state must submit a revised draft Evaluation Design within sixty (60) days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Design, the document will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) days of CMS approval. The state must implement the evaluation design and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in theses STCs. Once CMS approves the evaluation design, if the

state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

91. Evaluation Questions and Hypotheses. Consistent with attachments F and G (Developing the Evaluation Design and Preparing the Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

Domain of Focus: The Evaluation Design must, at a minimum, address the research questions/topics listed below and the goals of the demonstration as outlined in Section I of the STCs. For questions that cover broad subject areas, the state may propose a more narrow focus of the evaluation.

a. The impact of rebalancing the LTC system in favor of HCBS.
b. The costs and benefits of providing early intervention for individuals with, or at-risk, for having LTC needs.
c. The cost-effectiveness and efficiency of DSHP Plus in ensuring that appropriate health care services are provided in an effective and coordinated fashion.
d. 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.
e. The extent to which the PROMISE services improve the overall health status and quality of life of the individuals enrolled in PROMISE.
f. 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.
g. 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.
h. If the addition of adult dental benefits increases access to dental services and ultimately improved health outcomes for adults in Delaware.

93. Interim Evaluation Reports. The state must submit an Interim Evaluation Report for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Report must be posted to the state's website with the application for public comment.

a. The interim evaluation report will discuss evaluation progress and present findings to date as per the approved evaluation design.
b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses, and how the design was adapted should be included. If the state is not requesting a renewal for a demonstration, an Interim Evaluation report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
d. The state must submit the final Interim Evaluation Report 60 calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
e. The Interim Evaluation Report must comply with Attachment G of these STCs.

94. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment G of these STCs. The state must submit a draft Summative Evaluation Report for the demonstration's current approval period, August 1, 2019 through December 31, 2023, within 18 months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within 60 calendar days of receiving comments from CMS on the draft.
b. The final Summative Evaluation Report must be posted to the state's Medicaid website within 30 calendar days of approval by CMS.

XVIII. SCHEDULE OF STATE DELIVERABLES FOR THE DEMONSTRATION

EXTENSION PERIOD

The state is held to all reporting requirements as outlined in the STCs; this schedule of deliverables should serve only as a tool for informational purposes only.

Date - Specific	Deliverable	STC Reference
30 days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 days after SUD program approval date	SUD Implementation Plan	STC 31(a)
150 days after SUD Implementation Plan approval date	SUD Monitoring Protocol	STC 31(b)
180 days after approval date	Draft Evaluation Design	STCs 31(e)
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STCs 31(e)
30 days after CMS Approval	Approved Evaluation Design published to state's website	STCs 31(e)(i)
December 31, 2021	SUD Mid-Point Assessment	STC 31(c)
One year prior to the end of the demonstration, or with renewal application	Draft Interim Evaluation Report	STC 90
60 days after receipt of CMS comments	Final Interim Evaluation Report	STC 90(d)
18 months of the end of the demonstration	Draft Summative Evaluation Report	STC 91(a)
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 91(a)
30 calendar days of CMS approval	Approved Final Summative Evaluation Report published to state's website	STC 91(b)
60 days prior to implementation of any LOC changes	LOC Criteria, required to share a revised Attachment E	

	Deliverable	STC Reference
Annual	By April 1st - Draft Annual Report	Section XII, STC 55
Each Quarter (05/31, 08/31, 11/30)	Quarterly Operational Reports	Section XII, STC 55
	Quarterly Enrollment Reports	Section XII, STC 55
	CMS-64 Reports	Section XIII, STC 67
	Eligible Member Months	Section XIII STC 67(e)

ATTACHMENT A
Quarterly Report Content and Format

Under Section XIII, STC 55, the state is required to submit quarterly progress reports to CMS. The purpose of the quarterly report is to inform CMS of significant demonstration activity from the time of approval through completion of the demonstration. The reports are due to CMS 60 days after the end of each quarter.

The following report guidelines are intended as a framework and can be modified when agreed upon by CMS and the state. A complete quarterly progress report must include an updated budget neutrality monitoring workbook. An electronic copy of the report narrative, as well as the Microsoft Excel workbook is provided.

NARRATIVE REPORT FORMAT:

Title Line One – Diamond State Health Plan

Title Line Two - Section 1115 Quarterly Report

Demonstration/Quarter Reporting Period:
Example:
Demonstration Year: 12 (1/1/2007 – 12/31/2007)
Federal Fiscal Quarter: 1/2007 (1/07 - 3/07)

Introduction
Information describing the goals of the demonstration, what it does, and key dates of approval /operation (this should be the same for each report).

Enrollment Information

Please complete the following table that outlines all enrollment activity under the demonstration. The state should indicate "N/A" where appropriate. If there was no activity under a particular enrollment category, the state should indicate that by "0".

Enrollment Counts
Note: Enrollment counts should be person counts, not member months

Demonstration Populations (as hard coded in the CMS 64)	**Current Enrollees** (to date)	**Disenrolled in Current Quarter**
Population 1: Former AFDC Children less than 21 [DSHP TANF Children]		
Population 2: Former AFDC Adults aged 21and over [DSHP TANF Adult]		
Population 3: Disabled Children less than 21 [DSHP SSI Children]		
Population 4: Aged and Disabled Adults 21 and older [DSHP SSI Adults]		
Population 5: Infants less than one year of age with income levels above 185 percent FPL through 200 percent FPL: optional targeted low income children. [DSHP MCHP]		

Demonstration Populations (as hard coded in the CMS 64)	**Current Enrollees** (to date)	**Disenrolled in Current Quarter**
Population 8: DSHP Plus State Plan		
Population 9: DSHP Plus HCBS		
Population 10: DSHP TEFRA-Like		
Population 11: DSHP Adult Group		
Population 12: PROMISE		
Population 13: Former Foster Care Youth		

Outreach/Innovative Activities
Summarize outreach activities and/or promising practices for the current quarter.

Operational/Policy Developments/Issues
Identify all significant program developments/issues/problems that have occurred in the current quarter or anticipated to occur in the near future that affect health care delivery, including but not limited to, approval and contracting with new plans, benefit changes, enrollment; grievances; proposed or implemented LOC changes; quality of care; access; changes in provider qualification standards; access; proposed changes to payment rates; health plan financial performance that is relevant to the demonstration; and other operational issues. Also identify all significant policy and legislative developments/issues/problems that have occurred in the current quarter or anticipated to occur in the near future.

Expenditure Containment Initiatives
Identify all current activities, by program and or demonstration population. Include items such as status, and impact to date as well as short and long term challenges, successes and goals.

Financial/Budget Neutrality Development/Issues
Identify all significant developments/issues/problems with financial accounting, budget neutrality, and CMS 64 reporting for the current quarter. Identify the state's actions to address these issues.

Member Month Reporting
Enter the member months for each of the EGs for the quarter.

A. For Use in Budget Neutrality Calculations

Eligibility Group	**Month 1**	**Month 2**	**Month 3**	**Total for Quarter Ending XX/XX**
DSHP TANF Children				
DSHP TANF Adult				
DSHP SSI Children				

DSHP SSI Adults				
DSHP MCHP (Title XIX match)*				
DSHP Plus State Plan				
DSHP Adult				
SUD IMD				
DSHP Plus HCBS				
DSHP TEFRA-Like				
DSHP PROMISE				
* This EG does not include children funded through title XXI. Please note within the report, if the state must use title XIX funds for other uninsured children meeting the definition specified in section 2110(b)(1) of the Social Security Act if the state exhausts title XXI funds.				

Eligibility Group	**Total Member Months for the Quarter**	**PMPM**	**Total Expenditures** *(Member months multiplied by PMPM)*
DSHP TANF Children			
DSHP TANF Adult			
DSHP SSI Children			
DSHP SSI Adults			
DSHP MCHP (Title XIX match)*			
DSHP Plus State Plan			
DSHP Adult			
SUD IMD			
DSHP Plus HCBS			
DSHP TEFRA-Like			
DSHP PROMISE			
* This EG does not include children funded through title XXI. Please note within the report, if the state must use title XIX funds for other uninsured children meeting the definition specified in section 2110(b)(1) of the Social Security Act if the state exhausts title XXI funds.			

B. For Informational Purposes Only

Eligibility Group	**Month 1**	**Month 2**	**Month 3**	**Total for Quarter Ending XX/XX**
DSHP MCHP (Title XXI match)				

Consumer Issues
A summary of the types of complaints or problems consumers identified about the program in the current quarter. Include any trends discovered, the resolution of complaints, and any actions taken or to be taken to prevent other occurrences. Also discuss feedback received from the MCARP and other consumer groups.

Quality Assurance/Monitoring Activity
Identify any quality assurance/monitoring activity in current quarter. As part of the annual report, the state must also report on the effectiveness of the updated comprehensive Quality Strategy as it impacts the demonstration.

Managed Care Reporting Requirements
Address network adequacy reporting from plans including GeoAccess mapping, customer service reporting including average speed of answer at the plans and call abandonment rates; summary of MCO appeals for the quarter including overturn rate and any trends identified; enrollee complaints and grievance reports to determine any trends; and summary analysis of MCO critical incident report which includes, but is not limited to, incidents of abuse, neglect and exploitation. The state must include additional reporting requirements within the annual report as outlined in STC 66(e).

Demonstration Evaluation
Discuss progress of evaluation design and planning.

Enclosures/Attachments
Identify by title any attachments along with a brief description of what information the document contains.

State Contact(s)
Identify individuals by name, title, phone, fax, and address that CMS may contact should any questions arise.

Date Submitted to CMS

ATTACHMENT B
Historical Budget Neutrality Data

The table below lists the calculated per-member per-month (PMPM) figures for the Diamond State Health Plan by eligibility group and service, as well as the negotiated trend rates for each of the demonstration years preceding this extension. During the 2006 renewal, the service categories listed below (pharmacy, behavioral health, and managed care) were collapsed into one PMPM per eligibility group.

In 2012, the DSHP PLUS (known as PLUS) MEG was added to the state plan budget neutrality agreement. This MEG was included for DY 17 and DY 18 (CY 2012 and CY 2013). As part of the DY 19 – DY 23 renewal, the PLUS MEG was split into DSHP PLUS State Plan and DSHP PLUS HCBS. The PLUS HCBS MEG became a waiver population for purposes of budget neutrality for DY 19 – DY 23 (CY 2014 –CY 2018). In the DY 24 – DY 28, the PLUS HCBS MEG became a hypothetical MEG.

Several hypothetical MEGs have been added to the demonstration. These state may not earn budget neutrality savings on these populations, however, the State is at risk for the cost of services provided to these populations. A separate table is included to identify these MEGS and their related PMPMs.

Note: During DSHP's extension under the authority of section 1115(f), demonstration year eight was converted from the Federal fiscal year to a calendar year. Therefore, an additional three months (noted below as Oct – Dec. 2003) was added to the extension period in order to put the Demonstration on a calendar year basis.

			TANF Children		**TANF Adults**		**SSI Children**		**SSI Adults**	
DY	Time Period	Service Category	Trend Rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM
1	FFY 1996	*Pharmacy*	25.3%	$ 9.66	32%	$ 29.08	21%	$ 51.51	27.4%	$ 58.95
		Behavioral Health	29.8%	$ 31.64	29.8%	$ 1.15	29.8%	$ 85.17	29.8%	$ 119.28
		Managed Care	6.79%	$ 92.60	6.17%	$ 215.39	6.85%	$ 647.08	6.85%	$ 523.85
2	FFY 1997	*Pharmacy*	6.79%	$ 10.31	6.17%	$ 30.87	6.85%	$ 55.04	6.85%	$ 169.84
		Behavioral Health	6.79%	$ 33.79	6.17%	$ 1.22	6.85%	$ 85.17	6.85%	$ 119.28
		Managed Care	6.79%	$ 98.89	6.17%	$ 228.67	6.85%	$ 691.41	6.85%	$ 559.74
3	FFY 1998	*Pharmacy*	6.79%	$ 11.01	6.17%	$ 32.78	6.85%	$ 58.81	6.85%	$ 181.47
		Behavioral Health	6.79%	$ 36.08	6.17%	$ 1.29	6.85%	$ 97.23	6.85%	$ 136.19
		Managed Care	6.79%	$ 105.60	6.17%	$ 242.78	6.85%	$ 738.77	6.85%	$ 598.08

4	FFY 1999	*Pharmacy*	6.79%	$ 11.76	6.17%	$ 34.80	6.85%	$ 62.83	6.85%	$ 193.90
		Behavioral Health	6.79%	$ 38.53	6.17%	$ 1.37	6.85%	$ 103.89	6.85%	$ 145.51
		Managed Care	6.79%	$ 112.77	6.17%	$ 257.76	6.85%	$ 789.37	6.85%	$ 639.05
5	FFY 2000	*Pharmacy*	6.79%	$ 12.56	6.17%	$ 36.95	6.85%	$ 67.14	6.85%	$ 207.18
		Behavioral Health	6.79%	$ 41.15	6.17%	$ 1.46	6.85%	$ 111.01	6.85%	$ 155.48
		Managed Care	6.79%	$ 120.43	6.17%	$ 273.67	6.85%	$ 843.45	6.85%	$ 682.82
6	FFY 2001	*Pharmacy*	6.79%	$ 13.41	6.17%	$ 39.23	6.85%	$ 71.74	6.85%	$ 221.37
		Behavioral Health	6.79%	$ 43.94	6.17%	$ 1.55	6.85%	$ 118.62	6.85%	$ 166.13
		Managed Care	6.79%	$ 128.61	6.17%	$ 290.55	6.85%	$ 901.22	6.85%	$ 729.59
7	FFY 2002	*Pharmacy*	6.79%	$ 14.32	6.17%	$ 41.65	6.85%	$ 76.65	6.85%	$ 236.54
		Behavioral Health	6.79%	$ 46.93	6.17%	$ 1.64	6.85%	$ 126.74	6.85%	$ 177.51
		Managed Care	6.79%	$ 137.34	6.17%	$ 308.48	6.85%	$ 962.95	6.85%	$ 779.57
8	FFY 2003	*Pharmacy*	6.79%	$ 15.29	6.17%	$ 44.22	6.85%	$ 81.90	6.85%	$ 236.54
		Behavioral Health	6.79%	$ 50.11	6.17%	$ 1.74	6.85%	$ 135.42	6.85%	$ 189.67
		Managed Care	6.79%	$ 146.67	6.17%	$ 327.51	6.85%	$ 1,028.92	6.85%	$ 832.97
	Oct – Dec. 2003	*Pharmacy*	6.79%	$ 15.54	6.17%	$ 44.89	6.85%	$ 83.27	6.85%	$ 256.96
		Behavioral Health	6.79%	$ 50.94	6.17%	$ 1.77	6.85%	$ 137.68	6.85%	$ 192.84
		Managed Care	6.79%	$ 149.10	6.17%	$ 332.45	6.85%	$ 1,046.10	6.85%	$ 846.88

			TANF Children		TANF Adults		SSI Children		SSI Adults		DSHP Plus	
DY	Time Period	Service Category	Trend Rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM	Trend rate	PMPM
9	CY 2004	*Pharmacy*	6.79%	$ 16.60	6.17%	$ 47.66	6.85%	$ 88.97	6.85%	$ 74.56		
		Behavioral Health	6.79%	$ 54.40	6.17%	$ 1.88	6.85%	$ 147.11	6.85%	$ 206.05		
		Managed Care	6.79%	$ 159.22	6.17%	$ 352.96	6.85%	$ 1,117.76	6.85%	$ 904.89		
10	CY 2005	*Pharmacy*	6.79%	$ 17.73	6.17%	$ 50.60	6.85%	$ 95.07	6.85%	$ 93.37		
		Behavioral Health	6.79%	$ 58.09	6.17%	$ 1.99	6.85%	$ 157.19	6.85%	$ 220.16		
		Managed Care	6.79%	$ 170.03	6.17%	$ 374.74	6.85%	$ 1,194.33	6.85%	$ 966.88		
11	CY 2006	*Pharmacy*	6.79%	$ 18.93	6.17%	$ 53.72	6.85%	$ 101.58	6.85%	$ 13.47		
		Behavioral Health	6.79%	$ 62.04	6.17%	$ 2.11	6.85%	$ 167.96	6.85%	$ 235.25		
		Managed Care	6.79%	$ 181.58	6.17%	$ 397.86	6.85%	$ 1,276.14	6.85%	$ 1,033.11		
12	CY 2007		6.79%	$ 280.38	6.17%	$ 481.68	6.85%	$ 1,651.56	6.85%	$ 1,690.19		
13	CY 2008		5.84%	$ 296.75	5.16%	$ 506.54	5.42%	$ 1,741.07	5.42%	$ 1,781.79		
14	CY 2009		5.84%	$ 314.08	5.16%	$ 532.54	5.42%	$ 1,835.44	5.42%	$ 1,878.37		
15	CY 2010		5.84%	$332.40	5.16%	$560.21	5.20%	$1,930.89	5.20%	$1,976.02		
16	CY 2011		5.84%	$351.81	5.16%	$589.12	5.20%	$2,031.30	5.20%	$2,078.77		
17	CY 2012		5.84%	$372.36	5.16%	$619.52	5.20%	$2,136.93	5.20%	$2,186.87	2.76%	$2,394.17

18	CY 2013	[redacted]	5.84%	$394.11	5.16%	$651.49	5.20%	$2,248.05	5.20%	$2,300.59	2.76%	$2,460.24
19	CY 2014		5.00%	$413.82	5.16%	$685.11	5.00%	$2,360.45	4.50%	$2,404.12	2.76%	$2,528.14
20	CY 2015		5.00%	$434.51	5.16%	$720.46	5.00%	$2,478.47	4.50%	$2,512.31	2.76%	$2,597.92
21	CY 2016		5.00%	$456.24	5.16%	$757.64	5.00%	$2,602.40	4.50%	$2,625.36	2.76%	$2,669.62
22	CY 2017		5.00%	$479.05	5.16%	$796.73	5.00%	$2,732.52	4.50%	$2,743.50	2.76%	$2,743.30
23	CY 2018		5.00%	$503.00	5.16%	$837.84	5.00%	$2,869.14	4.50%	$2,866.96	2.76%	$2,819.02

Expansion populations were added in 2010 to reflect the treatment of Expansion Adults and FP Expansion populations as allowed under ACA. Prior to April 1, 2010, Expansion Adults were treated as a waiver population. TEFRA Kids were added with the DY 19 extension as were PROMISE services though PROMISE was not implemented until DY 20.

		[redacted]	**Expansion adults**		**FP Expansion**		**TEFRA Kids**		**PROMISE**	
DY	Time period		Trend rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM	Trend Rate	PMPM
15	CY 2010		5.02%	$763.70	3.83%	$6.89				
16	CY 2011		5.02%	$802.05	3.83%	$7.15				
17	CY 2012		5.02%	$842.33	3.83%	$7.47				

18	CY 2013		5.02%	$884.63	6.10%	$7.93				
19	CY 2014		5.10%	$463.14			5.00%	$2360.45		
20	CY 2015		5.10%	$486.76			5.00%	$2478.47	5.10%	$1233.54
21	CY 2016		5.10%	$511.58			5.00%	$2602.40	5.10%	$1296.54
22	CY 2017		5.10%	$537.68			5.00%	$2732.52	5.10%	$1362.57
23	CY 2018		5.10%	$565.10			5.00%	$2869.14	5.10%	$1432.06

ATTACHMENT C
DSHP Plus HCBS Service Definitions

HCBS Service	Service Definition
Case Management	Case management includes services assisting participants in gaining access to needed demonstration and other state plan services, as well as medical, social, educational and other services, regardless of the funding source for the services to which access is gained. Case managers are responsible for the ongoing monitoring of the provision of services included in the participant's service plan and/or participant health and welfare. Case managers are responsible for initiating the process to evaluate the/or re-evaluate the individual's level of care and/or the development of service plans. Case managers are responsible for assisting the participant in gaining access to needed services regardless of the funding source. All DSHP Plus members will receive case management. The case manager provides intensive case management for DSHP Plus members in need of long term care services though service planning and coordination to identify services; brokering of services to obtain and integrate services, facilitation and advocacy to resolve issues that impede access to needed services; monitoring and reassessment of services based on changes in member's condition; and gate keeping to assess and determine the need for services to members.
Community-based residential alternatives that include Assisted Living Facilities	Community-based residential services offer a cost-effective, community based alternative to nursing facility care for persons who are elderly and/or adults with physical disabilities. This currently includes assisted care living facilities. Community-based residential services include personal care and supportive services (homemaker, chore, attendant services, and meal preparation) that are furnished to participants who reside in homelike, non-institutional settings. Assisted living includes a 24-hour on-site response capability to meet scheduled or unpredictable resident needs and to provide supervision, safety and security. Services also include social and recreational programming, and medication assistance (to the extent permitted under state law). As needed, this service may also include prompting to carry out desired behaviors and/or to curtail inappropriate behaviors. Services that are provided by third parties must

HCBS Service	Service Definition
	be coordinated with the assisted living provider. Personal care services are provided in assisted living facilities as part of the community-based residential service. To avoid duplication, personal care (as a separate service) is not available to persons residing in assisted living facilities.
Personal Care/ Attendant Care Services	Personal care includes assistance with ADLs (e.g. bathing, dressing, personal hygiene, transferring, toileting, skin care, eating and assisting with mobility). When specified in the service plan, this service includes assistance with instrumental activities of daily living (IADLs) (e.g. light housekeeping chores, shopping, meal preparation). Assistance with IADLs must be essential to the health and welfare of the participant based on the assessment of the Case Manager and with input from the participant and their family caregivers. This service is not available to persons residing in Assisted Living.
Respite Care	Respite care includes services provided to participants unable to care for themselves furnished on a short-term basis because of the absence or need for relief of those persons who normally provide care for the participant. FFP is not claimed for the cost of room and board. This is provided both at home and in Nursing and Assisted Living Facilities. This service is limited to no more than fourteen (14) days per year. The managed care organization may authorize service request exceptions above these limits on a case-by-case basis when it determines that: • No other service options are available to the member, including services provided through an informal support network; • The absence of the service would present a significant health and welfare risk to the member; and • Respite service provided in a nursing home or assisted living facility is not utilized to replace or relocate an individual's primary residence.
Adult Day Services	Services furnished in a non-institutional, community-based setting, encompassing both health and social services needed to ensure the optimal functioning of the participant. Meals provided as part of these services shall not constitute a "full nutritional regimen" (3 meals per day). Physical, occupational and speech

HCBS Service	Service Definition
	therapies indicated in the individual's plan of care will be furnished as component parts of this service. The service is reimbursed at two levels: the basic rate and the enhanced rate. The enhanced rate is authorized only when staff time is needed to care for participants who demonstrate ongoing behavioral patterns that require additional prompting and/or intervention. Such behaviors include those which might result from an acquired brain injury. The behavior and need for intervention must occur at least weekly. This service is not available to persons residing in Assisted Living. The meals provided as part of this service are only provided when the participant is at the Adult Day Care Center. The cost of such meals is rolled into the Adult Day Care provider's reimbursement rate. The provider does not bill separately for the meal.
Day Habilitation	Day Habilitation includes assistance with acquisition, retention, or improvement in self-help, socialization and adaptive skills that takes place in a non-residential setting, separate from the participant's private residence. Activities and environments are designed to foster the acquisition of skills, appropriate behavior, greater independence, and personal choice. Meals provided as part of these services shall not constitute a "full nutritional regimen" (3 meals per day). Day habilitation services focus on enabling the participant to attain or maintain his or her maximum functional level and shall be coordinated with any physical, occupational, or speech therapies in the service plan. In addition, day habilitation services may serve to reinforce skills or lessons taught in other settings. This service is provided to participants who demonstrate a need based on cognitive, social, and/or behavioral deficits such as those that may result from an acquired brain injury. This service is not available to persons residing in Assisted Living.
Cognitive Services	Cognitive Services are necessary for the assessment and treatment of individuals who exhibit cognitive deficits or maladaptive behavior, such as those that are exhibited as a result of a brain injury. This service is not

HCBS Service	Service Definition
	available to persons residing in Assisted Living and Nursing Facilities. Cognitive services are limited to twenty (20) visits per year plus an assessment. The managed care organization may authorize service request exceptions above this limit. Cognitive Services include two key components: • Multidisciplinary Assessment and consultation to determine the participant's level of functioning and service needs. This Cognitive Services component includes neuropsychological consultation and assessments, functional assessment and the development and implementation of a structured behavioral intervention plan. • Behavioral Therapies include remediation, programming, counseling and therapeutic services for participants and their families which have the goal of decreasing or modifying the participant's significant maladaptive behaviors or cognitive disorders that are not covered under the Medicaid State Plan. These services consist of the following elements: Individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under state law.), services of social workers, trained psychiatric nurses, and other staff trained to work with individuals with psychiatric illness, individual activity therapies that are not primarily recreational or diversionary, family counseling (the primary purpose of which treatment of the individual's condition) and diagnostic services.
Personal Emergency Response System	A Personal Emergency Response System (PERS) is an electronic device that enables a waiver participant to secure help in an emergency. As part of the PERS service, a participant may be provided with a portable help button to allow for mobility. The PERS device is connected to the participant's phone and programmed to signal a response center and/or other forms of assistance once the help button is activated. This service is not available to persons residing in Assisted Living.

HCBS Service	Service Definition
Support for Participant Direction	DSHP Plus members may opt to self-direct their Personal Care/Attendant services. Support for Participant Direction combines two functions: financial management services (FMS) and information and assistance in support of participant direction (support brokerage). Providers of Support for Participant Direction carry out activities associated with both components. The Support for Participant Direction service provides assistance to participants who elect to self-direct their personal care services. Participant direction affords DSHP Plus members the opportunity to have choice and control over how personal care services are provided and who provides the services. Member participation in participant direction is voluntary. Members may participate in or withdraw from participant direction at any time. To the extent possible, the member shall provide his/her personal care provider ten (10) days advance notice regarding his/her intent to withdraw from participant direction. Providers of this service perform various functions to support participants in planning for and carrying out their responsibilities as common-law employers of personal care attendants. (A) **Financial Management Services.** Financial management services provide assistance to members with managing funds associated with the services elected for self-direction. The following supports are provided • Assist participants in verifying personal care attendant's citizen status • Collect and process personal care attendants' timesheets • Process payroll, withholding, filing and payment of applicable federal, state, and local employment-related taxes and insurance • Execute and hold Medicaid provider agreements • Receive and disperse funds for the payment of services to personal care attendants (B) **Support Brokerage.** Support Brokerage service offers the

HCBS Service	Service Definition
	following support: • Coordinate with participants to develop, sign, and update individual service plans • Recruit personal care attendants • Maintain a roster of personal care attendants • Secure background checks on prospective personal care attendants on behalf of participants • Provide information on employer/employee relations • Provide training to participants and personal care attendants • Provide assistance with problem resolution • Maintain participant files • Provide support in arranging for emergency back-up care
Independent Activities of Daily Living (Chore) Services	Chore services constitute housekeeping services that include assistance with shopping, meal preparation, light housekeeping, and laundry. This is an in-home service for frail older persons or adults with physical disabilities. The service assists them to live in their own homes as long as possible. The service must be provided by trained housekeepers. This service is not available to persons residing in Assisted Living.
Nutritional Supports	Nutritional supports for individuals diagnosed with AIDS that are not covered under the state plan. This service is for individuals diagnosed with HRD/AIDS to ensure proper treatment in those experiencing weight loss, wasting, malabsorption and malnutrition. Such oral nutritional supplements are offered as a service to those identified at nutritional risk. This service covers supplements not otherwise covered under the state plan service. This service does not duplicate a service provided under the state plan as an EPSDT service. Prior authorized by CM. Service must be prior authorized by case manager in conjunction with the consultation of a medical professional's recommendation for service. Standard for assessing the nutritional risk factors: • Weighing less than 90% of usual body weight; • Experiencing weight loss over a one to six month period;

HCBS Service	Service Definition
	• Losing more than five pounds within a preceding month; • Serum albumin is less than 3.2 or very high indicating dehydration, difficulty swallowing or chewing, or persistent diarrhea; or • Wasting syndrome affected by a number of factors including intake, nutrient malabsorption & physiological and metabolic changes.
Specialized Medical Equipment and Supplies	Specialized medical equipment and supplies not covered under the Medicaid State Plan. This service includes: (a) devices, controls, or appliances specified in the plan of care that enable the member to increase his/her ability to perform activities of daily living; (b) devices, controls, or appliances that enable the member to perceive, control, or communicate with the environment in which he/she lives; (c) items to address physical conditions along with ancillary supplies and equipment necessary to the proper functioning of such items; (d) such other durable and non-durable medical equipment not available under the state plan that is necessary to address participant functional limitations; and, (e) necessary medical supplies not available under the state plan. Items reimbursed under DSHP Plus are in addition to any medical equipment and supplies furnished under the state plan and exclude those items that are not of direct medical or remedial benefit to the member. This service does not duplicate a service provided under the state plan as an EPSDT service.
Minor Home Modifications	Minor home modifications are funded up to $6,000 per project; $10,000 per benefit year; and $20,000 per lifetime. The contractor case manager may authorize service request exceptions above this limit when it determines the expense is cost-effective. This service is not available to persons residing in Assisted Living. Provision and installation of certain home mobility aids (e.g., a wheelchair ramp and modifications directly related to and specifically required for the construction or installation of the ramp, hand rails for interior or exterior stairs or steps, grab bars and other devices) and minor physical adaptations to the interior of a member's place of residence which are necessary to ensure the health, welfare

HCBS Service	Service Definition
	and safety of the individual, or which increase the member's mobility and accessibility within the residence, such as widening of doorways or modification of bathroom facilities. Excluded are installation of stairway lifts or elevators and those adaptations which are considered to be general maintenance of the residence or which are considered improvements to the residence or which are of general utility and not of direct medical or remedial benefit to the individual, such as installation, repair, replacement or roof, ceiling, walls, or carpet or other flooring; installation, repair, or replacement of heating or cooling units or systems; installation or purchase of air or water purifiers or humidifiers; and installation or repair of driveways, sidewalks, fences, decks, and patios. Adaptations that add to the total square footage of the home are excluded from this benefit. All services shall be provided in accordance with applicable State or local building codes.
Home Delivered Meals	Home-delivered meals (up to 1 meal per day). Nutritionally well-balanced meals, other than those provided under Title III C-2 of the Older Americans Act or through SSGB funds, that provide at least one-third but no more than two-thirds of the current daily Recommended Dietary Allowance (as estimated by the Food and Nutrition Board of Sciences – National Research Council) and that will be served in the enrollee's home. Special diets shall be provided in accordance with the individual Plan of Care when ordered by the enrollee's physician. These meals are delivered to the participant's community residence and not to other setting, such as Adult Day Programs or Senior Centers. The contractor must coordinate the delivery of these meals with staff within the Division of Services for Aging & Adults with Physical Disabilities (DSAAPD) that authorize home-bound meals utilizing Title III (Older Americans Act) and Social Service Block Grant (SSBG) funds.

Medicaid beneficiaries eligible to enroll in the MCO applying for services must be screened by DSAMH using a standardized clinical and functional assessment developed for Delaware and based on national standards.

Individuals eligible for and enrolled in PROMISE may also be enrolled in the DSHP Plus program if meeting the criteria for both programs unless the PROMISE individual has been identified as a Community Reintegration Support Project (CRISP) individual under the American with Disabilities (ADA) settlement. If the individual is identified as a CRISP individual, the individual will be enrolled in the PROMISE program only and not DSHP Plus; the enrollee will receive all services necessary for community living from the PROMISE program through CRISP. The CRISP program will not provide any services under the acute care MCO benefit. The PROMISE program will ensure that Medicaid payments are backed out of any state-only capitated payments made for the CRISP program thus ensuring no duplicate payment between CRISP/PROMISE and DSHP Plus. For individuals in PROMISE and DSHP Plus, medically necessary PROMISE services will be provided, in addition to any services that the individual is otherwise eligible for in DSHP Plus if the individual is assessed as needing additional services and the services are outlined on the individual's Recovery Plan. The PROMISE care manager will coordinate with the DSHP Plus case manager, who will lead the individual's care team.

The Delaware-specific American Society for Addiction Medicine (ASAM) tool integrates the assessment and evaluation of both mental health and SUD conditions into a single document with an algorithm that can be used to determine functional eligibility and is designed to ensure appropriate treatment of individuals based on their medical and functional needs. State Medicaid eligibility staff will review financial criteria to ensure that applicants meet the community financial eligibility criteria.

To be eligible under PROMISE program, individuals must meet one of the targeting criteria and the corresponding functional criteria under the Delaware-specific tool. The following are acceptable combinations for individuals eligible under the demonstration:

- Target criteria A and functional criteria A or C
- Target criteria B and functional criteria B or C

Targeting Criteria

Target Criteria A: An individual must have formally received one of the included Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnoses that constitute the targeted portion of the State's definition of SPMI, or a diagnosis of post-traumatic stress disorder (PTSD) by a qualified clinician. Diagnoses include the following:

DSAMH Current SPMI Diagnosis Codes (updated 7/1/2012)			
DSM IV Code	**DSM 5 Code**	**Disorder**	**DSM IV Category**
295.10	295.90	Schizophrenia, Disorganized Type *(In DSM 5 Disorganized subtype no longer used)*	Psychotic Disorders[4]
295.20	295.90	Schizophrenia, Catatonic Type *(In DSM 5 Catatonic subtype no longer used)*	Psychotic Disorders
295.30	295.90	Schizophrenia, Paranoid Type *(In DSM 5 Paranoid subtype no longer used)*	Psychotic Disorders
295.40	295.40	Schizophreniform Disorder	Psychotic Disorders
295.60	295.90	Schizophrenia, Residual Type *(In DSM 5 Residual subtype no longer used)*	Psychotic Disorders
295.70	295.70	Schizoaffective Disorder	Psychotic Disorders
295.90	295.90	Schizophrenia, Undifferentiated Type *(In DSM 5 Undifferentiated subtype no longer used)*	Psychotic Disorders
296.30	296.30	Major Depressive Disorder, Recurrent, Unspecified	Mood Disorders[5]
296.32	296.32	Major Depressive Disorder, Recurrent, Moderate	Mood Disorders
296.33	296.33	Major Depressive Disorder, Recurrent, Severe Without Psychotic Features *(In DSM 5, "Without Psychotic Features" is not a further specifier)*	Mood Disorders
296.34	296.34	Major Depressive Disorder, Recurrent, Severe With Psychotic Features *(In DSM 5, "With psychotic features" is its own specifier, and, when present, is used instead of Mild, Moderate, or Severe, not in addition to Severe)* [6]	Mood Disorders
296.40	296.40	Bipolar I Disorder, Most Recent Episode Hypomanic[7]	Mood Disorders
296.42	296.42	Bipolar I Disorder, Most Recent Episode Manic, Moderate	Mood Disorders
296.43	296.43	Bipolar I Disorder, Most Recent Episode Manic, Severe Without Psychotic Features *(In DSM 5, "Without Psychotic Features" is not a further specifier)*	Mood Disorders
296.44	296.44	Bipolar I Disorder, Most Recent Episode Manic, Severe With Psychotic Features *(In DSM 5, "With psychotic features" is its own specifier, and, when present, is used instead of Mild, Moderate, or Severe, not in addition to Severe)*[8]	Mood Disorders
296.50	296.50	Bipolar I Disorder, Most Recent Episode Depressed, Unspecified	Mood Disorders
296.52	296.52	Bipolar I Disorder, Most Recent Episode Depressed, Moderate	Mood Disorders

[4] In DSM 5, the associated diagnostic category is labeled, "Schizophrenia Spectrum and Other Psychotic Disorders".
[5] In DSM 5, mood disorders are broken out into "Depressive Disorders" and "Bipolar and Related Disorders".
[6] The DSM 5 code for Major Depressive Disorder, Recurrent, with Psychotic Features is 296.34.
[7] In DSM 5 code 296.40 is also used for "Bipolar I Disorder, Current or Most Recent Episode Manic, Unspecified".
[8] The DSM 5 code for "Bipolar I Disorder, Current or Most Recent Episode Manic, with Psychotic Features" is 296.44.

DSAMH Current SPMI Diagnosis Codes (updated 7/1/2012)			
DSM IV Code	**DSM 5 Code**	**Disorder**	**DSM IV Category**
296.53	296.53	Bipolar I Disorder, Most Recent Episode Depressed, Severe w/o Psychotic Features *(In DSM 5, "Without Psychotic Features" is not a further specified)*	Mood Disorders
296.54	296.54	Bipolar I Disorder, Most Recent Episode Depressed, Severe w/ Psychotic Features *(In DSM 5, "With psychotic features" is its own specifier, and, when present, is used instead of Mild, Moderate, or Severe, not in addition to Severe)*[9]	Mood Disorders
296.60		Bipolar I Disorder, Most Recent Episode Mixed, Unspecified *(This Bipolar 1 sub-type was removed from DSM 5)*	Mood Disorders
296.62		Bipolar I Disorder, Most Recent Episode Mixed, Moderate *(This Bipolar 1 sub-type was removed from DSM 5)*	Mood Disorders
296.63		Bipolar I Disorder, Most Recent Episode Mixed, Severe Without Psychotic Features *(This Bipolar 1 sub-type was removed from DSM 5)*	Mood Disorders
296.64		Bipolar I Disorder, Most Recent Episode Mixed, Severe With Psychotic Features *(This Bipolar 1 sub-type was removed from DSM 5)*	Mood Disorders
296.70	296.70	Bipolar Disorder, Most Recent Episode Unspecified	Mood Disorders
296.89	296.89	Bipolar II Disorder	Mood Disorders
297.1	297.1	Delusional Disorder	Psychotic Disorders
301.0	301.0	Paranoid Personality Disorder	Personality Disorders
301.20	301.20	Schizoid Personality Disorder	Personality Disorders
301.22	301.22	Schizotypal Personality Disorder	Personality Disorders
301.83	301.83	Borderline Personality Disorder	Personality Disorders
309.81	309.81	Posttraumatic Stress Disorder (PTSD)	Anxiety Disorders[10]

Target Criteria B: Individuals may also meet other targeted DSM diagnoses. The DSM diagnosis must be among those that are included in the following larger DSM categories (excluding pervasive developmental disorders):

- Mood Disorders:

[9] The DSM 5 code for "Bipolar I Disorder, Current or Most Recent Episode Depressed, with Psychotic Features" is 296.54.
[10] In DSM 5, PTSD is moved to another diagnostic category, called "Trauma- and Stressor-Related Disorders".

- *In DSM 5 "Depressive Disorders" and "Bipolar and Related Disorders" are separated out as diagnostic groupings*

- Anxiety Disorders:
  - *DSM 5 includes a separate category, "Obsessive-Compulsive and Related Disorders"*
  - *DSM 5 includes a separate category, "Trauma- and Stressor-Related Disorders"*

- Schizophrenia and Other Psychotic Disorders:
  - *In DSM 5 this category is labeled, "Schizophrenia Spectrum and Other Psychotic Disorders".*

- Dissociative Disorders

- Personality Disorders

- Substance-Related Disorders:

  - *In DSM 5 this category is labeled, "Substance-Related and Addictive Disorders"*

Functioning Criteria

Each person who is screened and thought to be eligible for PROMISE must receive the State-required diagnostic and functional assessment using the Delaware-specific ASAM tool.

Functional Criteria A: If the individual meets Targeting Criteria A, the individual must be assessed with a rating of moderate on at least one of the six Delaware-specific ASAM dimensions. The six dimensions include the following[11]:

1. Acute intoxication and/or withdrawal potential — substance use
2. Biomedical conditions/complications
3. Emotional/behavioral/cognitive conditions or complications (with five sub-dimensions, including suicidality, self-control/impulsivity, dangerousness, self-care, and psychiatric/emotional health)
4. Readiness to change (with two sub-dimensions, including understanding of illness and recovery, and desire to change)
5. Relapse, continued use, continued problem potential
6. Recovery environment (with two sub-dimensions, including recovery environment and interpersonal/social functioning)

Functional Criteria B: If the individual does not meet Targeting Criteria A, but does meet

[11] 2nd edition ASAM by Dr. David Mee-Lee et al. at http://www.asam.org/publications/patient-placement-criteria/ppc-2r.

Targeting Criteria B, the individual must be assessed with a rating of severe on at least one of the above six Delaware-specific ASAM dimensions.

Functional Criteria C: An adult who has previously met the above targeting and functional criteria and needs subsequent medical necessary services for stabilization and maintenance. The individual continues to need at least one HCBS service for stabilization and maintenance (i.e., at least one PROMISE service described in the below).

Services
Care management
Benefits counseling
Community psychiatric support and treatment
Community-based residential supports, excluding assisted living
Financial coaching
Independent activities of daily living/chore
Individual employment supports
Non-medical transportation
Nursing
Peer support
Personal care
Psychosocial rehabilitation
Respite
Short-term small group supported employment
Community Transition Services

PROMISE Service	Service Definition
Care management (CM)	CM includes services assisting beneficiaries in gaining access to needed demonstration and other State Plan services, as well as medical, social, educational, and other services, regardless of the funding source for the services to which access is gained. Care managers are responsible for the ongoing monitoring of the provision of services included in the beneficiary's Recovery Plan and/or beneficiary health and welfare. Care managers are responsible for initiating the process to evaluate and/or re-evaluate the beneficiary's level of care/needs-based eligibility and/or development of Recovery Plans. Care managers are responsible for assisting the beneficiary in gaining access to needed services regardless of the funding source. The care manager provides intensive CM for PROMISE members in need of supports services through service planning and coordination to identify services; brokering of services to obtain and integrate services, facilitation, and advocacy to resolve issues that impede access to needed services; monitoring and reassessment of services based on changes in member's condition; and gate keeping to assess and determine the need for services to members. In the performance of providing information to beneficiaries, the care manager will: • Inform beneficiaries about the HCBS, required needs assessments, the person-centered planning process, service alternatives, service delivery options (opportunities for beneficiary-direction), roles, rights, risks, and responsibilities. • Inform beneficiaries on fair hearing rights and assist with fair hearing requests when needed and upon request. In the performance of facilitating access to needed services and supports, the care manager will: • Collect additional necessary information including, at a minimum, beneficiary preferences, strengths, and goals to inform the development of the beneficiary-centered Recovery Plan. • Assist the beneficiary and his/her service planning team in identifying and choosing willing and qualified providers. • Coordinate efforts and prompt the beneficiary to ensure the completion of activities necessary to maintain HCBS program eligibility. In the performance of the coordinating function, the care manager will: • Coordinate efforts in accordance with department requirements and prompt the beneficiary to participate in the completion of a needs assessment as required by the State to identify appropriate levels of need and to serve as the foundation for the development of and updates to the Recovery Plan. • Use a person-centered planning approach and a team process which may include peer care managers to develop the beneficiary's Recovery Plan to meet the beneficiary's needs in the least restrictive manner possible. At a minimum, the approach shall: o Include people chosen by the beneficiary for Recovery Plan meetings, review assessments, include discussion of needs, to gain understanding of the beneficiary's preferences, suggestions for services, and other activities key to ensure a beneficiary-centered Recovery Plan. o Provide necessary information and support to ensure that the beneficiary directs the process to the maximum extent possible and is enabled to make informed choices and decisions. o Be timely and occur at times and locations of convenience to the beneficiary; reflect cultural considerations of the beneficiary. o Include strategies for solving conflict or disagreement within the process. o Offer choices to the beneficiary regarding the services and supports they receive and the providers who may render them. o Inform beneficiaries of the method to request updates to the Recovery Plan.

PROMISE Service	Service Definition
CM (cont'd)	o Ensure and document the beneficiary's participation in the development of the Recovery Plan. • Develop and update the Recovery Plan in accordance with the State requirements based upon the standardized needs assessment and person-centered planning process annually, or more frequently as needed. • Explore coverage of services to address beneficiary identified needs through other sources, including services provided under the State Plan, Medicare, and/or private insurance or other community resources. These resources shall be used until the plan limitations have been reached or a determination of non-coverage has been established and prior to any service's inclusion in the Recovery Plan, in accordance with department standards. • Actively coordinate with other individuals and/or entities essential in the physical and/or behavioral care delivery for the beneficiary, including MCO care coordinators, to ensure seamless coordination between physical, behavioral, and support services. • Coordinate with providers and potential providers of services to ensure seamless service access and delivery. • Coordinate with the beneficiary's family, friends, and other community members to cultivate the beneficiary's natural support network, to the extent that the beneficiary (adult) has provided permission for such coordination. In the performance of the monitoring function, the care manager will: • Monitor the health, welfare, and safety of the beneficiary and Recovery Plan implementation through regular contacts (monitoring visits with the beneficiary, paid and unpaid caregivers, and others) at a minimum frequency as required by the department. • Respond to and assess emergency situations and incidents and assure that appropriate actions are taken to protect the health, welfare, and safety of the beneficiary. • Review provider documentation of service provision and monitor beneficiary progress on outcomes and initiate Recovery Plan team discussions or meetings when services are not achieving desired outcomes. Outcomes include housing status, employment status, involvement in the criminal justice system, response to treatment, and other services, and satisfaction with services. • Through the Recovery Plan monitoring process, solicit input from beneficiary and/or family, as appropriate, related to satisfaction with services. • Arrange for modifications in services and service delivery, as necessary, to address the needs of the beneficiary, consistent with an assessment of need and department requirements, and modify the Recovery Plan accordingly. • Advocate for continuity of services, system flexibility and integration, proper utilization of facilities and resources, accessibility and beneficiary rights. • Participate in any department identified activities related to quality oversight. The maximum caseload for a care manager providing services through this waiver is set by Medicaid or its designee, which includes individuals in other waiver programs and other funding sources, unless the requirement is waived by the department. CM agencies must use an information system as approved and required by the department to maintain case records in accordance with department requirements.

PROMISE Service	Service Definition
Benefits Counseling	Benefits Counseling provides work incentive counseling services to PROMISE participants seeking to work while maintaining access to necessary healthcare and other benefits. Benefits counseling will provide information to individuals regarding available benefits and assist individuals to understand options for making an informed choice about going to work while maintaining essential benefits. This service will assist individuals to understand the work incentives and support programs available and the impact of work activity on those benefits. This service will assist individuals to understand their benefits supports and how to utilize work incentives and other tools to assist them to achieve self-sufficiency through work. This service will also include the development and maintenance of proper documentation of services, including creating Benefits Summaries and Analyses and Work Incentive Plans. Services must be delivered in a manner that supports the participant's communication needs including, but not limited to, age appropriate communication, translation/interpretation services for participants that are of limited-English proficiency or who have other communication needs requiring translation, assistance with the provider's understanding and use of communication devices used by the participant.
Community psychiatric support and treatment (CPST)	CPST services are provided as part of a comprehensive specialized psychiatric program available to all Medicaid eligible adults with significant functional impairments meeting the need levels in the PROMISE program resulting from an identified mental health or substance abuse disorder diagnosis. The medical necessity for these treatment and rehabilitative services must be determined by a licensed behavioral health practitioner (LBHP) or physician who is acting within the scope of his/her professional license and applicable state law and furnished by or under the direction of a licensed practitioner, to promote the maximum reduction of symptoms and/or restoration of a beneficiary to his/her best age-appropriate functional level. The LBHP or physician may conduct an assessment consistent with state law, regulation, and policy. A unit of service is defined according to the healthcare common procedure coding system (HCPCS) approved code set unless otherwise specified. **Definitions:** The services are defined as follows: • CPST are goal-directed supports and solution-focused interventions intended to achieve identified goals or objectives as set forth in the beneficiary's Recovery Plan. CPST is a face-to-face intervention with the beneficiary present; however, family or other collaterals may also be involved. This service may include the following components: o Assist the beneficiary and family members or other collaterals to identify strategies or treatment options associated with the beneficiary's mental illness and/or SUD, with the goal of minimizing the negative effects of symptoms or emotional disturbances or associated environmental stressors which interfere with the beneficiary's daily living, financial management, housing, academic and/or employment progress, personal recovery or resilience, family and/or interpersonal relationships, and community integration. o Provide beneficiary supportive counseling, solution-focused interventions, emotional and behavioral management support, and behavioral analysis with the beneficiary, with the goal of assisting the beneficiary with developing and implementing social, interpersonal, self-care, daily living, and independent living skills to restore stability, to support functional gains, and to adapt to community living. o Facilitate participation in and utilization of strengths-based planning and treatments, which include assisting the beneficiary and family members or other collaterals with identifying strengths and needs, resources, natural supports, and developing goals and objectives to utilize personal strengths, resources, and natural supports to address functional deficits associated with their mental illness and/or SUD.

PROMISE Service	Service Definition
CPST (cont'd)	o Assist the beneficiary with effectively responding to or avoiding identified precursors or triggers that would risk their remaining in a natural community location, including assisting the beneficiary and family members or other collaterals with identifying a potential psychiatric or personal crisis, developing a crisis management plan and/or as appropriate, seeking other supports to restore stability and functioning. o Provide restoration, rehabilitation, and support to develop skills to locate, rent, and keep a home, to enable landlord/tenant negotiations; to select a roommate and to understand and exercise renter's rights and responsibilities. o Assist the beneficiary to develop daily living skills specific to managing their own home including managing their money, medications, and using community resources and other self-care requirements. o Implement interventions using evidence-based techniques, drawn from cognitive-behavioral therapy and other evidence-based psychotherapeutic interventions that ameliorate targeted symptoms and/or recover the person's capacity to cope with or prevent symptom manifestation.
Community-based residential alternatives supports that exclude assisted living	Community-based residential supports (excluding assisted living) offer a cost-effective, community-based alternative to institutional levels of care for persons with BH needs. Community-based residential services are supportive and health-related residential services provided to beneficiaries in settings licensed by the State. Residential services are necessary, as specified in the Recovery Plan, to enable the beneficiary to remain integrated in the community and ensure the health, welfare, and safety of the beneficiary. Community-based residential services include personal care and supportive services (homemaker, chore, attendant services, and meal preparation) that are furnished to beneficiaries who reside in homelike, non-institutional, integrated settings. In addition, they include 24-hour onsite response capability to meet scheduled and unscheduled or unpredictable beneficiary needs to provide supervision and safety. Services also include social and recreational programming, and medication assistance (to the extent permitted under State law). This service includes assisting beneficiaries in acquiring, retaining, and improving skills such as communication, self-help, domestic, self-care, socialization, fine and gross motor skills, mobility, personal adjustment, relationship development, use of community resources and adaptive skills necessary to reside successfully in home and community-based settings. As needed, this service may also include prompting to carry out desired behaviors and/or to curtail inappropriate behaviors as well as habilitative services to instruct beneficiaries in accessing and using community resources such as transportation, translation, and communication assistance related to a habilitative outcome and services to assist the beneficiary in shopping and other necessary activities of community and civic life, including self-advocacy. Finally, assistance with activities of daily living (ADLs) and instrumental activities of daily living (IADLs) are included. This service will be provided to meet the beneficiary's needs as determined by an assessment performed in accordance with department requirements and as outlined in the beneficiary's Recovery Plan. ADLs include tasks related to caring for and moving the body. ADLs include: • Walking. • Bathing. • Dressing. • Toileting. • Brushing teeth. • Eating.

Community-based residential alternatives supports that exclude assisted living (cont'd)	IADLs are the activities are not directly related to functional activities, rather they are an additional set of more complex life functions necessary for maintaining a person's immediate environment and living independently in the community. IADLs include: • Cooking and meal planning. • Performing ordinary housework. • Getting around in the community. • Using the telephone or computer. • Shopping for groceries. • Supporting the beneficiary in exploring employment opportunities . • Keeping track of finances. • Managing medication, including assisting with setting up medication administration mechanisms (e.g. pill jars) and ensuring that individuals have the supports necessary to timely take medications (Not appropriate for Peer Specialists). The provider will be encouraged to hire staff to deliver personal care services separate from staff who provide habilitation services that involved the development of ADL and IADL skills, if there is more than one staff member on site at the residence during normal hours, who can provide personal care services. This will ensure that the clinical boundary issues that would otherwise complicate habilitation services (if the same staff were also delivering personal care services) will be mitigated. Services must be delivered in a manner that supports the beneficiary's communication needs including, but not limited to age appropriate communication, translation services for beneficiaries that are of limited-English proficiency or who have other communication needs requiring translation, assistance with the provider's understanding and use of communication devices used by the beneficiary. The cost of transportation provided by residential service providers to and from activities is included as a component of the residential services and; therefore, is reflected in the rate for the service. Providers of residential services are responsible for the full range of transportation services needed by the beneficiaries they serve to participate in services and activities specified in their Recovery Plan. This includes transportation to and from daily activities and employment services, as applicable. The service provider must maintain documentation in accordance with department requirements. The documentation must be available to the care manager for monitoring at all times on an ongoing basis. The care manager will review the authorized tier on an ongoing basis and monitor the community character of the residence during regularly scheduled contact with the beneficiary. Results of this monitoring will be reported to the department. If the monitoring suggests that a change in tiers is needed, the care manager will recommend a re-assessment to re-evaluate the beneficiary to determine the appropriateness of the assigned tier in accordance with department requirements. The following levels of residential services are available to beneficiaries as determined necessary, based upon a quarterly assessment, documented in the Recovery Plan and approved by the department. Model 1 — habilitative supports in the home (the beneficiary is encouraged to seek BH treatment for SPMI in the community) (Tiers 1 and 2). **Tier 1: A beneficiary requires:** • Limited supervision as the beneficiary is able to make safe decisions when in familiar surroundings, but requires occasional increased need for assistance or to address unanticipated needs, with supports available on a 24-hour on call or as-needed basis, AND • Incidental or intermittent hands-on assistance or cueing for at least one ADL and at least one IADL, OR • Incidental or intermittent hands-on assistance or cueing with at least three IADLs, OR

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	• Instruction in accessing and using community resources, such as transportation, translation, and communication assistance related to a habilitative outcome and services to assist the beneficiary in shopping and other necessary activities of community and civic life, including self-advocacy. Instruction in developing or maintaining financial stability and security (e.g., understanding budgets, managing money, and the right to manage their own money).

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Financial coaching	Financial Coaching Plus uses a financial coaching model to assist individuals in establishing financial goals, creating a plan to achieve them, and providing information, support, and resources needed to implement stated goals in the financial plan. The financial coach will assist the client seeking to improve his/her financial situation in order to improve economic self-sufficiency. Financial Coaching Plus includes the development of a personal budget and identifies reliable and trusted savings, credit, and debt programs that promote financial stability. The content and direction of the coaching is customized to respond to the individual financial goals set by the participant. Financial coaching is provided to the client one-on-one in a setting convenient for the client over a time-limited series of sessions and follow-up to increase the opportunity for self-directed behavior skills learning. The Financial Coach will: • Assist the client in developing financial strategies to reach participant's goals with care to ensure that personal strategies reflect considerations related to benefits, as identified through benefits counseling; • Ensure that individuals understand the availability of various tax credits such as the Earned Income Tax Credit, Child Care Tax Credit, and others; • Refer individuals as needed to benefit counselors; • Provide information to complement information provided through benefits counseling regarding appropriate asset building; • Use an integrated dashboard of available community-based asset building opportunities and financial tools/services to ensure participants are leveraging all resources to increase economic self-sufficiency; • Provide information about how to protect personal identify and avoid predatory lending schemes; • Provide assistance with filing yearly taxes either through the IRS VITA program or its virtual program that involves self-filing. The Financial Coaching Plus service will include the collection and maintenance of proper documentation of services provided as required by the Department that will track goals, actions, and outcomes of individual participants. The Financial Coaching Plus service may complement information provided on the use of public benefits and/or work incentives through Benefits Counseling or other services. Documentation is maintained that the service is not available under a program funded under section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.) or other services

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IADL/chore	IADL/chore services are delivered to beneficiaries that reside in a private home and are necessary, as specified in the Recovery Plan, to enable the beneficiary to integrate more fully into the community and to ensure the health, welfare, and safety of the beneficiary. This service will be provided to meet the beneficiary's needs, as determined by an assessment performed in accordance with department requirements and as outlined in the beneficiary's Recovery Plan. IADL services consist of the performance of general household tasks (e.g., meal preparation, cleaning, laundry, and other routine household care) provided by a qualified homemaker when the beneficiary regularly responsible for these activities is absent or unable to manage the home and care for him or herself or others in the home, or when no landlord or provider agency staff is responsible to perform the IADL services. Chore services consist of services provided to maintain the home in a clean, sanitary, and safe condition. This service includes heavy household chores, such as: • Washing floors, windows, and walls. • Tacking down loose rugs and tiles. • Moving heavy items of furniture in order to provide safe access and egress. • Removing ice, snow and/or leaves. • Yard maintenance. The providers of this service must review and be familiar with the crisis support plan. IADL/chore services may not be billed at the same time as personal care or respite services. IADL/chore services are limited to 40 hours per beneficiary per service plan Recovery Plan year when the beneficiary or family member(s) or friend(s) with whom the beneficiary resides is temporarily unable to perform and financially provide for the IADL/chore functions.
Individual employment support services (IESS)	IESS are services to beneficiaries needing on-going individualized support to learn a new job or to maintain a job in a competitive or customized integrated work setting that meets job and career goals (including self-employment). Beneficiaries in a competitive employment arrangement receiving IESS are compensated at or above the minimum wage and receive similar wages and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. IESS are necessary, as specified in the Recovery Plan, to support the beneficiary to live and work successfully in home and community-based settings, enable the beneficiary to integrate more fully into the community and ensure the health, welfare, and safety of the beneficiary.

Supported beneficiary employment may also include support to establish or maintain self-employment, including home-based self-employment. Supported employment services are individualized and may include any combination of the following services: on-going vocational/job-related discovery or assessment not otherwise covered in the annual career planning, on-going person-centered employment planning not otherwise covered in the annual career planning, job placement, job development negotiation with prospective employers, job analysis, job carving, training and systematic instruction, individual supports, benefits support, training, planning, transportation, asset development and career advancement services, implementation of assistive technology, and other workforce support services including services not specifically related to job skill training that enable the waiver beneficiary to be successful in integrating into the job setting. Supported employment includes person-centered, comprehensive employment planning and support services that provide assistance for waiver program beneficiaries to obtain, maintain, or advance in competitive employment or self-employment. This employment planning includes engaging a beneficiary in identifying a career direction and developing a plan for achieving competitive, integrated employment at or above the state's minimum wage. The outcome of this activity is identification of the beneficiary's stated career objective and development of a career plan used to guide beneficiary employment support in competitive employment.

Competitive or customized integrated employment, including self-employment, shall be considered the first option when serving beneficiaries with disabilities who are of working age. IESS adopt a "rapid job search" approach to achieving competitive employment and services planned do not assume that a beneficiary must achieve greater readiness for competitive employment before competitive employment is sought.

Supported employment may provide work experiences where the beneficiary can develop strengths and skills that contribute to employability in paid employment in integrated community settings. IESS include supervision, monitoring, training, education, demonstration, or support to assist with the acquisition and retention of skills and training and education in self-determination.

Skills development as a part of placement and training may occur as a one-to-one training experience in accordance with department requirements. IESS may be utilized for a beneficiary to gain work related experience considered crucial for job placement (e.g., unpaid internship), if such experience is vital to the person achieve his or her vocational goal. Provide and support the acquisition of skills necessary to enable the beneficiary to obtain competitive, integrated work where the compensation for the beneficiary is at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities, which is considered to be the optimal outcome of IESS.

In addition to the elements note above, IESS provides two components in accordance with an assessment: intensive IESS and extended follow-along.

Intensive IESS is an essential component of individual employment support services and may include:

- On the job training and skills development.
- Assisting the beneficiary with development of natural supports in the workplace.
- Helping the beneficiary to attend school and providing academic supports, when that is their preference.
- Coordinating with employers or employees, coworkers and customers, as necessary. (Note: Coordinating with employers and other employees is done only if the beneficiary prefers to have her or his mental illness disclosed and gives permission. Supporting the beneficiary's preference in this area is fundamental to recovery.)
- Providing work incentives planning prior to or during the process of job placement. Work incentives planning involves helping the beneficiary review her or his options for working (number of hours per week, etc.), given the hourly pay the beneficiary is being offered, or is likely to be offered, the beneficiary's current income needs, and the rules concerning how Social

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	Security Administration benefits, medical benefits, medical subsidies, and other subsidies (housing, food stamps, etc.) change based on income from paid employment. (This includes providing information on Ticket to Work, etc.). Work incentives planning allows beneficiaries to make informed decisions about how many hours per week to work, as well as their preferred timing in moving from part-time to full-time work. Beneficiaries also are given information and assistance about reporting earnings to various sources of entitlements/benefits. • Assisting beneficiaries in making informed decisions about whether to disclose their mental illness condition to employers and co-workers. • Intensive IESS includes assisting the beneficiary in meeting employment expectations, performing business functions, addressing issues as they arise, and also includes travel training, and diversity training to the specific business where the beneficiary is employed. Intensive IESS provides support to assist beneficiaries in stabilizing in an integrated situation (including self-employment) and may include activities on behalf of the beneficiary when the beneficiary is not present to assist in maintaining job placement. Once the beneficiary is stable in the position, extended follow along will ensue. Extended follow-along is ongoing support available for an indefinite period as needed by the beneficiary to maintain their paid employment position once they have been stabilized in their position (generally receiving onsite support once per month or less). Extended follow-along support may include reminders of effective workplace practices and reinforcement of skills gained during the period of intensive IESS.
Non-medical transportation	Non-medical transportation services are offered, in addition to any medical transportation furnished under the 42 CFR 440.17(a) in the State Plan. Non-medical transportation services are necessary, as specified by the Recovery Plan, to enable beneficiaries to gain access to waiver services that enable them to integrate more fully into the community and ensure the health, welfare, and safety of the beneficiary. In order to be approved, non-medical transportation would need to be directly related to a goal on the beneficiary's treatment plan (e.g., to a supported employment job) and not for the general transportation needs of the client (e.g., regular trips to the grocery store). This service will be provided to meet the beneficiary's needs as determined by an assessment performed in accordance with department requirements and as specifically outlined in the beneficiary's Recovery Plan. Transportation services consist of: • Transportation (mile): This transportation service is delivered by providers, family members, and other qualified, licensed drivers. Transportation (mile) is used to reimburse the owner of the vehicle or other qualified, licensed driver who transports the beneficiary to and from services and resources related to outcomes specified in the beneficiary's Recovery Plan. The unit of service is one mile. Mileage can be paid round trip. A round trip is defined as from the point of first pickup to the service destination and the return distance to the point of origin. When transportation (mile) is provided to more than one beneficiary at a time, the provider will divide the shared miles equitably among the beneficiaries to whom transportation is provided. The provider is required (or it is the legal employer's responsibility under the Vendor Fiscal/Employer Agent model) to track mileage, allocate a portion to each beneficiary, and provide that information to the care manager for inclusion in the beneficiary's Recovery Plan. • Public transportation: The utilization of public transportation promotes self-determination and is made available to beneficiaries as a cost-effective means of accessing services and activities. This service provides payment for the beneficiary's use of public transportation. The care manager will monitor this service quarterly and will provide ongoing assistance to the beneficiary to identify alternative community-based sources of transportation.
Nursing	Nursing services are prescribed by a physician in addition to any services under the State Plan as determined by an assessment in accordance with department requirements. Nursing services are necessary, as specified in the Recovery Plan, to enable the beneficiary to integrate more fully into the

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	community and ensure the health, welfare, and safety of the beneficiary. This service is intended to be utilized in the beneficiary's home. Services are provided by a registered nurse or a licensed practical nurse under the supervision of a registered nurse licensed to practice in the State. The physician's order to reauthorize must be obtained every ninety (90) days for continuation of service. If changes in the beneficiary's status take place after the physician's order, but prior to the reauthorization of the service, and result in a change in the level of services authorized in the Recovery Plan, the provider is responsible for reporting to the ordering physician and care manager. Nursing services must be performed by a registered nurse or licensed practical nurse as defined by the State Nurse Practice Act. Skilled nursing is typically provided on a one to one basis and can be continuous, intermittent, or short-term, based on the beneficiary's assessed need. • Short-term or intermittent nursing: Nursing that is provided on a short-term or intermittent basis, not expected to exceed 75 units of service in a Recovery Plan year and are over and above services available to the beneficiary through the State Plan. • Long-term or continuous nursing: Long-term or continuous nursing is needed to meet ongoing assessed needs that are likely to require services in excess of 75 units per Recovery Plan year, are provided on a regular basis and are over and above services available to the beneficiary through the State Plan. Services must be delivered in a manner that supports the beneficiary's communication needs including, but not limited to age appropriate communication, translation services for beneficiary's that are of limited-English proficiency or who have other communication needs requiring translation, assistance with the provider's understanding and use of communication devices used by the beneficiary. • The nursing service provider must maintain documentation in accordance with department requirements. The documentation must be available to the care manager for monitoring at all times on an ongoing basis. The care manager will monitor on a quarterly basis to see if the objectives and outcomes are being met.

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Peer supports (PS)	PS services are beneficiary-centered services with a rehabilitation and recovery focus designed to promote skills for coping with and managing psychiatric symptoms, while facilitating the utilization of natural resources and the enhancement of recovery-oriented attitudes such as, hope and self-efficacy, and community living skills. Activities included must be intended to achieve the identified goals or objectives as set forth in the beneficiary's individualized care plan, which delineates specific goals that are flexibly tailored to the beneficiary and attempt to utilize community and natural supports. The structured, scheduled activities provided by this service emphasize the opportunity for beneficiaries to support each other in the restoration and expansion of the skills and strategies necessary to move forward in recovery.

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PS (cont'd)	A certified peer/recovery coach would be a beneficiary who has self-identified as a beneficiary or survivor of mental health or SUD services and meets the qualifications set by the State including specialized training, to be considered in accordance with State standards, certification, and registration. The training provided/contracted by DSAMH shall be focused on the principles and concepts of PS and how it differs from clinical support. It will also provide practical tools for promoting wellness and recovery, knowledge about beneficiary rights and advocacy, as well as approaches to care that incorporate creativity. To qualify for peer certification training a peer/recovery coach must self-identify as a person with a lived experience of mental illness and/or substance abuse, be at least 21 years of age, have at minimum a high school education or General Education Development certificate, (preferably with some college background) and be currently employed as a peer supporter in Delaware. It is required that peers/recovery coaches must complete Delaware State-approved standardized peer specialist training that includes academic information as well as practical knowledge and creative activities. A peer/recovery coach uses lived experience with a mental illness, SUD, or another co-occurring disorder such as PH, developmental disability, etc. or assist in supporting beneficiaries in their recovery path. This service may include the following components: • Helps beneficiaries aspire to and attain roles which emphasize their strengths by: o Sharing parts of their own personal recovery story and first hand experiences. Providing mutual support, hope, reassurance, and advocacy. o Provides PS to beneficiaries regarding understanding their symptoms of mental illness and effects of trauma and trauma history, developing positive coping skills. o Engaging beneficiaries through outreach and support. o Assists beneficiaries to advocate for self and others. o Promotes recovery through modeling by: ▪ Sharing one's own personal recovery story.

- Display of self-confidence and self-determination.
- Use of natural supports including connections to friends and family, peer mutual help groups, and other supports in the community.
- Display of personal achievements of personal recovery goals.
- Helps the beneficiary to develop a network for information and support from others who have been through similar experiences.
- Assists the beneficiary with gaining and regaining the ability to make independent choices and to take a proactive role in treatment, including discussing questions or concerns about medications, diagnoses or treatment approaches with their treating clinician.
- Assists the beneficiary with identifying and effectively responding to or avoiding identified precursors or triggers that result in functional impairments.
- Assists the beneficiary to complete peer-related elements of a comprehensive assessment.
- Prepares the beneficiary to attend their recovery plan meetings and is present to assist them express their goals and needs.
- Assists beneficiary to accomplish their life goals of living in a chosen community, including working in a job and engaging in activities, including leisure activities, to support community integration, having a natural support system in place, and having a number of hobbies or activities that are creative and integrated community leisure activities.
- Works with the beneficiary and staff in developing and implementing person-directed beneficiary recovery plans, using both their own expertise, based on their lived experience, as well as evidence-based tools, such as Wellness Recovery Action Planning.
- Assists in helping the beneficiary to work on their beneficiary wellness plan for physical and emotional wellness. These services might include physical exercise, dietary assistance, recognition of medical/healthcare needs, introduction to alternative healing techniques such as meditation or massage, etc. PS specialists are primarily expected to engage beneficiaries and provide personalized individualized support toward recovery. However, PS specialists may assist with IADLs, when they are assessed to be important aspects of the recovery process for a person to whom the PS specialist is providing services, consistent with the broader PS role.
- Facilitates peer recovery support groups. Accompanies beneficiaries to appointments which connect them to community resources and services. Under this service, the peer staff should not provide transportation. If the peer provides non-medical transportation, the peer should be enrolled as a transportation provider and separately charge for the non-medical transportation service instead of peer support. Peers should not be routinely used to provide client transportation.
- Acts as an advocate for beneficiaries to secure needed services, financial entitlements, and effectively raise complaints and suggestions about unmet needs, and helps beneficiaries develop self-advocacy skills.
- Locates peer-run programs and support groups for interested beneficiaries.
- Participates in the ongoing engagement of beneficiaries.

A peer specialist/recovery coach should ensure that the following occur:

- Maintains compliance with all applicable practice standards and guidelines.
- Maintains beneficiary confidentiality and adherence to Health Insurance Portability & Accountability Act requirement at all times.
- Completes all required documentation in a timely manner consistent with agency guidelines.
- Maintains agency required productivity standards.

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	Peer specialists/recovery coaches may function within a team or work with the beneficiary on a beneficiary basis. Peer specialists/recovery coaches may serve on ACT and ICM teams. If the PS functions within a team, then the peer/recovery coach: • Provides training and education to the beneficiary and other members of the beneficiary's team on: o Recovery-oriented care and processes. o Local and national PS resources and advocacy organizations. o Psychiatric advance directives: advocacy, information, and referral. o Recovery planning, illness self-management, and wellness tools. o Trauma informed care. o Use of expressive therapies. ▪ Is not used primarily to complete tasks that clinicians or other specialists on the team do not want to complete, such as transport beneficiaries, complete paper work, and so on.
Personal Care	Personal care includes care with ADLs (e.g., bathing, dressing, personal hygiene, transferring, toileting, skin care, eating, and assisting with mobility). When specified in the Recovery Plan, this service includes care with IADLs (e.g., light housekeeping, chores, shopping, meal preparation). Care with IADLs must be essential to the health and welfare of the beneficiary based on the assessment of the care manager and identified within the Recovery Plan as a goal that was identified by the beneficiary. Input should also be obtained from the beneficiaries' family or other natural supports, when appropriate and desired by the beneficiary. Personal care services primarily provide hands-on care to beneficiaries that reside in a private home and that are necessary, as specified in the Recovery Plan, to enable the beneficiary to integrate more fully into the community and ensure the health, welfare, and safety of the beneficiary. This service will be provided to meet the beneficiary's needs, as determined by an assessment, in accordance with department requirements and as outlined in the beneficiary's Recovery Plan. The provider and beneficiary will be encouraged to hire staff to deliver personal care services separate from staff who provide habilitation services that involved the development of ADL and IADL skills,

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	if there is more than one staff member on site at the residence during normal hours who can provide personal care services. This will ensure that the clinical boundary issues that would otherwise complicate habilitation services (if the same staff were also delivering personal care services) will be mitigated. Personal care services are aimed at assisting the beneficiary with completing ADLs that would be performed independently if they had no disability. These services include: • Care to assist with daily living activities (e.g., eating, bathing, dressing, personal hygiene), cueing to prompt the beneficiary to perform a task and providing supervision to assist a beneficiary who cannot be safely left alone. • Health maintenance, such as bowel and bladder routines, ostomy care, catheter, wound care, and range of motion, as indicated in the beneficiary's Recovery Plan and permitted under applicable State requirements. • Routine support services, such as meal planning, keeping of medical appointments, and other health regimens needed to support the beneficiary. • Care and implementation of prescribed therapies. • Overnight personal care services to provide intermittent or ongoing awake, overnight care to a beneficiary in their home for up to eight hours. Overnight personal care services require awake staff. Personal care may include care with the following activities when incidental to personal care and necessary to complete ADLs: • Activities that are incidental to the delivery of the personal care to assure the health, welfare, and safety of the beneficiary such as changing linens, doing the dishes associated with the preparation of a meal, laundering of towels from bathing may be provided and must not comprise the majority of the service. Services to accompany the beneficiary into the community for purposes related to personal care, such as shopping in a grocery store, picking up medications, and providing care with any of the activities noted above to enable the completion of those tasks.
Psychosocial rehabilitation (PSR)	PSR services are provided as part of a comprehensive specialized psychiatric program available to all Medicaid eligible adults with significant functional impairments meeting the need levels in the PROMISE program resulting from an identified mental health or substance abuse disorder diagnosis. The medical necessity for these rehabilitative services must be determined by a LBHP or physician who is acting within the scope of his/her professional license and applicable state law and furnished by or under the direction of a licensed practitioner, to promote the maximum reduction of symptoms and/or restoration of a beneficiary to his/her best age-appropriate functional level conducting an assessment consistent with state law, regulation, and policy. A unit of service is defined according to the HCPCS approved code set unless otherwise specified. **Definitions** PSR services are designed to assist the beneficiary with compensating for or eliminating functional deficits and interpersonal and/or environmental barriers associated with their mental illness and/or SUD. Activities included must be intended to achieve the identified goals or objectives as set forth in the beneficiary's Recovery Plan. The intent of PSR is to restore the fullest possible integration of the beneficiary as an active and productive member of his or her family, community, and/or culture with the least amount of ongoing professional intervention. PSR is a face-to-face intervention with the beneficiary present. Services may be provided individually or in a group setting and should utilize (with documentation) evidence-based rehabilitation interventions. Group PSR sessions may not include more than eight beneficiaries in attendance. This service may include the following components: • Restoration, rehabilitation, and support with the development of social and interpersonal skills to increase community tenure, enhance personal relationships, establish support networks, increase

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	community awareness, develop coping strategies, and effective functioning in the beneficiary's social environment including home, work, and school. • Restoration, rehabilitation, and support with the development of daily living skills to improve self-management of the negative effects of psychiatric or emotional symptoms that interfere with a beneficiary's daily living. Supporting the beneficiary with development and implementation of daily living skills and daily routines critical to remaining in home, school, work, and community. • Assisting the beneficiary with implementing learned skills so the beneficiary can remain in a natural community location. • Assisting the beneficiary with effectively responding to or avoiding identified precursors or triggers that result in functional impairments. • Ongoing in-vivo assessment of the beneficiary's functional skill and impairment levels that is used to select PSR interventions and periodically assess their effectiveness. Workers who provide PSR services should periodically report to a supervising licensed practitioner on the beneficiaries' progress toward the recovery and re-acquisition of skills.
Respite	Respite care includes services provided to beneficiaries unable to care for themselves furnished on a short-term basis because of the absence or need for relief of those persons who normally provide care for the beneficiary. Respite may be provided in an emergency to prevent hospitalization. Respite provides planned or emergency short-term relief to a beneficiary's unpaid caregiver or principle caregiver who is unavailable to provide support. This service will be provided to meet the beneficiary's needs as determined by an assessment performed in accordance with department requirements and as outlined in the beneficiary's Recovery Plan. Beneficiaries are encouraged to receive Respite in the most integrated and cost-effective settings appropriate to meet their respite needs. Respite services may include the following activities: • Assistance with the beneficiary's social interaction, use of natural supports and typical community services available to all people and participation in volunteer activities. • Activities to improve the beneficiary's capacity to perform or assist with activities of daily living and instrumental activities of daily living. • Onsite modeling of behavior, behavior support, intensive behavior episode intervention, training, cueing, and/or supervision. **Respite 15-minute Unit** Respite (15-minute unit) may be provided in the beneficiary's home or out of the beneficiary's home (not in a facility) in units of 15-minutes, for up to 12 hours a day. It is intended to provide short-term respite. **Respite Per diem** Respite (per diem) may be provided in a facility on a per diem basis. It is intended to provide short-term respite. Services must be delivered in a manner that supports the beneficiary's communication needs including, but not limited to, age appropriate communication, translation services for beneficiaries that are of limited-English proficiency or who have other communication needs requiring translation, assistance with the provider's understanding, and use of communication devices used by the beneficiary. If the beneficiary is to receive respite on an ongoing basis, the care manager will monitor on a quarterly basis, as applicable, to see if the objectives and outcomes are being met.
Short-term small group supported employment	Short-term small group supported employment services provide support to beneficiaries to gain skills to enable transition to integrated, competitive employment. This service is provided, instead of IESS only when the beneficiary specifically chooses this service over IESS, based on a desire to work in a group context, or to earn income more quickly than might be possible with an individualized rapid job search through IESS. Short-term small group supported employment supports are services and training activities provided in regular business, industry, and community settings for groups of two (2)

PROMISE Service	Service Definition
	to four (4) workers with disabilities. Examples include mobile crews and other employment work groups. Small group employment support must be provided in a manner that promotes integration into the workplace and interaction between beneficiaries and people without disabilities in those workplaces. The outcome of this service is sustained paid employment and work experience leading to further career development and beneficiary integrated community-based employment. Within this service, the beneficiary is compensated at or above minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. Short-term small group supported employment supports may be a combination of the following services: on the job supports, initial and ongoing employment planning and advancement, employment assessment not otherwise covered in the annual career planning, job placement, job development, negotiation with prospective employers, job analysis, training and systematic instruction, job coaching, benefits supports training and planning transportation. If the beneficiary has received a career assessment that has determined that the beneficiary is in need of acquiring particular skills in order to enhance their employability, those identified skill development areas must be addressed within the beneficiary's Recovery Plan and by the short-term small group supported employment support. Beneficiaries receiving this service must have an employment outcome goal included in their Recovery Plan. On the job support includes: onsite job training, assisting the beneficiary to develop natural supports in the workplace, coordinating with employers and coworkers, as necessary, to assist the beneficiary in meeting employment expectations and addressing issues as they arise. Other workplace support services may include services not specifically related to job skill training that enable the waiver beneficiary to be successful in integrating in to the job setting. Short-term small group supported employment supports includes person-centered, comprehensive employment planning and support service that provides assistance for waiver program beneficiaries to obtain, maintain, or advance in competitive employment or self-employment. This employment planning includes engaging a beneficiary in identifying a career direction and developing a plan for achieving competitive, integrated employment at or above the state's minimum wage. The outcome of this activity is documentation of the beneficiary's stated career objective and a career plan used to guide beneficiary employment support.

Short-term small group supported employment supports emphasize the importance of rapid job search for a competitive job and provide work experiences where the beneficiary can develop strengths and skills that contribute to employability in individualized paid employment in integrated community settings. Short-term small group supported employment supports include the provision of scheduled activities outside of a beneficiary's home that support acquisition, retention, or improvement in self-care, sensory-motor development, socialization, daily living skills, communication, community living, and social skills. Short-term small group supported employment supports include supervision, monitoring, training, education, demonstration, or support to assist with the acquisition and retention of skills and training and education in self-determination. Skills development as a part of placement and training may occur as a one-to-one training experience in accordance with department requirements. Short-term small group supported employment supports will be utilized for a beneficiary to gain work related experience considered crucial for job placement (e.g., unpaid internship). Provide and support the acquisition of skills necessary to enable the beneficiary to obtain competitive, integrated work where the compensation for the beneficiary is at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities, which is considered to be the optimal outcome of short-term small group supported employment supports.

Services must be delivered in a manner that supports the beneficiary's communication needs including, but not limited to age appropriate communication, translation services for beneficiaries that are of limited-English proficiency or who have other communication needs requiring translation, assistance with the provider's understanding, and use of communication devices used by the beneficiary.

This service may be delivered in Delaware and in states contiguous to Delaware.

The short-term small group supported employment supports service provider must maintain documentation in accordance with department requirements. The documentation must be available to the care manager for monitoring at all times on an on-going basis. The care manager will monitor on a quarterly basis to see if the objectives and outcomes are being met.

Competitive and integrated employment, including self-employment, shall be considered the first option when serving persons with disabilities who are of working age.

Short-term small group supported employment supports emphasize the importance of rapid job search for a competitive job and provide work experiences where the beneficiary can develop strengths and skills that contribute to employability in individualized paid employment in integrated community settings. Short-term small group supported employment supports include the provision of scheduled activities outside of a beneficiary's home that support acquisition, retention, or improvement in self-care, sensory-motor development, socialization, daily living skills, communication, community living, and social skills. Short-term small group supported employment supports include supervision, monitoring, training, education, demonstration, or support to assist with the acquisition and retention of skills and training and education in self-determination. Skills development as a part of placement and training may occur as a one-to-one training experience in accordance with department requirements. Short-term small group supported employment supports will be utilized for a beneficiary to gain work related experience considered crucial for job placement (e.g., unpaid internship). Provide and support the acquisition of skills necessary to enable the beneficiary to obtain competitive, integrated work where the compensation for the beneficiary is at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities, which is considered to be the optimal outcome of short-term small group supported employment supports.

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This service may be delivered in Delaware and in states contiguous to Delaware.

PROMISE Service	Service Definition
	The short-term small group supported employment supports service provider must maintain documentation in accordance with department requirements. The documentation must be available to the care manager for monitoring at all times on an on-going basis. The care manager will monitor on a quarterly basis to see if the objectives and outcomes are being met. Competitive and integrated employment, including self-employment, shall be considered the first option when serving persons with disabilities who are of working age.
Community Transitions Services	Community Transitions Services are non-recurring set-up expenses for individuals who are transitioning from an institutional or another provider-operated living arrangement to a living arrangement where the person has a lease (e.g., apartment) or is in a private residence. The individual is directly responsible for his or her own living expenses. Allowable expenses are those necessary to enable a person to establish a basic household that do not constitute room and board and may include: (a) security deposits that are required to obtain a lease on an apartment or home; (b) essential household furnishings and moving expense required to occupy and use a community domicile, including furniture, window coverings, food preparation items, and bed/bath linens; (c) set-up fees or deposits for utility or service access, including telephone, electricity, heating and water; (d) services necessary for the individual's health and safety such as pest eradication and one-time cleaning prior to occupancy; (e) moving expenses; (f) necessary home accessibility adaptations; and, (g) activities to assess need, arrange for and procure need resources. Community Transition Services are furnished only to the extent that they are reasonable and necessary as determining through the service plan development process clearly identified in the service plan and the person is unable to meet such expense or when the services cannot be obtained from other sources. Community Transition Services do not include monthly rental or mortgage expense; food, regular utility charges; and/or household appliances or items that are intended for purely diversional/recreational purposes. Community Transition Services may not include payment for room and board. The payment of a security deposit is not considered rent. When Community Transition Services are furnished to individuals returning to the community from a Medicaid institutional setting through entrance to the waiver, the costs of such services are considered to be incurred and billable when the person leaves the institutional setting and enters PROMISE. The individual must be reasonably expected to be eligible for and to enroll in the waiver. If for any unseen reason, the individual does not enroll in the waiver (e.g., due to death or a significant change in condition), transitional services may be billed to Medicaid as an administrative cost. Community Transition Services may be furnished as a PROMISE service to individuals who transition from provider-operated settings other than Medicaid reimbursable institutions to their own private residence in the community. Community Transition Services may not be used to pay for furnishing living arrangements that are owned or leased by a PROMISE provider where the provision of these items and services are inherent to the service they are already providing. Community Transition Services are limited to $1,800 per person but may be exceeded on a case-by-case basis with prior authorization based on medical necessity.

I. Critical Events or Incidents

The Managed Care Organizations under the 1115 waiver demonstration are required to develop and implement a critical incident reporting system on sentinel incidents that occur with its members related to the provision of DSHP and DSHP Plus covered services.

Under DSHP Plus, the MCO authorizes services in a variety of settings, including private homes, adult day care centers and licensed long-term care facilities such as nursing facilities and assisted living facilities. In Delaware, responses to critical events depend in large part on the location in which the event takes place. For events which take place in licensed long-term care facilities, Delaware has split the responsibility between two agencies: the Division of Long Term Care Residents Protection (DLTCRP) and the Office of the State Ombudsman (OSO). These agencies are both located within the Department of Health of Social Services (DHSS). Delaware law gives authority to the DLTCRP to respond to and investigate critical events in licensed long term care facilities. The OSO works closely with DLCTRP by responding to other complaints made by or on behalf of residents in licensed long- term care facilities.

Authority is given to DHSS's Adult Protective Services Program (APS) to respond to and investigate critical events made by or on behalf of impaired adults who live outside of licensed facilities. APS operates an after-hours service and provides a contact number to police and first responders. The after-hours contact number is now available to the general public. The Division of Family Services (DFS) within the Department of Services for Children, Youth and Their Families is the designated agency to receive, investigate, and respond to critical incidents of abuse or neglect of children living in the community. DFS operates the toll free Child Abuse and Neglect Report Line number 24 hours a day, seven days a week.

Delaware has established a Home and Community-Based Services Ombudsman within the OSO. The community ombudsman responds to complaints made on or behalf of older persons and adults with physical disabilities who receive community-services; resolves issues with providers and serves as a mediator; provides information to consumers and their family members; advocates a home care consumer’s right to appeal home health care services; and performs other advocacy functions.

DLTCRP has statutory authority under Title 29 DE Code; OSO has authority under Title 16 DE Code, APS has authority under Title 31 DE Code and DFS has authority under Title 16 DE Code, § 903 and § 904.

In Delaware, a critical event or incident is referred to as an "incident" under

DLTCRP's Investigative Protocol. Under Delaware law, an incident can be defined as anything that has a negative outcome on the resident. For APS, critical events or incidents (as defined in Title 31, Chapter 39 §3910) include abuse, mistreatment, exploitation, and neglect. In addition, APS investigates cases of inadequate self-care (self-neglect) and disruptive behavior.

DMMA has outlined the reporting process to the MCOs: what must be reported; to which agency according to incident type; timeframes to report and frequency of reporting. In all cases, the MCOs shall immediately report by telephone all current information received or known about actual or suspected abuse, neglect, or exploitation to DMMA followed in writing, within 8 hours of identifying any incident. Through working with the appropriate agency, facilitated by DMMA, the MCOs shall cooperate in investigating, resolving and documenting actual and suspected incidents. Further, analysis and trending shall be included in the Quality Management programs of the MCOs and DMMA in an effort to address route causes if any.

II. Member Training and Education

The MCO must provide to all its members information concerning protections from abuse, neglect, and exploitation. Processes for providing information concerning protections from abuse, neglect, and exploitation for persons receiving services in long-term care facilities and for persons receiving services are the responsibilities of the MCO.

The MCOs shall educate DSHP and DSHP Plus members, family members, and/or legal representatives as appropriate during the initial assessment. This information shall also be included in the MCO's Member Handbook or on websites and further communicated if requested.

III. Responsibility for Review of and Response to Critical Events or Incidents

1. APS is the designated agency to receive, investigate, and respond to critical incidents of abuse or neglect of adults living in the community.

   When the APS social worker substantiates the complaint and determines that the adult is in need of protective services, the APS worker establishes a care plan within *5* days of the home visit. The care plan is developed in conjunction with the members, their families, and/or legal representatives. This information is shared with the MCO staff. The MCO must integrate the goals and objectives of the APS care plan into the DSHP Plus member's care plan, developed by the MCO case manager. When there is a danger of imminent harm, the

appropriate victim assistance services are implemented immediately.

2. The Division of Family Services within the Department of Services for Children, Youth and Their Families is the designated agency to receive, investigate, and respond to critical incidents of abuse or neglect of children living in the community.

3. Per, any person, agency, organization or entity who knows or in good faith suspects child abuse or neglect must make a report to the Division of Family Services.

IV. Quality Oversight and Improvement

The quality oversight structure consists of representatives from DLTCRP, OSO, APS, DMMA and the MCOs. DMMA leads the Quality Improvement Committee but partners with the listed agencies and organizations to track, trend and implement processes to address route causes. This committee shall utilize a combination of guidelines, policies and procedures that are unique to the specific agency (ex.: Professional Regulations, Division of Public Health, the Attorney General's office) as well as guidance informed by Title 16 of the Delaware Code, § 903, relevant sections of the QMS, and the contract with the MCOs.

As a distinct component of the 1115 demonstration Waiver's Quality Improvement Strategy (QMS), the state will comply with all aspects of HCBS assurances and standards for the PROMISE program including oversight by the Medicaid agency. An amendment to the State's QMS to include PROMISE will be submitted within 90 days of demonstration waiver approval.

As a distinct component of the 1115 demonstration Waiver's Quality Improvement Strategy (QMS), the state, on an ongoing basis, identify, address and seek to prevent occurrence of abuse, neglect and exploitation.

For each performance measure/indicator the state uses to assess compliance, the state utilizes data provided by the MCOs to analyze and assess progress toward the performance measure. Each source of data is analyzed statistically/deductively or inductively. Themes are identified or conclusions drawn and recommendations are formulated where appropriate.

Issues that cannot be resolved at the case manager are brought to the attention of the case manager supervisor for further intervention. Problems with service delivery can be brought to the attention of MCO's Quality Improvement Committee (QIC) and DMMA's Quality Initiative Improvement (QII) Task Force for resolution and remediation. As needed, the MCO terminates the contract of a provider whose service provision is inadequate and notifies DMMA of the action.

APS staff members participate in the overall quality management strategy by providing feedback to the MCO and DMMA. Staff representatives from DLTCRP and OSO are available to meet with the QIC quarterly and on an as-needed basis.

Lastly, the MCO case managers can refer member concerns about provider agencies to the Division of Public Health (for licensing issues), or to the DMMA SUR Unit (for fraud and billing irregularities).

An individual applying for nursing facility care or home and community-based services through the Diamond State Health Plan Plus program must meet medical eligibility criteria.

Medical Eligibility Determinations

The state's Division of Medicaid & Medical Assistance Pre-Admission Screening (PAS) team completes a level of care (LOC) screening to determine if the applicant requires the level of care LOC provided by the program. An individual must be in need of skilled or intermediate level of care as determined by PAS and as defined below in order to be medically approved for the DSHP Plus program's enhanced services. During the LOC determination process, the PAS Team obtains a comprehensive medical evaluation of the level of care needed in a facility or the community. Physician orders are required for skilled nursing needs. The medical evaluation must be signed and dated not more than 365 days before the date of referral for the DSHP Plus program.

Referrals to PAS may come from the family of the applicant as well as other sources.

LOC Criteria with Implementation of DSHP Plus – With implementation of DSHP Plus, Delaware revised the nursing facility (NF) LOC definition for individuals entering a nursing facility to reflect that they must need assistance with at least two Activities of Daily Living (ADLs) rather than the previous minimum requirement of assistance with one ADL. There will be no impact on eligibility as a result of this change. Individuals requesting HCBS must be determined by PAS to be "at-risk" of institutionalization by requiring assistance with at least one ADL. Those Medicaid participants already residing in Nursing Facilities as of implementation of DSHP Plus will be automatically enrolled in the DSHP Plus program and their nursing facility services will continue to be covered by Medicaid as long as they continue to require assistance with at least one ADL.

"Activity of daily living (ADL)" means a personal or self-care skill performed, with or without the use of assistive devices, on a regular basis that enables the individual to meet basic life needs for food, hygiene, and appearance. The ADL need may look 'independent', but assessment will reflect, without supervision and/or assistance, clients' ability to function and live independently, will be compromised. Assessment will reflect client's inability to manage their own hydration, nutrition, medication management, mobility and hygiene, as applicable.

Nursing Facility Level of Care– PAS determines that an individual requires an NF LOC when

the individual requires assistance with at least two ADLs. This LOC requirement only applies to individuals newly entering a NF. All individuals receiving services in a NF prior to implementation of DSHP Plus will be grandfathered at the LOC requirement of requiring assistance with at least one ADL as long as they continue to require assistance with at least one ADL. In addition, children residing in the community are medically eligible under TEFRA if they are determined to require a NF LOC.

Level of Care for Individuals At-Risk of Institutionalization – PAS determines that an individual meets medical eligibility criteria for home and community based services under the DSHP Plus program when the individual is at-risk of institutionalization and requires assistance with one ADL. PAS determines that a TEFRA-like child meets medical eligibility criteria for State plan services when the individual requires assistance with one ADL.

Acute Hospital Level of Care – An Acute Hospital LOC is assigned to individuals that require the highest intensity of medical and nursing services provided within a structured environment providing 24-hour skilled nursing and medical care. Individuals with HIV/AIDS may be determined to require a Hospital LOC when they reside in the community without supportive services and are potentially at high risk for in-patient hospital care. In addition, children residing in the community are medically eligible under TEFRA if they are determined to require a hospital LOC. Such children require the highest intensity of medical and nursing services and, as a result, are potentially at high risk for in-patient hospital care.

Pre-Admissions Screening and Resident Reviews (PASRR)

By federal mandate, all individuals applying for placement in a Medicaid certified nursing facility, regardless of payment source, must have a Level I Pre-Admission Screening and Resident Review (PASRR) for Mental Illness (MI) or Intellectual Disability/Related Condition (MR/RC).

Based on results of a Level I PASRR Screening, the PAS RN may determine that further screening, a Level II PASRR, is warranted. A Level II PASRR evaluates clients with MI and MR/RC and determines if nursing home placement, either with or without specialized services, is appropriate. In addition to the PAS RN, an Independent Contracted Psychiatrist also makes placement recommendations. However, the final decision on appropriate placement for individuals with MI or MR/RC is made by the State Mental Health Authority for MI or the Division of Developmental Disabilities Services for MR/RC.

- **A Level I PASRR Screening is completed on all residents or potential residents of a Medicaid certified Nursing home.**
  A Level I screening is the process of identifying individuals who are suspected of having a mental illness or an intellectual disability or related condition. The Nursing Facility is responsible for completing the Level I screening for non-Medicaid individuals. The Division of Medicaid and Medical Assistance is responsible for completing the Level I screening for Medicaid and potential Medicaid individuals when notified.

- **Determination is made regarding the need for a Level II PASRR screening.**
  No further evaluation is needed, if, based on the Level I screening, the individual will meet one of three categories:
    - No indication of mental illness/mental retardation/related condition – nursing home admission/continued stay is appropriate - No further evaluation is needed.
    - There are indicators of mental illness/mental retardation/related condition however individual meets any of the following Physician's Exemption Criteria:
        - Primary Diagnosis of Dementia or related disorder.
        - Convalescent Care not to exceed 30 days - PAS nurses will track this exemption and initiate Level II PASRR evaluation prior to expiration if continued NF stay is warranted.
        - Terminal Illness – a life expectancy of 6 months or less if the illness runs its normal course.
        - Medical dependency with a severe physical illness.

  A Level II PASRR Assessment must be completed when the Level I screen reveals indicators of mental illness, intellectual or developmental disabilities.

ATTACHMENT F
Developing the Evaluation Design

Introduction

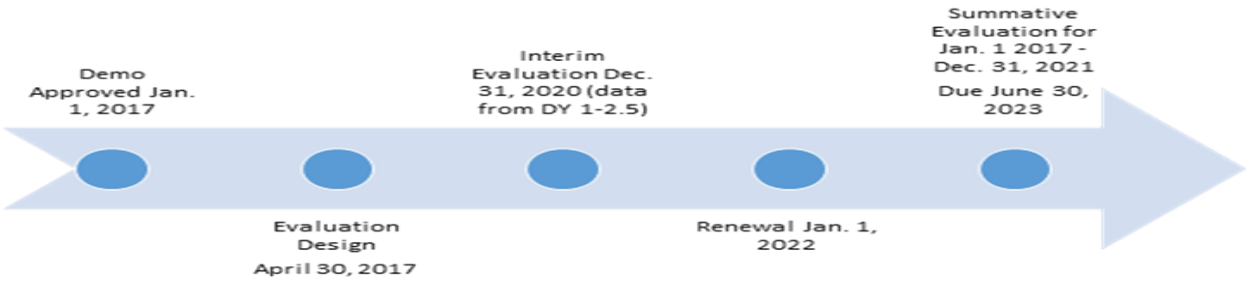
For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals**.**

The format for the Evaluation Design is as follows:
General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines
There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs
The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams: https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf

3) Identify the state's hypotheses about the outcomes of the demonstration:

4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;

5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?

2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.

3) *Evaluation Period* – Describe the time periods for which data will be included.

4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by "owning", defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:

    a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.

    b. Qualitative analysis methods may be used, and must be described in detail.

    c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.

    d. Proposed health measures could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

    e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).

    f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.

5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

    If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:

    a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.

c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).

d. The application of sensitivity analyses, as appropriate, should be considered.

7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

1) When the state demonstration is:
   a. Long-standing, non-complex, unchanged, or
   b. Has previously been rigorously evaluated and found to be successful, or

c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)

2) When the demonstration is also considered successful without issues or concerns that would require more regular reporting, such as:
   a. Operating smoothly without administrative changes; and
   b. No or minimal appeals and grievances; and
   c. No state issues with CMS-64 reporting or budget neutrality; and
   d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.

2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.

3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT G
Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

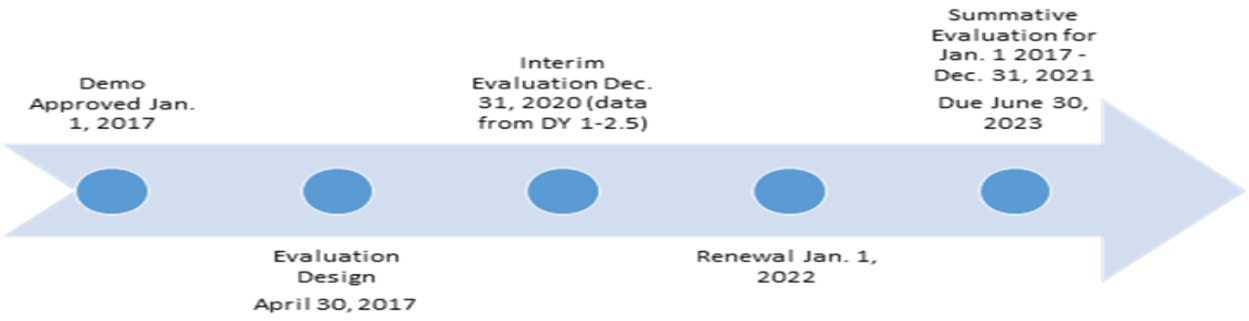
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

The format for the Interim and Summative Evaluation reports is as follows:

A. Executive Summary;
B. General Background Information;
C. Evaluation Questions and Hypotheses;
D. Methodology;
E. Methodological Limitations;
F. Results;
G. Conclusions;
H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
I. Lessons Learned and Recommendations; and
J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS , pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports
The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

A. Executive Summary – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.

B. General Background Information about the Demonstration – In this section, the state should include basic information about the demonstration, such as:

1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.

2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;

3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;

4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.

5) Describe the population groups impacted by the demonstration.

C. Evaluation Questions and Hypotheses – In this section, the state should:

1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

2) Identify the state's hypotheses about the outcomes of the demonstration;
   a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
   b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
   c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

A. Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?

2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:

   a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state's Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the "opportunities" for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?

2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation

Design

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

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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.

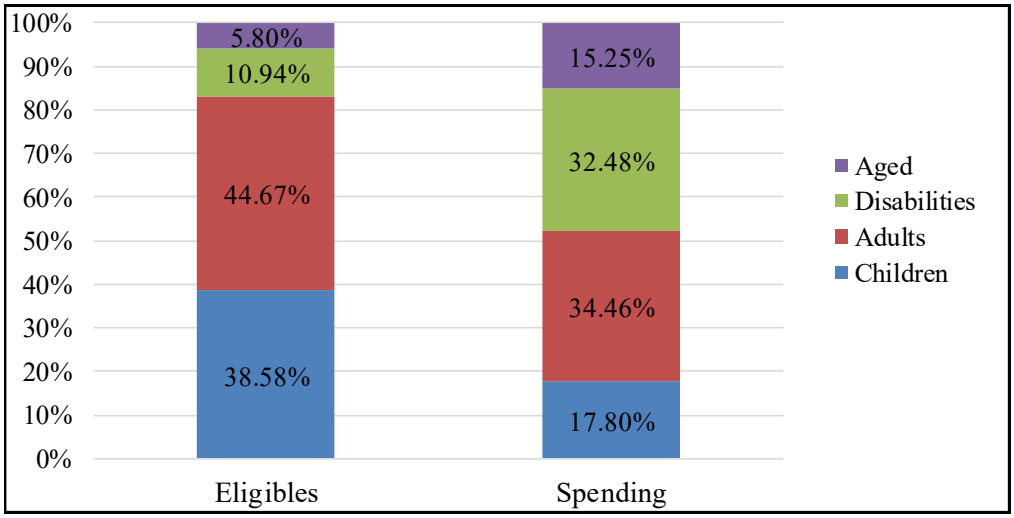
In June 2018, Delaware submitted a five-year demonstration extension and an amendment to provide the state with authority to provide high-quality, clinically appropriate SUD treatment services for short-term residents in residential and inpatient treatment settings that qualify as an IMD. The demonstration 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

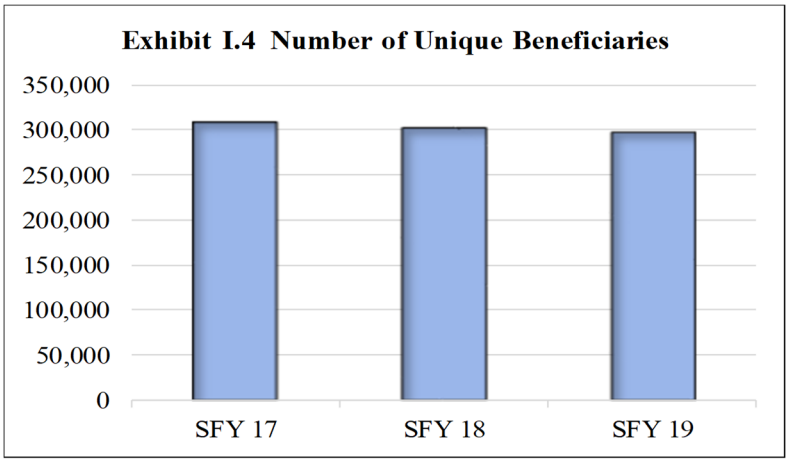
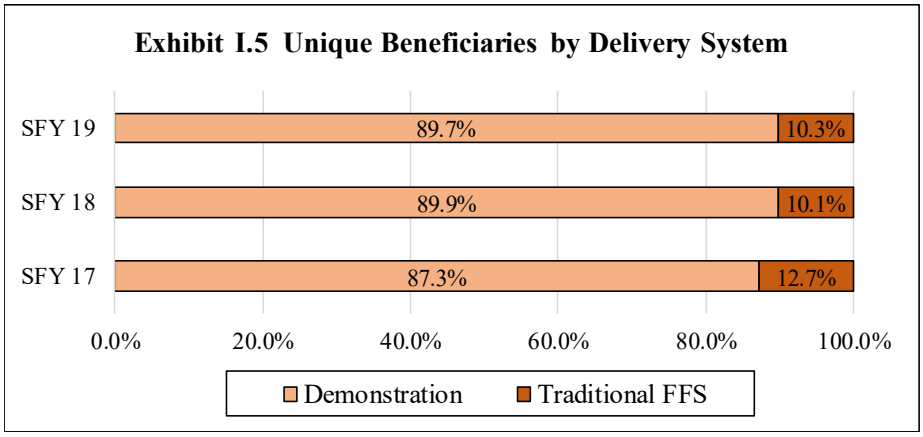


Exhibit I.5 Unique Beneficiaries by Delivery System



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

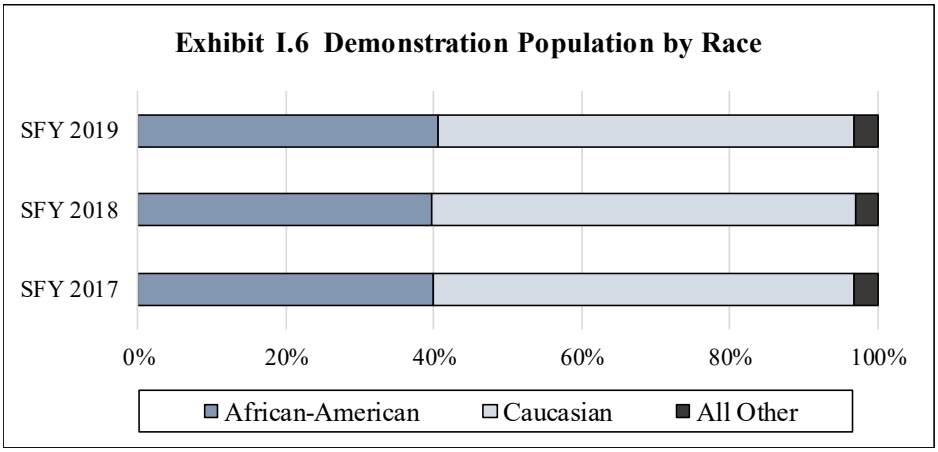
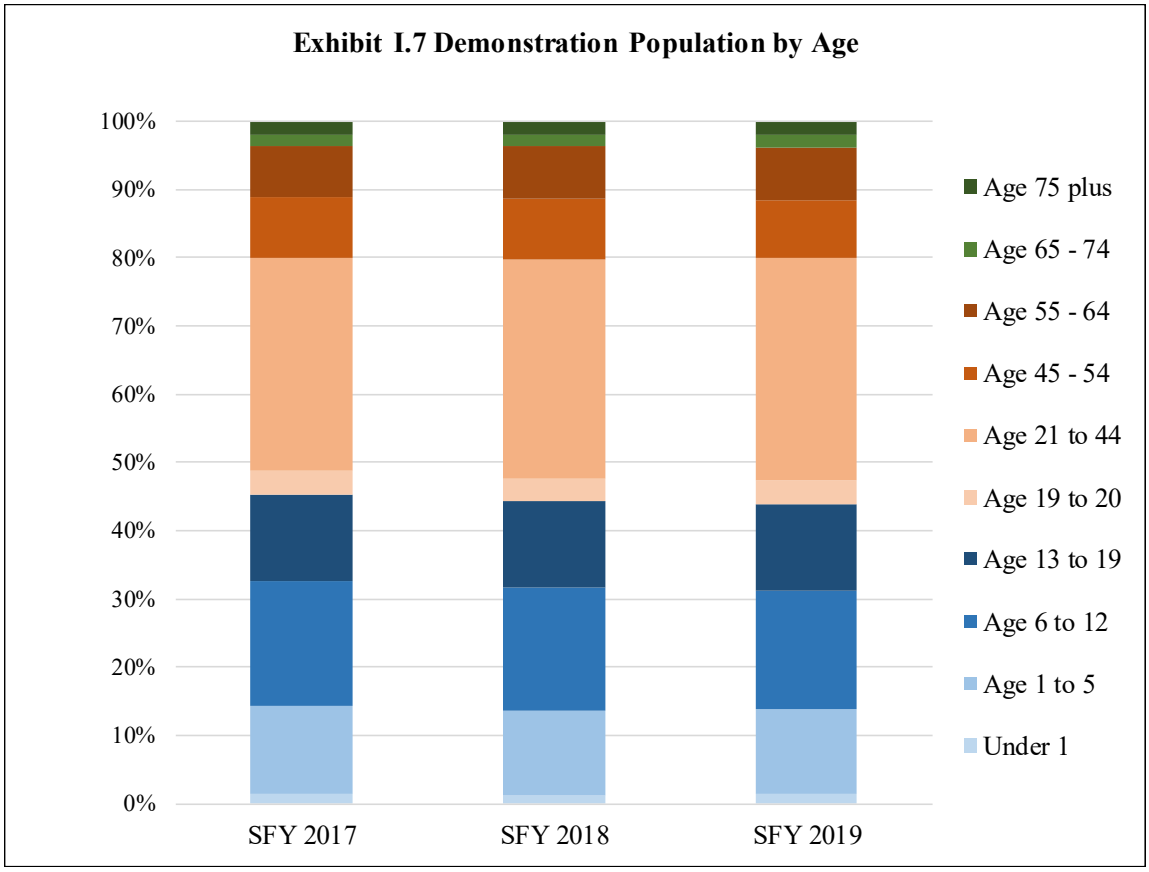


Exhibit I.7 distributes enrollment in the demonstration by the age of the members. In this exhibit, the blue colors represent different age groups among children while the peach/orange colors represent different age groups among adults age 64 and under. The green colors represent adults age 65 and older.



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.

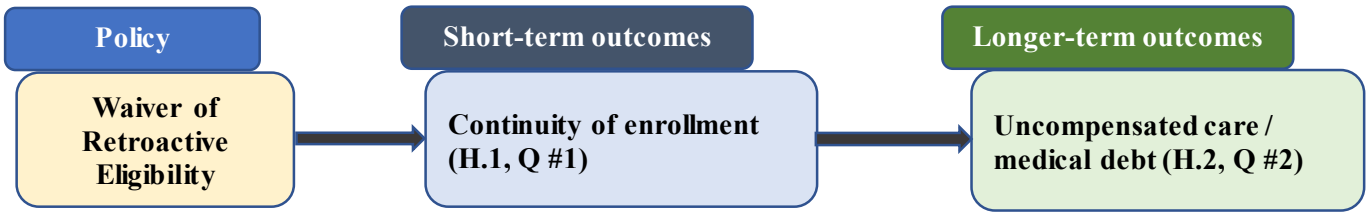
1. Maintain Continuity of Enrollment
2. Maintain Access to Care,
3. Maintain or Improve Health Outcomes, and
4. Rebalance Long-term Care Services and Supports (LTSS) in favor of Home and Community-based Services (HCBS).

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

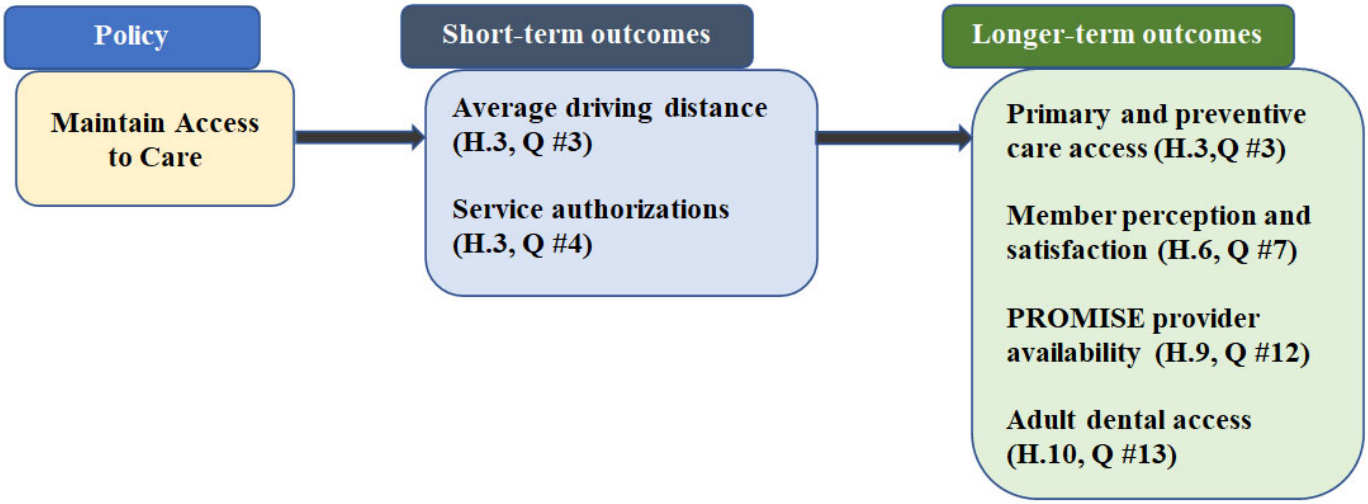


Maintain Access to Care

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.

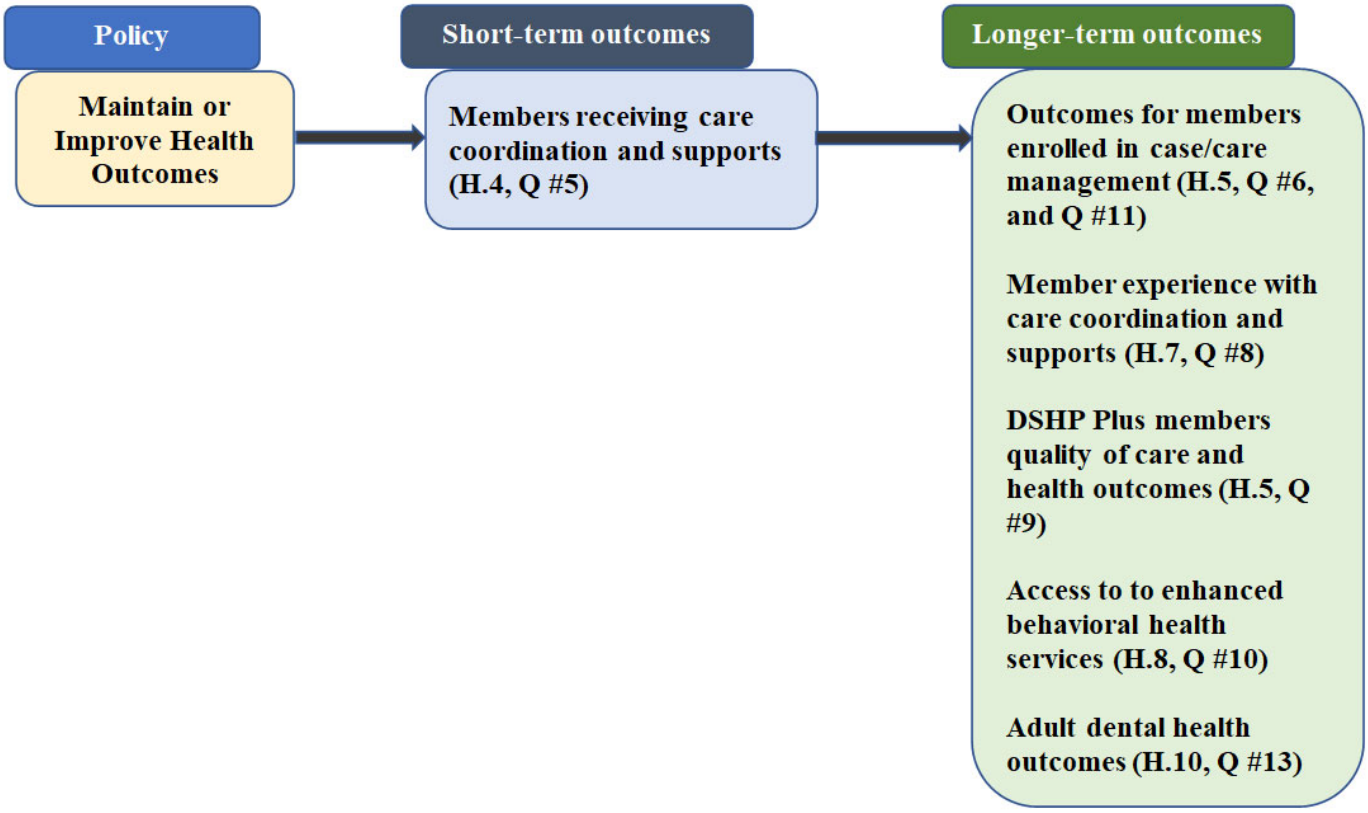
Exhibit II.3
Logic Model 2: Maintain or Improve Access



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.

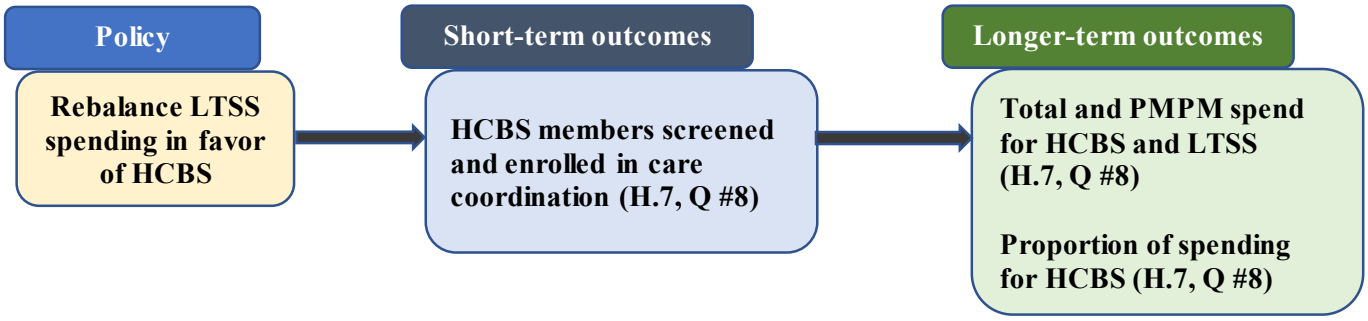
Exhibit II.4
Logic Model 3: Maintain or Improve Health Outcomes



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

		Method					Analytic Method Examples
	Hypothesis Description	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.

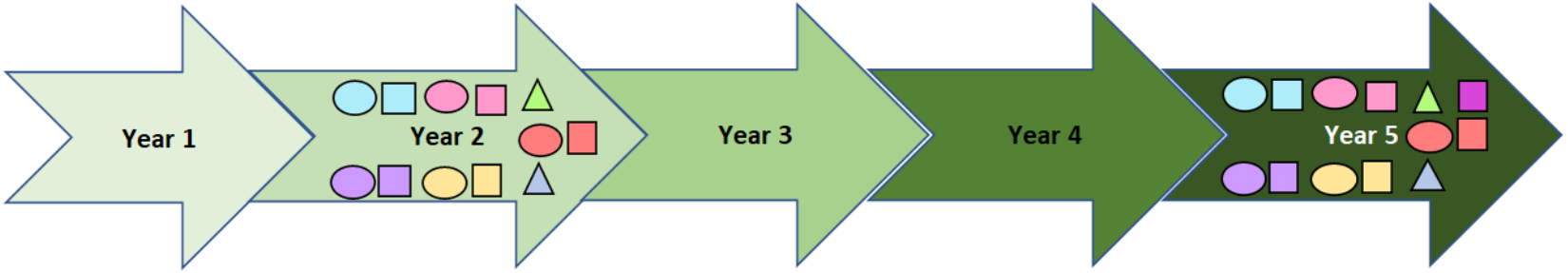
Whereas the Delaware Medicaid administrative data will be collected and used on a monthly basis throughout the waiver period and after the waiver concludes to produce the Summative Evaluation, B&A anticipates that data from our sources will be collected in CY 2021 and CY 2024 for use in evaluation activities. 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]:

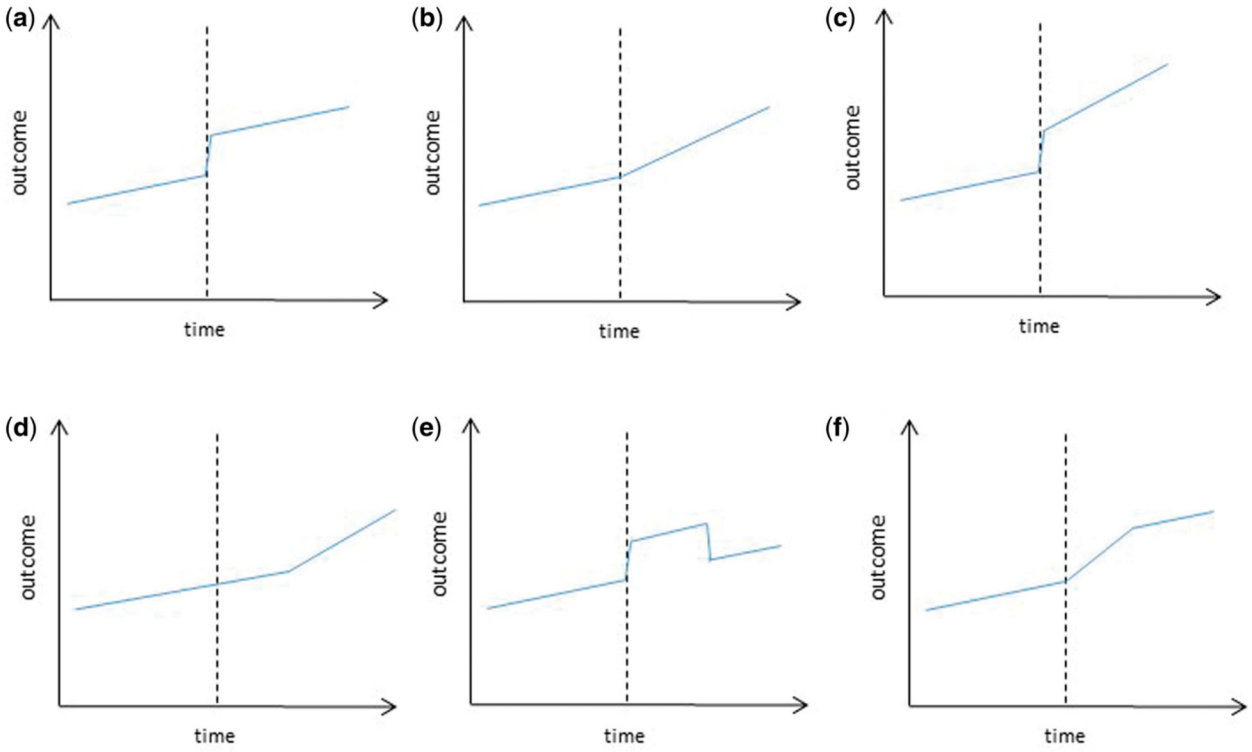
$$\hat{Y}_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time\_after\_intervention_t + e_t$$

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).

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
- 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 2021	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 3

Indicates ongoing work toward task

Indicates submission to CMS

Task Number	Task Name	Jan 2022	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 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

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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.

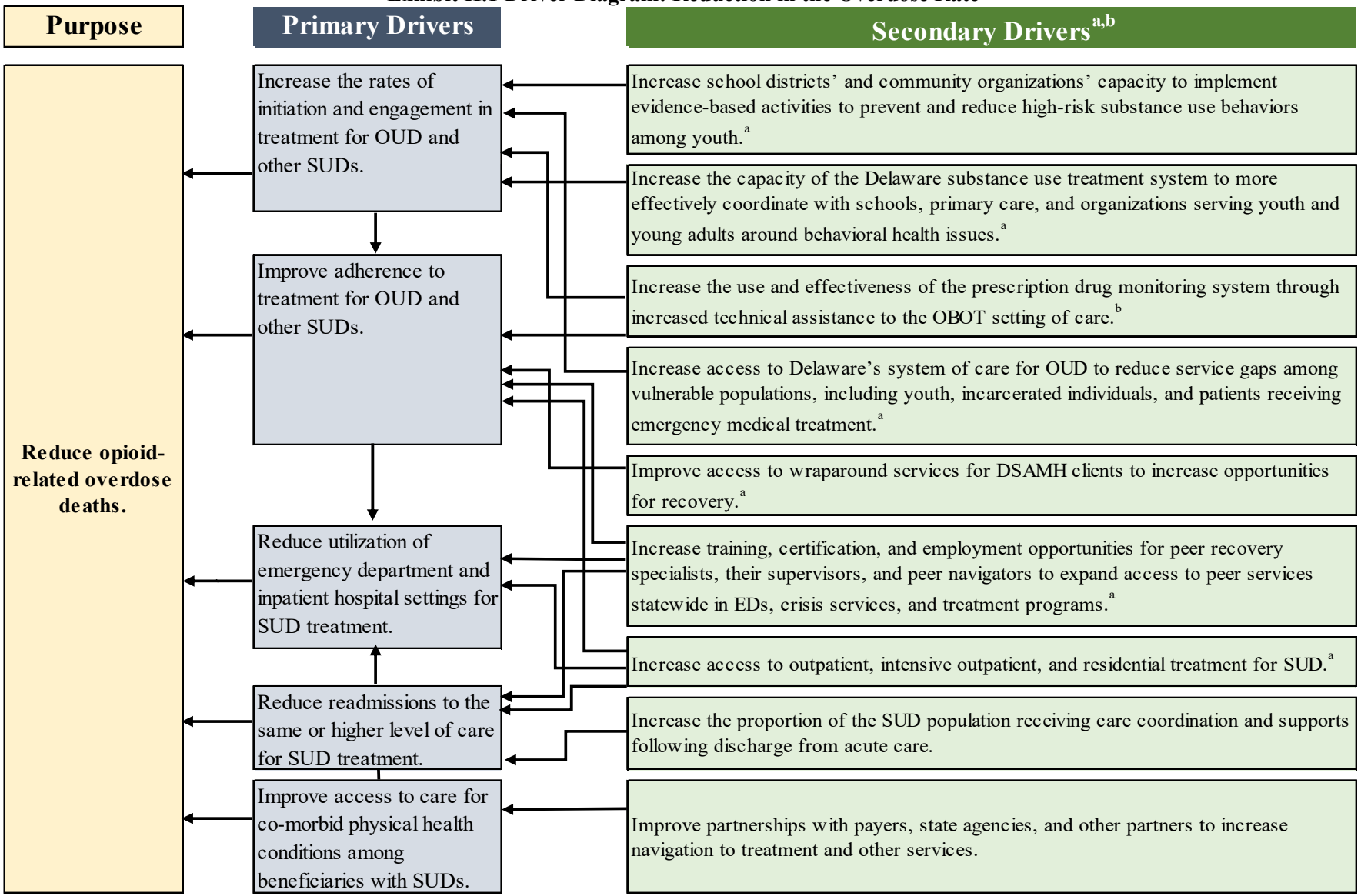
Overdose deaths is an important measurable health outcome of interest and, therefore, is the aim of the driver diagram. CMS's goals represent primary drivers all of which identified as having the potential to contribute to a reduction in overdose deaths. The specific actions described in the concurrent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

	Hypothesis Description	Method					Analytic Method Examples
		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

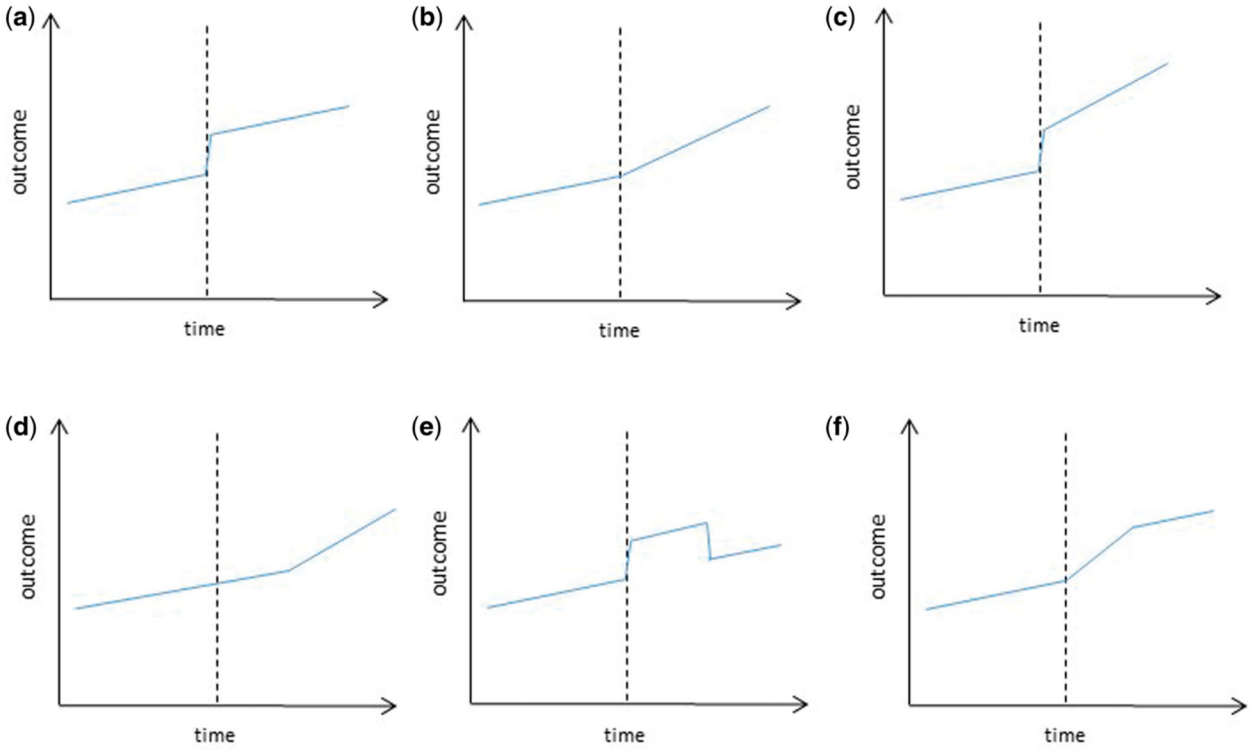
β_3 estimates the change in trend in the post-intervention segment

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).

<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
- 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)

ATTACHMENT I
SUD Implementation Plan

Delaware Health and Social Services

Division of Medicaid & Medical Assistance

Delaware Diamond State Health Plan (DSHP)

Section 1115 Demonstration Waiver

SUD Implementation Plan

State of Delaware

Stephen Groff, Director

Division of Medicaid & Medical Assistance (DMMA)

OCTOBER 2019

Updated March 2020

DELAWARE SUD 1115 IMPLEMENTATION PLAN

Table I: SUD Implementation Plan

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
Access to Critical Levels of Care for OUD and other SUDs (STC #31(a)(i))	Delaware's Medicaid State Plan provides coverage for comprehensive inpatient, outpatient, crisis intervention, residential OUD/SUD services, medically-supervised withdrawal management and MAT, consistent with individuals' assessed treatment needs. Delaware administers its SUD services consistent with ASAM Patient Placement Criteria. Coverage, services and provider qualifications are described in the Delaware Medicaid State Plan, Attachment 3.1 – A, Item 13.d, and in the Delaware Adult Behavioral Health DHSS Service Certification and Reimbursement Manual at https://dhss.delaware.gov/dhss/dsamh/files	2) Not applicable.	3) There are no anticipated actions needed by DMMA for fulfillment of this milestone.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	/ReimbursementManual.pdf Per Section 3.4.2 of the DSHP MCO Contract, the DSHP benefit package includes: "Substance use disorder services, including all levels of the American Society of Addiction Medicine (ASAM), Medication Assisted Treatment (MAT) and licensed opioid treatment programs"		
Use of Evidence-based, SUD-specific Patient Placement Criteria and Patient Placement (STC #31(a)(ii and iii) a) beneficiaries have access to SUD services at the appropriate level of care b) interventions are appropriate for the diagnosis and	4) In 2010, Delaware adopted Substance Abuse Treatment Standards that integrated ASAM criteria into program standards. 5) 6) Admission guidelines for each level of care are consistent with The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions. ASAM criteria are used by providers to determine a	17) DMMA is constantly seeking to improve its review and monitoring of its managed care organizations relative to utilization management. Ongoing review 18) of policies and procedures to ensure they include use of evidence-based practices and SUD-specific 19) criteria will occur to determine if any additional education or changes are warranted.	20) 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. 21)

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
level of care, and c) there is an independent process for reviewing placement in residential treatment settings.	beneficiary's eligibility for SUD services. DMMA does not mandate providers use a specific assessment tool; however, the assessment tool must reflect the ASAM guidelines. 7) The DSHP MCOs are responsible for implementing a utilization management (UM) approach consistent with ASAM Criteria. UM policies and practices areoutlined in MCO contracts as well as provider manuals. For PROMISE enrollees who receive behavioral health services in FFS through DSAMH, the medical necessity and utilization management policies are also consistent with ASAM Criteria. Examples of DSHP MCO contract provisions are copied below.		

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	Section 3.12.6.3 of the DSHP MCO Contract requires: 3.12.6.3 Requests for Initial and Continuing Service Authorizations 3.12.6.3.1 The Contractor must have in effect mechanisms to ensure consistent application of review criteria. 8) 3.12.6.3.2 The Contractor shall use the Delaware American Society for Addiction Medicine (DE-ASAM) criteria for behavioral health services. **Section 3.12.4 of the DSHP MCO Contract requires:** 3.12.4 Monitoring of Inpatient Behavioral Health Service Utilization 3.12.4.1 The Contractor shall work with DSAMH to develop a collaboration protocol that includes strategies and agreements to achieve the inpatient behavioral health utilization reduction		

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	targets contained within the DOJ Settlement Agreement. The collaboration agreement, which shall be developed by the Start Date of Operations, shall include at a minimum: 3.12.4.1.1 How the Contractor will monitor adult inpatient behavioral health admissions, readmissions and lengths of stay. 3.12.4.1.2 The process and frequency with which the Contractor will share adult inpatient behavioral health utilization data with DSAMH. 3.12.4.1.3 How the Contractor will collaborate with local emergency rooms and behavioral health providers to appropriately utilize adult inpatient diversion services, such as crisis intervention or other available home and community-based		

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	Covered Services or additional services. 3.12.4.1.4 How the Contractor will collaborate with DSAMH in the admission process, utilization review, and discharge planning for adult members participating in PROMISE. 9) 3.12.4.1.5 How the Contractor will provide ongoing utilization review and directly assist with discharge planning for adult members not participating in PROMISE. 10) **11) The DSHP MCO contract also requires the following key staff position:** 12) 3.20.2.1.4 A full-time Behavioral Health Medical Officer/Medical Director (BH CMO) who is a board certified Psychiatric Mental Health Nurse Practitioner or Clinical Nurse Specialist with an Advanced Practice Nursing (APN)		

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	license in the State of Delaware and has at least five years of combined experience in mental health and substance use services. This person shall oversee and be responsible for all behavioral health activities, including oversight of coordination activities with DSAMH. 13) 14) Examples, of relevant state law include:  SB109.pdf 15) 16)  Engrossment.pdf  SB 41 - Engrossment.pdf		
Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment	22) See below. 23) 24) 25) 26) 27) 28)	35) Not applicable. 36) 37) 38) 39) 40) 41)	49) There are no anticipated actions needed by DMMA for fulfillment of this milestone. 50)

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
Facilities and Standards of Care (STC #31(a)(iv)-(vi)) a) Implementation of residential treatment provider qualifications (in licensure requirements, policy manuals, managed care contracts, or other guidance) that meet the ASAM Criteria or other nationally-recognized, SUD-specific program standards regarding the types of services, hours of clinical care and credentials of staff for residential treatment settings;	29) In 2010, Delaware adopted Substance Abuse Treatment Standards that establish integration of ASAM criteria into OUD/SUD treatment program standards. The standards also address licensure criteria and suspension and revocation of licensure. 30) Residential treatment providers must be a licensed organization, pursuant to the residential service provider qualifications described in Title 16, DHSS, Delaware Administrative Code, Section 6001, 4.1. 31) The DSAMH Licensed and Certified Provider Directory contains licensure information for all substance abuse programs that are licensed by the Division of Substance Abuse and Mental Health in the state of Delaware. Currently, a provider's licensure status is identified	42) Delaware is considering updates to the provider qualifications in State rules. 43) 44) 45) 46) 47) 48)	

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
b) Implementation of a state process for reviewing residential treatment providers to assure compliance with these standards; and c) Implementation of a requirement that residential treatment facilities offer MAT on-site or facilitate access off-site.	(e.g., Full or Provisional) as well as the name of the service the provider delivers (e.g., Residential Services). 32) 33) The Delaware Division of Substance Abuse and Mental Health (DSAMH), part of DHSS, is responsible for assuring continual compliance through reviews of residential treatment centers for compliance with these standards. 34) The State Plan definition of residential addiction services includes MAT when medically necessary, including the direct administration of medication.		
Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD (STC #31(a)(vii)	Gaps remain in the service delivery continuum for many of Delaware's most at risk and underserved groups, including Medicaid beneficiaries. An essential component of ensuring that Medicaid beneficiaries receive	51) The assessment under the SUPPORT Act Grant will inform infrastructure improvements to increase provider capacity to provide OUD and other SUD treatment and recovery services in Medicaid and help establish a long-term	52) In September 2019, CMS awarded Delaware a SUPPORT ACT Section 1003 Project Planning Grant to assess the Mental Health and SUD treatment needs of the State of Delaware. The aims of the proposed

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	treatment and recovery services is ensuring access to continuum of care that is timely, comprehensive, evidence-based, and sustainable. This includes a pipeline of clinical and nonclinical providers skilled in working with Medicaid beneficiaries around opioid use disorder (OUD) and other SUD, a cohesive health system that allows for seamless movement between treatment levels and providers, and payment models that support providers.	data collection and monitoring plan.	assessment of the mental health and SUD treatment needs of the State of Delaware (the assessment) are to: 1) Understand the mental health and substance abuse treatment needs of the population receiving Medicaid in the state, and 2) Determine the extent to which additional providers are needed to address Medicaid beneficiaries' unmet SUD treatment and recovery needs. 53) 54) By December 2020 (or as updated in the SUPPORT Act Grant), as described in Delaware's SUPPORT Act Project Planning Grant, Delaware will: 55) 1.Estimate the number and percentage of OUD

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
			and other SUD among Medicaid-beneficiaries, and OUD and other SUD treatment and recovery needs. 56) 2. Complete a workforce assessment to determine SUD provider and service capacity for Medicaid beneficiaries. 57) 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. 58) DMMA recognizes that these steps, as planned for in the SUPPORT Act Planning Grant, are slightly longer than the 12 months requested by CMS for SUD 1115 Waivers. However, we are requesting that CMS permit DMMA to align our efforts between the 1115 and the SUPPORT Act Grant activities to focus on one review of provider capacity at critical levels of care. If the Support Act Grant dates are revised by mutual

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
			agreement between Delaware and CMS, DMMA will seek CMS approval for a corresponding update to the Implementation Plan.
Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD (STC #31(a)(viii)) a) implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse b) expanded coverage of, and access to, naloxone for overdose reversal c) implementation of strategies to increase utilization and improve functionality of prescription drug	(a) Effective April 1, 2017 the Delaware Uniform Controlled Substance Act rules and regulations were revised to add a new Section 9.0 pertaining to the safe prescribing of opioid analgesics: Safe Prescribing of Opioid Analgesics. 59) This Section provides requirements for the prescribing of opioid analgesics in order to address potential prescription drug overdose, abuse, and diversion and encourage the proper and ethical treatment of pain. Pursuant to the requirements of this Section, the practitioner can meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care.	63) Not applicable. 64)	65) There are no anticipated actions needed by DMMA for fulfillment of this milestone.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
monitoring programs	60) (b) Pharmacists can now dispense the overdose antidote over the counter under SB 48 (attached).  SB 48 - Engrossment.pdf 61) 62) (c) The Delaware Prescription Monitoring Act (16 Del. C.§ 4798) authorizes the Office of Controlled Substances (OCS) in the Delaware Division of Professional Regulation to establish, maintain and monitor the Prescription Monitoring Program (PMP). The purpose of the PMP is to reduce misuse of controlled substances in Delaware and to promote improved professional practice and patient care. The Delaware Prescription Drug Monitoring		

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	Program Advisory Committee regularly focuses on strategies to improve functionality of the PDMP. Examples from the September meeting are attached.  63279_Minutes-... (d) There are no copays on Nalaxone. For up-to-date details on Delaware's initiatives to expand access to Naloxone, see the Overdose Prevention section on helpisherede.com		
SUD HIT Plan (STC #31(a)(ix)	See Table II	66)	67)
Improved Care Coordination and Transitions between Levels of Care (Implementation of policies to ensure residential and inpatient	68) ASAM level of care guidelines require that residential facilities begin discharge/transfer planning services upon a beneficiary's admission. In addition, programs	DMMA will continue to monitor MCO compliance with existing contract requirements in effort to assure beneficiary needs are met relative to linkage with community-based services.	79) DMMA's EQRO will perform a focus study to assess MCO performance on Care Coordination and Transitions between Levels of Care for individuals with OUD and other SUD in 2021 (for

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
facilities link beneficiaries with community-based services and supports following stays in these facilities.) (STC #31(a)(x)	must provide referral and assistance as needed for beneficiaries to gain access to other needed SUD or mental health services. 69) 70) Examples of relevant DSHP MCO Contract language includes: 71) 3.6.4 Clinical Practice Guidelines 3.6.4.1 The Contractor's care coordination program shall utilize evidence-based practice guidelines. 72) 73) 3.6.4.2 The Clinical care coordination program shall be described and included in the contractor's utilization management program description. 74) 3.6.3.3 Level 1: Resource Coordination 75) 3.6.3.3.1 The Contractor shall actively assist providers in discharge planning for Level 1 members following acute episodes of care involving at a	78)	review of 2020 activities.) Since PROMISE enrollees are also enrolled in DSHP MCOs, the EQRO will include a review of care coordination and care transitions for MCO members receiving PROMISE services in FFS. Expected report release by August 2021. 80) 81) DMMA will determine if additional policies to ensure coordination of care for co-occurring physical and mental health conditions are needed: July 2020 (assessment) and September 2021 (implementation as needed, to align with the release of the EQRO special study results.) 82) 83)

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	minimum one of the following services: inpatient psychiatric stay, ambulatory surgery, hospital inpatient stay, and rehabilitation facility services. Contractor assistance shall include but not be limited to: appointment setting, referrals and linkages to services, coordination of DME, and coordination of prior authorizations as needed to support the member's timely access to services in the community. 76) 3.8.4.2.3 The Contractor shall actively assist with discharge planning when members are receiving behavioral health services within higher levels of care including institutional or residential settings. 77) 3.8.4.2.4 The Contractor shall work with Treatment Access Center case managers in providing treatment for drug court related cases.		

Table II. Delaware SUD HIT Plan

Section I

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
PDMP Functionalities: Enhanced interstate data sharing in order to better track patient specific prescription data.	The Delaware PMP is part of the PMP Interconnect (PMPi). Delaware is currently connected with 35 states, Puerto Rico, and the Department of Defense.	The PMP is authorized in state law until 2025. The Delaware Department of Public Health received a CDC Overdose Data to Action (ODTA) grant that will be utilized, in part, to maintain and enhance the PMP for the next 3 years.	84) There are no anticipated actions needed by DMMA for fulfillment of this milestone. Delaware will include regularly-occurring updates in the SUD Monitoring Plan.
PDMP Functionalities: Enhanced "ease of use" for prescribers and other state and federal stakeholders	The PMP Advisory Committee (https://dpr.delaware.gov/boards/pmp/) focuses on prescriber tools and enhanced "ease of use" at its regular meetings. Examples of recent enhancements to the PMP include: allowing users to more easily reset their password via text message (in response to feedback received in the 2018 PMP user survey); improved quarterly prescriber reports that provide information such as	The PMP Advisory Committee will continue to seek feedback from prescribers and make improvement that enhance ease of use.	85) There are no anticipated actions needed by DMMA for fulfillment of this milestone. 86) Delaware will include regularly-occurring updates in the SUD Monitoring Plan.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	simplified format, clearer specialty comparison, trend data, and per patient statistics, as requested through prescriber feedback (under development.)		
PDMP Functionalities: Enhanced connectivity between the state's PDMP and any statewide, regional or local health information exchange	Currently the Delaware PMP is part of the PDMP interconnect collaboration with Appriss Health and the National Association of Boards of Pharmacy, which is the national PDMP data exchange hub that enables the secure sharing of PDMP data across states and systems. Delaware's DHIN (HIE) links to the PMP. Approximately 57 health systems/provider practices and 160 pharmacies have integrated access to the PMP. Delaware was also selected to pilot integration with the Veteran's Administration.	Delaware intends to continue to promote integration of the PMP into provider/health systems.	87) There are no anticipated actions needed by DMMA for fulfillment of this milestone. 88) Delaware will include regularly-occurring updates in the SUD Monitoring Plan.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
PDMP Functionalities: Enhanced identification of long-term opioid use directly correlated to clinician prescribing patterns	State law requires practitioners to query the PMP for subsequent prescriptions (beyond the first) and chronic pain patients. State law also explicitly authorizes the use of the PMP in a number of circumstances designed to identify long-term opioid use and/or use for reasons other than treatment of an existing medical condition. Details can be found at: https://delcode.delaware.gov/title16/c047/sc07/		89) There are no anticipated actions needed by DMMA for fulfillment of this milestone. 90) Delaware will include updates in the SUD Monitoring Plan.
Current and Future PDMP Query Capabilities: Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state's master patient index (MPI) strategy with regard to PDMP query)	As noted in the SMHP, the Community Health Record (CHR) within the DHIN (Delaware's HIE with the MPI data) has Medication History. The DHIN links to the PMP. Users of the CHR can retrieve 12 months of prescription fill history (provided by a number of national sources, to include		Delaware will report on future planned PDMP query capabilities within 6 months of CMS approval of the SUD HIT Plan and provide regular updates as part of the Monitoring Report.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	SureScripts, health plan pharmacy benefits managers, and others) upon demand. For those who do not choose to subscribe to the full service, there is a URL link embedded in the DHIN web portal that takes the user to the Delaware Prescription Monitoring database, where they can at minimum (and for no charge) view the controlled substance fill history for the patient.		
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes: Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow Develop enhanced supports for clinician	The PMP Advisory Committee (https://dpr.delaware.gov/boards/pmp/) focuses on prescriber tools and administrative/analytics at its regular meetings and makes regular enhancements to the PMP in support of clinicians with changing office workflows and business processes. Approximately 57 health systems/provider practices and 160		91) There are no anticipated actions needed by DMMA for fulfillment of this milestone. 92) Delaware will include updates in the SUD Monitoring Plan.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription	pharmacies already have integrated access to the PMP. Section 3.10.2.1.24 of the MCO contracts requires participating providers to comply with the requirements of the Delaware Prescription Monitoring Program (PMP) and to query the PMP to view information about client usage before prescribing Schedule II or III controlled substances.		
Master Patient Index / Identity Management: Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	As noted in the SMHP, the Community Health Record within the DHIN (Delaware's HIE) has Medication History. Users of the CHR can retrieve 12 months of prescription fill history (provided by a number of national sources, to include SureScripts, health plan pharmacy benefits managers, and others) upon demand. For those who do not choose to subscribe to the full service, there is a URL link embedded in the DHIN web		DMMA will report on any planned future enhancements in support of SUD care delivery and the status of implementation within 6 months of CMS approval of the SUD HIT Plan.

MILESTONE AND STC	CURRENT STATE	FUTURE STATE	SUMMARY OF ACTIONS NEEDED
	portal that takes the user to the Delaware Prescription Monitoring database, where they can at minimum (and for no charge) view the controlled substance fill history for the patient.		
Overall Objective for Enhancing PDMP Functionality & Interoperability: Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids	In accordance with CDC guidelines, Delaware has implemented maximum quantity and dosage limits for opioid prescriptions for intractable, non-cancer pain, helping to ensure that Medicaid does not inappropriately pay for opioids.		Within 6 months of CMS approval of the SUD IP, Delaware will provide and update description of the future state and updates on actions need.

Delaware assures that it has a sufficient health IT infrastructure/ “ecosystem” at every appropriate level (i.e. state, delivery system, MCO and individual provider) to achieve the goals of the demonstration. The SUD Health IT Plan is aligned with the SMHP. Delaware will continue to make ongoing enhancements to the PMP over the life of the demonstration as needs are identified. Delaware will report on these enhancements in the SUD Monitoring Plan.

Section II – Implementation Administration

Please provide the contact information for the state’s point of contact for the SUD Health IT Plan.

Name and Title: Glyne Williams, Chief—Policy, Planning and Quality
Telephone Number: (302) 255-9628
Email Address: Glyne.Williams@delaware.gov

Section III – Relevant Documents

Please provide any additional documentation or information that the state deems relevant to successful execution of the implementation plan.

Attached is the most recent version of the SMHP.

2018 DE SMHP.pdf

ATTACHMENT J
SUD Monitoring Protocol

1. Title Page for the State's SUD Demonstration or SUD Components of Broader Demonstration

The state should complete this Title Page as part of its SUD Monitoring Protocol. This form should be submitted as the title page for all Monitoring Reports. The content of this table should stay consistent over time.

State	Delaware
Demonstration name	Diamond State Health Plan
Approval date for demonstration	08/01/2019
Approval period for SUD	08/01/2019 – 12/31/2023
Approval date for SUD, if different from above	
Implementation date of SUD, if different from above	
SUD (or if broader demonstration, then SUD - related) demonstration goals and objectives	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.

2. Proposed Modifications to SUD Narrative Information on Implementation, by Milestone or Reporting Topic

Summary of proposed modification	Related metric (if any)	Justification for modification
1. Assessment of Need and Qualification for SUD Services		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
2. Access to Critical Levels of Care for OUD and other SUDs (Milestone 1)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
3. Use of Evidence-based, SUD-specific Patient Placement Criteria (Milestone 2)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
4. Use of Nationally Recognized SUD-specific Program Standards to Set Provider Qualifications for Residential Treatment Facilities (Milestone 3)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
5. Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD (Milestone 4)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		

Summary of proposed modification	Related metric (if any)	Justification for modification
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
6. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and OUD (Milestone 5)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
7. Improved Care Coordination and Transitions between Levels of Care (Milestone 6)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
8. SUD Health Information Technology (Health IT)		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
9. Other SUD-related Metrics		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
10. Budget Neutrality		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		

Summary of proposed modification	Related metric (if any)	Justification for modification
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
11. SUD-Related Demonstration Operations and Policy		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
12. SUD Demonstration Evaluation Update		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
13. Other Demonstration Reporting		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		
14. Notable State Achievements and/or Innovations		
☐ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information with the modifications described above.		
☒ The state has reviewed the corresponding prompts for narrative information in the SUD Monitoring Report Template and confirms that it will report the narrative information as requested (no modifications).		

3. Acknowledgement of Budget Neutrality Reporting-

☒ The state has reviewed the Budget Neutrality workbook provided by the project officer and understands the expectations for quarterly and annual monitoring reports. The state will provide the requested budget neutrality information (no modifications).

4. Retrospective reporting

If a state's monitoring protocol is approved after its first quarterly monitoring report submission date, the state should report data to CMS retrospectively for any prior quarters of SUD demonstration implementation. States are expected to submit retrospective metrics data in the state's second monitoring report submission after monitoring protocol approval, or propose an alternative plan for reporting retrospectively on its SUD demonstration.

In the monitoring report submission containing retrospective metrics data, the state should also provide a general assessment of metrics trends from the start of the state's demonstration through the end of the current reporting period. The state should report this information in Part B of its report submission (Table 3: Narrative Information on Implementation, by Milestone and Reporting Topic). This general assessment is not intended to be a comprehensive description of every trend observed in metrics data (for example, unlike other monitoring report submissions, the state is not required to describe all metrics changes (+ or - greater than 2 percent). Rather, the assessment is an opportunity for states to provide context for its retrospective metrics data, to support CMS's review and interpretation. For example, consider a state that submits data showing an increase in the number of medication assisted treatment (MAT) providers (Metric #14) over the course of the retrospective reporting period. The state may decide to highlight this trend to CMS in Part B of its report (under Milestone 4) by briefly summarizing the trend and providing context that during this period, the state implemented a grant that supported training for new MAT providers throughout the state.

☐ The state will report retrospectively for any quarters prior to monitoring protocol approval as described above, in the state's second monitoring report submission after protocol approval.

☒ The state proposes an alternative plan to report retrospectively for any quarters prior to monitoring protocol approval: *DY2Q4 will be submitted on March 31, 2021 for approval. Once approved retrospective reports for DY1Q3-DY2Q3 will be submitted on August 29, 2021.*

5. Reporting SUD Demonstration Metrics and Narrative Information

The state should review the guidance in Appendix A of the instructions document in order to attest it will follow CMS's guidance on reporting metrics and narrative information, or propose any deviations. The state should complete Table A below to reflect its proposed reporting schedule for the duration of its SUD demonstration approval period.

☒ The state has completed the table below according to the guidance in Appendix A of the instructions document and attests to reporting metrics and narrative information in its quarterly and annual reports according as described.

☐ The state has reviewed Appendix A of the instructions document and completed the table below with the following deviations: *Insert narrative description of proposed changes to reporting. State should provide justification for any proposed deviation.*

Table A. Delaware reporting in quarterly and annual monitoring reports

Dates of reporting quarter	Broader 1115 DY (if applicable)	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
August 1, 2019 –September 30, 2019*	DY24Q3	DY1Q3	11/29/2019	• Protocol in development
October 1, 2019 – December 31, 2019	DY24Q4 (annual monitoring report)	DY1Q4	3/31/2020	• Protocol in development
January 1, 2020 – March 31, 2020	DY25Q1	DY2Q1	5/30/2020	• Protocol in development
April 1, 2020 – June 30, 2020	DY25Q2	DY2Q2	8/29/2020	• Protocol in development
July 1, 2020 – September 30, 2020	DY25Q3	DY2Q3	11/29/2020	• Protocol in development
October 1, 2020 – December 31, 2020	DY25Q4 (annual monitoring report)	DY2Q4	3/31/2021	• Narrative information for SUD DY2Q4 • Other monthly and quarterly metrics for SUD DY2Q3
January 1, 2021 – March 31, 2021	DY26Q1	DY3Q1	5/30/2021	• Narrative information for SUD DY3Q1 • Other monthly and quarterly metrics for SUD DY2Q4 • Other annual metrics for SUD DY2 (which for DE is CY 2020)
April 1, 2021 – June 30, 2021	DY26Q2	DY3Q2	8/29/2021	• Narrative information for SUD DY3Q2 • Other monthly and quarterly metrics for SUD DY3Q1

Dates of reporting quarter	Broader 1115 DY (if applicable)	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category

				• Annual metrics that are established quality measures for SUD DY2 (calculated for CY 2020)
				• Retrospective Reporting:
				  ○ Monthly and quarterly metrics for SUD DY1Q3 – SUD DY2Q3
				  ○ Annual metrics that are established quality measures for SUD DY1 (which for DE is CY 2019)
				• Other annual metrics for SUD DY1 (which for Delaware is CY 2019)

July 1, 2021 – September 30, 2021	DY26Q3	DY3Q3	11/29/2021	• Narrative information for SUD DY3Q3 • Other monthly and quarterly metrics for SUD DY3Q2
October 1, 2021 – December 31, 2021	DY26Q4 (annual monitoring report)	DY3Q4	3/31/2022	• Narrative information for SUD DY3Q4 • Other monthly and quarterly metrics for SUD DY3Q3
January 1, 2022 – March 31, 2022	DY27Q1	DY4Q1	5/30/2022	• Narrative information for SUD DY4Q1 • Other monthly and quarterly metrics for SUD DY3Q4 • Other annual metrics for SUD DY3
April 1, 2022 – June 30, 2022	DY27Q2	DY4Q2	8/29/2022	• Narrative information for SUD DY4Q2 • Other monthly and quarterly metrics for SUD DY4Q1 • Annual metrics that are established quality measures for SUD DY3 (calculated for CY 2021)
July 1, 2022 – September 30, 2022	DY27Q3	DY4Q3	11/29/2022	• Narrative information for SUD DY4Q3 • Other monthly and quarterly metrics for SUD DY4Q2

Dates of reporting quarter	Broader 1115 DY (if applicable)	SUD DY	Report due (per STCs schedule)	Measurement period associated with SUD information in report, by reporting category
October 1, 2022 – December 31, 2022	DY27Q4 (annual monitoring report)	DY4Q4	3/31/2023	• Narrative information for SUD DY4Q4 • Other monthly and quarterly metrics for SUD DY4Q3
January 1, 2023 – March 31, 2023	DY28Q1	DY5Q1	5/30/2023	• Narrative information for SUD DY5Q1 • Other monthly and quarterly metrics for SUD DY4Q4 • Other annual metrics for SUD DY4
April 1, 2023 – June 30, 2023	DY28Q2	DY5Q2	8/29/2023	• Narrative information for SUD DY5Q2 • Other monthly and quarterly metrics for SUD DY5Q1 • Annual metrics that are established quality measures for SUD DY4 (calculated for CY 2022)
July 1, 2023 – September 30, 2023	DY28Q3	DY5Q3	11/29/2023	• Narrative information for SUD DY5Q3 • Other monthly and quarterly metrics for SUD DY5Q2
October 1, 2023 – December 31, 2023	DY28Q4 (annual monitoring report)	DY5Q4	3/30/2024	• Narrative information for SUD DY5Q4 • Other monthly and quarterly metrics for SUD DY5Q3

* The SUD component of Delaware's broader section 1115 demonstration and the SUD implementation plan were approved on August 1, 2019. To align with the state's broader demonstration years, the first year of the SUD component is considered to include two quarters (SUD DY1Q3 and SUD DY1Q4), spanning August 1, 2019 – December 31, 2019. The "broader 1115 DY" column identifies the broader section 1115 demonstration years as defined in the STCs, for reference. The approval period for the current demonstration period ends December 31, 2023.

Medicaid Section 1115 SUD Demonstration Monitoring Protocol - Planned metrics
State: Delaware
Demonstration Name: Diamond State Health Plan
Submitted on: 4/15/2020; revised 12/15/2020; revised 03/05/2021

Standard information on CMS-provided metrics										Baseline, annual goals, and demonstration target			Alignment with CMS-provided technical specifications		Initial reporting date				
#	Metric name	Metric description	Milestone or reporting topic	Metric type	Reporting category	Measurement period	Reporting frequency	Reporting priority	State will report (Y/N)	Baseline Reporting Period (MM/DD/YYYY-MM/DD/YYYY)	Annual goal	Overall demonstration target	Attest that planned reporting matches the CMS-provided specification (Y/N)	Explanation of any deviations from the CMS-provided specifications (different data source, definition, codes, target population, etc.)	Dates covered by first measurement period for metric (MM/DD/YYYY - MM/DD/YYYY)	Name of first report in which the metric will be submitted (Format: DY1 Q3 report)	Submission date of first report in which the metric will be reported (MM/DD/YYYY)	State plans to phase in reporting (Y/N)	Explanation of any plans to phase in reporting over time
1	Assessed for SUD Treatment Needs Using a Standardized Screening Tool	Number of beneficiaries screened for SUD treatment needs using a standardized screening tool during the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Recommended	N										
2	Medicaid Beneficiaries with Newly Initiated SUD Treatment/Diagnosis	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period but not in the three months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
3	Medicaid Beneficiaries with SUD Diagnosis (monthly)	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period and/or in the 11 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
4	Medicaid Beneficiaries with SUD Diagnosis (annually)	Number of beneficiaries with a SUD diagnosis and a SUD-related service during the measurement period and/or in the 12 months before the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
5	Medicaid Beneficiaries Treated in an IMD for SUD	Number of beneficiaries with a claim for residential or inpatient treatment for SUD in IMDs during the measurement period	Assessment of need and qualification for SUD treatment services	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
6	Any SUD Treatment	Number of beneficiaries enrolled in the measurement period receiving any SUD treatment service, facility claim, or pharmacy claim during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
7	Early Intervention	Number of beneficiaries who used early intervention services (such as procedure codes associated with SBIRT) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
8	Outpatient Services	Number of beneficiaries who used outpatient services for SUD (such as outpatient recovery or motivational enhancement therapies, step down care, and monitoring for stable patients) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
9	Intensive Outpatient and Partial Hospitalization Services	Number of unique beneficiaries who used intensive outpatient and/or partial hospitalization services for SUD (such as specialized outpatient SUD therapy or other clinical services) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
10	Residential and Inpatient Services	Number of beneficiaries who use residential and/or inpatient services for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
11	Withdrawal Management	Number of beneficiaries who use withdrawal management services (such as outpatient, inpatient, or residential) during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
12	Medication Assisted Treatment	Number of beneficiaries who have a claim for MAT for SUD during the measurement period	Milestone 1	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
36	Average Length of Stay in IMDs	The average length of stay for beneficiaries discharged from IMD inpatient or residential treatment for SUD during the measurement period	Milestone 1	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
13	SUD Provider Availability	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period	Milestone 4	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
14	SUD Provider Availability - MAT	The number of providers who were enrolled in Medicaid and qualified to deliver SUD services during the measurement period and who meet the standards to provide buprenorphine or methadone as part of MAT	Milestone 4	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
15	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET-AD) [NCQA; NQF #0004; Medicaid Adult Core Set; Adjusted HEDIS measure]	Percentage of beneficiaries with a new episode of alcohol or other drug (AOD)AOD abuse or dependence who received the following: • Initiation of AOD Treatment—percentage of beneficiaries who initiated treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or MAT within 14 days of the diagnosis • Engagement of AOD Treatment—percentage of beneficiaries who initiated treatment and who had two or more additional AOD services or MAT within 34 days of the initiation visit The following diagnosis cohorts are reported for each rate: (1) Alcohol abuse or dependence, (2) Opioid abuse or dependence, (3) Other drug abuse or dependence, and (4) Total AOD abuse or dependence. A total of 9 separate rates are reported for this measure.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
18	Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) [PQA, NQF #2940; Medicaid Adult Core Set]	Percentage of beneficiaries age 19 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Beneficiaries with a cancer diagnosis or in hospice are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
19	Use of Opioids from Multiple Providers in Persons Without Cancer [PQA; NQF #2950]	The percentage of individuals ≥19 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤190 days.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
20	Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer [PQA, NQF #2951]	The percentage of individuals ≥19 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
21	Concurrent Use of Opioids and Benzodiazepines (COB-AD) [PQA]	Percentage of beneficiaries age 19 and older with concurrent use of prescription opioids and benzodiazepines. Patients with a cancer diagnosis or in hospice are excluded.	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
22	Continuity of Pharmacotherapy for Opioid Use Disorder [USC; NQF #3175]	Percentage of adults in the denominator with pharmacotherapy for OUD who have at least 190 days of continuous treatment	Milestone 5	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2018 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
16	SUB-3 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge [Joint Commission; NQF #1664]	SUB-3 rate: Patients who are identified with alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment. SUB-3a rate: Patients who are identified with alcohol or drug disorder who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment.[b]	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Recommended	N										
17(1)	Follow-up after Emergency Department Visit for Alcohol or Other Drug Dependence (FUA-AD) [NCQA; NQF #2605; Medicaid Adult Core Set; Adjusted HEDIS measure][b]	Percentage of ED visits for beneficiaries who have a principal diagnosis of AOD abuse or dependence and who had a follow-up visit with a corresponding principal diagnosis for AOD. Two rates are reported: - Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 7 days of the ED visit (9 total days). - Percentage of ED visits for AOD abuse or dependence for which the beneficiary received follow-up within 30 days of the ED visit (31 total days).	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
17(2)	Follow-up after Emergency Department Visit for Mental Illness (FUM-AD) [NCQA; NQF #2605; Medicaid Adult Core Set; Adjusted HEDIS measure][c]	Percentage of ED visits for beneficiaries who have a principal diagnosis of mental illness and who had a follow-up visit with a corresponding principal diagnosis for mental illness. Two rates are reported: - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (9 total days). - Percentage of ED visits for mental illness for which the beneficiary received follow-up within 30 days of the ED visit (31 total days)	Milestone 6	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q2 report	08/29/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
Q1	Utilization of Telehealth Services for SUD per 1,000	Total number of telehealth visits for SUD per 1,000 beneficiaries in the measurement period	Health IT	State-identified	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent			04/01/2019 - 06/30/2019	DY3 Q3 report	11/29/2021	Y	Data is not available. The state anticipates acquisition and reporting of this data by DY3 Q3 (2021)
Q2	Number of queries to the PMP	Unique count of PMP queries in quarter for DE and border state participating providers.	Health IT	State-identified	Other monthly and quarterly	Quarterly	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent			04/01/2019 - 06/30/2019	DY3 Q3 report	11/29/2021	Y	Data is not available. The state anticipates acquisition and reporting of this data by DY3 Q3 (2021)
Q3	Initial Opioid Prescribing for Long Duration(IOP-LD) in the PMP	The percentage of individuals ≥18 years of age with ≥1 initial opioid prescriptions for >7 cumulative days' supply. (Excludes patients in hospice care and those with cancer or sickle cell disease.) This measures will be statewide and include DE and Border State provider records. Specification maintained by PQA.	Health IT	State-identified	Other monthly and quarterly metric	Quarterly	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent			04/01/2019 - 06/30/2019	DY3 Q3 report	11/29/2021	Y	Data is not available. The state anticipates acquisition and reporting of this data by DY3 Q3 (2021)
23	Emergency Department Utilization for SUD per 1,000 Medicaid Beneficiaries	Total number of ED visits for SUD per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
24	Inpatient Stays for SUD per 1,000 Medicaid Beneficiaries	Total number of inpatient stays per 1,000 beneficiaries in the measurement period	Other SUD-related metrics	CMS-constructed	Other monthly and quarterly metric	Month	Quarterly	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		04/01/2019 - 06/30/2019	DY2 Q4 report	03/31/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1 Q3 - DY2 Q3)
25	Readmissions Among Beneficiaries with SUD	The rate of all-cause readmissions during the measurement period among beneficiaries with SUD.	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
26	Overdose Deaths (count)	Number of overdose deaths during the measurement period among Medicaid beneficiaries living in a geographic area covered by the demonstration. States are encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2021 - 12/31/2021	Consistent	Consistent	Y		01/01/2021 - 12/31/2021	DY4 Q1 report	05/31/2022	Y	Data is not available. The state anticipates acquisition and reporting of this data by DY3 (2021)
27	Overdose Deaths (rate)	Rate of overdose deaths during the measurement period among adult Medicaid beneficiaries living in a geographic area covered by the demonstration. States are encouraged to report the cause of overdose death as specifically as possible (for example, prescription vs. illicit opioid).	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Required	Y	01/01/2021 - 12/31/2021	Consistent	Consistent	Y		01/01/2021 - 12/31/2021	DY4 Q1 report	05/31/2022	Y	Data is not available. The state anticipates acquisition and reporting of this data by DY3 (2021)
28	SUD Spending	Total Medicaid SUD spending during the measurement period.	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	N	DE will use paid amounts reported by managed care organizations to identify costs for SUD encounters and paid amounts for costs for SUD fee-for-service claims.	01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
29	SUD Spending Within IMDs	Total Medicaid SUD spending on residential or inpatient treatment within IMDs during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	N	DE will use paid amounts reported by managed care organizations to identify costs for SUD encounters and paid amounts for costs for SUD fee-for-service claims.	01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
30	Per Capita SUD Spending	Per capita SUD spending during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	N	DE will use paid amounts reported by managed care organizations to identify costs for SUD encounters and paid amounts for costs for SUD fee-for-service claims.	01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
31	Per Capita SUD Spending Within IMDs	Per capita SUD spending within IMDs during the measurement period	Other SUD-related metrics	CMS-constructed	Other annual metric	Year	Annually	Recommended	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	N	DE will use paid amounts reported by managed care organizations to identify costs for SUD encounters and paid amounts for costs for SUD fee-for-service claims.	01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
32	Access to Preventive/ Ambulatory Health Services for Adult Medicaid Beneficiaries with SUD (AAP)	The percentage of Medicaid beneficiaries with SUD who had an ambulatory or preventive care visit during the measurement period.	Other SUD-related metrics	Established quality measure	Annual metric that is an established quality measure	Year	Annually	Required	Y	01/01/2019 - 12/31/2019	Consistent	Consistent	Y		01/01/2020 - 12/31/2020	DY3 Q1 report	05/30/2021	Y	After review of Q4 report and assuming approval within 30 days, DMMA will submit hisotric reports on 08/29/2021 (DY1)
33	Grievances Related to SUD Treatment Services	Number of grievances filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Quarter	Quarterly	Recommended	N										
34	Appeals Related to SUD Treatment Services	Number of appeals filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Quarter	Quarterly	Recommended	N										
35	Critical Incidents Related to SUD Treatment Services	Number of critical incidents filed during the measurement period that are related to SUD treatment services	Other SUD-related metrics	CMS-constructed	Grievances and appeals	Quarter	Quarterly	Recommended	N										

Add rows for any additional state-identified metrics

[a]There are no CMS-provided metrics related to milestone 2 or milestone 3.

The SUD Monitoring Protocol Workbook (Part A) is also available in spreadsheet format on Medicaid.gov