June 29, 2018

Judith Cash, Director
State Demonstrations Group
Centers for Medicare & Medicaid Services
Centers for Medicaid and CHIP Services
Mail Stop: S2-26-06
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Cash:

The Delaware Division of Medicaid and Medical Assistance (DMMA) is pleased to submit for CMS approval the attached Section 1115 Waiver amendment to provide coverage for substance use disorder (SUD) services in settings that qualify as institutions for mental diseases (IMDs). The goal of this demonstration amendment is for Delaware to improve outcomes for Medicaid individuals experiencing SUD by maintaining and expanding access to SUD services, including inpatient and residential SUD services in settings that qualify as an IMD, as part of a full continuum of treatment services.

DMMA looks forward to working with CMS towards an expedited review and approval of this amendment. If you have any questions, please contact me or Glyne Williams at 302-255-9628 or by email at Glyne.Williams@state.de.us.

Sincerely,

Stephen M. Groff, DMMA
Designee for
Kara Odom Walker, MD, MPH, MSHS
Secretary, DHSS
Delaware Health and Social Services

Delaware Diamond State Health Plan
Substance Use Disorders Treatment
Section 1115 Demonstration Amendment Application

to

The Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

State of Delaware

Stephen Groff, Director
Division of Medicaid & Medical Assistance (DMMA)

June 2018
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**Section I – Summary**

The Delaware Department of Health and Social Services (DHSS), Division of Medicaid and Medical Assistance (DMMA) is requesting an amendment to the Delaware Diamond State Health Plan (DSHP) Section 1115 Demonstration Waiver to continue, and potentially expand, the use of Institutions for Mental Diseases (IMDs) for substance use disorder (SUD) residential treatment as part of an essential continuum of care for Medicaid enrolled individuals with opioid or other substance use disorders. This waiver amendment is requested to be effective immediately upon approval.

Delaware Medicaid currently covers all American Society of Addiction Medicine (ASAM) levels of outpatient and residential care and Medicaid managed care organizations (MCOs) currently utilize IMDs as part of their SUD residential treatment provider network under the Medicaid managed care rules for “in lieu of” services. In the absence of this demonstration amendment, recent federal changes to the managed care rules and longstanding fee-for-service rules that limit payment for treatment in an IMD setting would further restrict access to residential treatment while Delaware is in the middle of an opioid epidemic. This demonstration amendment will enable Delaware to maintain and expand critical access to a range of existing SUD services and to create a more robust provider network.

**Section II – Program Background, Description, Goals and Objectives**

**Background**

Delaware, like other states across the nation, is facing an increasingly complex public health crisis related to the misuse and abuse of opioids. This includes prescription painkillers, as well as illegally obtained pills, heroin, and street-derived synthetic opioids, such as fentanyl. Over the past several years, Delaware has responded to this crisis in multiple ways: legislation has been passed that supports programs and initiatives that are designed to prevent opioid misuse and addiction; harm reduction strategies have expanded that reduce risk of overdose, and other associated health concerns related to misuse; and policymakers have supported increased expansion and access to treatment services. Delaware has also increased treatment capacity while creating a continuum of care that includes residential treatment options as well as medication assisted treatment (MAT), inpatient and outpatient detoxification programs. The treatment system in Delaware operates as a continuum in which clients may move from between levels of service intensity based on their individual treatment needs. A summary of a few of the approaches that Delaware has implemented to respond to the opioid epidemic are described below:

- **Expansion of the Medicaid SUD Continuum of Care.** Delaware Medicaid coverage includes all ASAM levels of care, including outpatient, intensive outpatient (IOP), medication assisted treatment (MAT), residential, inpatient, and MAT.

- **Coverage of MAT.** Delaware provides coverage for MAT, in combination with substance abuse counseling, to help individuals who have opioid dependence disorder manage their opioid addiction.

1. [https://www.delawareonline.com/topic/885f595b-ce73-4ce1-9002-092931aba2d0/heroin-delawares-deadly-crisis/](https://www.delawareonline.com/topic/885f595b-ce73-4ce1-9002-092931aba2d0/heroin-delawares-deadly-crisis/)
addiction. Coverage is provided for Methadone, Buprenorphine, and Naltrexone, often referred to by the brand name, Vivitrol.

- **Expansion of residential treatment capacity.** In 2016, Delaware:
  - Opened three 16-bed residential treatment programs and reconfigured the Delaware City program (78 to 95 beds)
  - Doubled sober living residential beds statewide (60 to 120 beds)
  - Doubled the residential treatment beds for individuals ages 18-25 recovering from addiction to opiates (16 to 32 beds)

Yet, according to the Prescription Opioid and Heroin Addiction Treatment Needs Assessment report produced for the Delaware Department of Justice (DOJ), the State’s residential treatment system is being underutilized, and entry into this system has been constrained by insurers’ policies, including Medicaid payment restrictions. Delaware has addressed some of these restrictions through the passage of Senate Bill 109, but federal Medicaid rules continue to limit payment for IMD settings. The Delaware DOJ has developed a nine-point plan that includes a recommendation to expand the availability of “quality treatment facilities that allow for extended residential and outpatient treatment.”

- **Prescription Monitoring Program**

Delaware enacted its Prescription Monitoring Program (PMP) in August 2013, with prescribers required to be fully registered and using PMP by January 1, 2014. All practitioners that have a controlled substance registration and pharmacists who dispense controlled substances in Delaware were to register with the system (veterinarian exception).

Evaluation of Delaware’s PMP from the Prescription Behavior Surveillance System at Brandeis University, which reports to the CDC, showed a greater than 50 percent decline (2012-2015), in the rate of multiple provider episodes in the state, which are correlated with “doctor shopping.” In addition, the survey indicated a 26 percent decline during the same time period of high dosage prescriptions (over 100 morphine milligram equivalents, MMEs). Data from the PMP has also been used to identify troubling prescribing patterns.

- **Prescribing Guidelines and Limits**

As of April 2017, Delaware clinicians are required to follow new prescription guidelines which are similar to the recommendations proposed by the CDC. Under these new regulations, medical practitioners can only prescribe a seven day supply of opioid medicine for first time

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4 Uniform Controlled Substances Act Regulations, Controlled Substance Advisory Committee, Title 24 Regulated Professions and Occupations Delaware Administrative Code, April 1, 2017.
patients with pain due to medical procedures or injuries. This will also apply to all minors who experience acute pain, whether first time patients or not. If more medicine is to be supplied, the PMP must be referenced for the patient’s history with prescription drugs, and clinicians should follow a set of prescribing guidelines that mirror the CDC guidelines. Doctors can still use their medical discretion to prescribe outside of these limits, but they must provide an explanation for their decision to do so. In addition to limits on prescriptions, patients who receive opioids must sign informed consent documents that acknowledge that they understand the risk associated with the use of opioids (Goss, 2017b). Also, physicians must follow up with patients who receive opioids to monitor for signs of misuse and addiction.

In addition to the recent prescribing guidelines, Delaware mandated prescriber education in 2015. Practitioners who want to gain or renew a Controlled Substance Registration must take a one hour class that outlines the laws, regulations, and programs regarding DE substance distribution.

- **Patient Review and Restriction Programs**

  Lock-In programs restrict Medicaid individuals whose utilization of medical services is documented as being excessive. Individuals are restricted to specific provider(s) in order to monitor services being utilized and reduce unnecessary or inappropriate utilization. For example, AmeriHealth Caritas Delaware’s lock-in programs assign members to a specific pharmacy to prevent and reduce the misuse of pharmacy services. A multi-disciplinary team reviews member medical and pharmacy utilization. If the team finds evidence of misuse, abuse, or potential fraud of pharmacy services from a member, they will lock-in the member and send notice to the member, the member’s primary care provider and the pharmacy assigned to the lock-in member. Providers can refer members to the lock-in program if they suspect misuse, abuse, or potential fraud of pharmacy services.

**Vision for Substance Use Disorder Treatment**

Despite these efforts, there is much more that can be done to reduce the harm caused by opioid misuse and other substance use disorders. Delaware is planning to develop a System of Care approach that has successfully been used with Trauma, Pediatric and Stroke programs to address opioid overdoses in the State. The System of Care is an organized approach to patient management throughout the continuum of care statewide. It involves coordination of care from pre-hospital transport through acute-care discharge, multidisciplinary involvement from dispatch, prehospital, hospitals, medical specialists, prevention, the use of documenting system data resulting in improved

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6 Amerihealthcaritas Pharmacy Lock-in Program
communication and collaboration among stakeholders to ensure patients receive the same quality of care no matter where in the state they enter the system.  

Delaware is also developing a Centers of Excellence (COE) Substance Use Model of Care, in recognition of national estimates suggesting that only 10-25% of individuals with a SUD received treatment and that silos occur between and within systems resulting in care gaps and incomplete treatment. The Opioid Use Disorder COE will operate alongside the existing provider networks and will serve as a vital link between engagement and treatment/recovery partners to ensure coordination and facilitate recovery-oriented and person-centered care transitions for individuals with OUD.

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9 Opioid Use Disorder Centers Of Excellence (OUD-COE), Request For Proposals For Professional Services, Issued By Department Of Health and Social Services, Division Of Substance Abuse And Mental Health, January 26, 2018.
Section III – Demonstration Goals and Objectives

The goal of this demonstration amendment is for Delaware to improve outcomes for Medicaid individuals experiencing SUD by maintaining and expanding access to SUD services, including inpatient and residential SUD services in settings that qualify as an IMD, as part of a full continuum of treatment services. For years, CMS has approved these IMD residential settings in Delaware as cost-effective alternatives to state plan residential treatment settings through the “in lieu of” services authority in the DSHP managed care program. However, recent changes to Medicaid managed care regulations and existing limitations in fee-for-service on the use of IMDs create barriers to ensuring that members are able to enter treatment at a level appropriate to their needs. At a minimum, this demonstration amendment seeks authority so that new federal Medicaid managed care restrictions on IMDs as SUD providers do not disrupt the Medicaid SUD continuum in Delaware and reduce access to services. Delaware also seeks to use the demonstration to remove any Medicaid payment barriers that may result in unnecessary underutilization of residential treatment by individuals in need of these services. By preserving and expanding residential treatment capacity, Delaware will be able to provide an effective SUD continuum of services with interventions that are capable of meeting individuals’ changing needs for various levels of care. As individuals move throughout the continuum in their recovery from SUD, they may need to transition to levels of care of greater or lesser intensity. Concurrent with the demonstration request, Delaware is continuing its efforts in to develop a vision and plan for a coordinated SUD System of Care approach with the OUD Centers of Excellence model as part of future improvements.

Delaware’s demonstration amendment will provide the State with authority to continue providing high-quality, clinically-appropriate SUD treatment services for all members, regardless of delivery system. This demonstration builds on the State’s existing efforts to improve models of care focused on supporting individuals in the community and home, outside of institutions, and strengthen a continuum of SUD services based on the ASAM criteria. Implementation of the demonstration will also result in a focus on using more data-informed approaches to monitor provider networks to ensure the availability of services in high-need areas, evaluating the service capacity of the provider network across levels of care, and establishing processes to ensure service provision consistent with ASAM guidelines.

During the demonstration period, Delaware seeks to achieve the following:

• Increase enrollee access to and utilization of appropriate SUD treatment services based on the ASAM Criteria;
• Decreased use of medically inappropriate and avoidable high-cost emergency department and hospital services by enrollees with SUD;
• Increased initiation of follow-up after discharge from emergency department for alcohol or other drug dependence; and
• Reduced readmission rates for SUD treatment.
Section IV – Eligibility, Benefits, Delivery System and Cost-Sharing

Eligibility
Medicaid eligibility requirements will not differ from the approved Medicaid state plan and approved DSHP 1115 demonstration. Delaware is not proposing changes to Medicaid eligibility standards in this amendment.

Benefits
Benefits will not differ from the approved Medicaid state plan and approved DSHP 1115 demonstration. The demonstration will permit Delaware Medicaid individuals with substance use disorders to receive high-quality, clinically appropriate state plan-approved SUD services in outpatient and community-based settings as well as in residential and inpatient treatment settings that qualify as an IMD. Delaware’s SUD benefit package covers a full-range of community-based care (e.g., crisis intervention and outpatient addiction treatment, which includes MAT), as well as residential addiction treatment services. The Delaware Medicaid State Plan was updated in 2016 to add the full continuum of SUD ASAM levels of care.

Delivery system
No changes to the current managed care and fee for service delivery systems are being proposed in this amendment.

Over 90% of Medicaid/CHIP beneficiaries in Delaware are enrolled in MCOs. DMMA currently contracts with two MCOs to serve DSHP and DSHP Plus beneficiaries. Mental health and SUD (MH/SUD) benefits are the shared responsibility of the Medicaid MCOs and fee-for-service (FFS), administered by the DHSS/Division of Substance Abuse and Mental Health (DSAMH) (for certain adults 18 and older) and the Delaware Department of Services for Children, Youth, and Their Families (DSCYF) (for children under 18.)

Children and Adolescents: MCOs are responsible for providing 30 units of MH/SUD outpatient services to members under 18. All inpatient and residential MH/SUD benefits and all outpatient MH/SUD benefits that exceed the MCO limit are provided in FFS through the DSCYF Division of Prevention and Behavioral Health Services (DPBHS).

Adults (PROMISE): DHSS has implemented recent initiatives designed to improve care in Delaware for Medicaid members, including new services for adults through the PROMISE program. The PROMISE program is administered by DSAMH through FFS and is for Medicaid individuals who have a severe and persistent mental illness (SPMI) and/or SUD and require Home- and Community-Based Services (HCBS) to live and work in integrated settings. Individuals eligible for PROMISE receive non-PROMISE services through the MCOs and PROMISE services, including state plan SUD services, through FFS.

Adults (non-PROMISE): MCOs are responsible for all MH/SUD benefits for members age 18 and older who are not enrolled in PROMISE.

The MCOs, DSAMH and DSCYF manage separate delivery systems and provider networks that have some overlap. The MCOs have been able to utilize IMDs as cost-effective alternative settings for SUD benefits through 1115 demonstration authority and, most recently, through the managed care “in lieu
of services flexibility. DSAMH and DSCYF administer FFS provider networks that do not include IMDs for Medicaid populations.

Cost-sharing
The cost-sharing requirements under this Demonstration will not differ from those provided under the Medicaid state plan.

Section V – Demonstration Hypothesis and Evaluation

The demonstration will test whether Delaware 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.

Goals
Delaware will evaluate whether the demonstration:

• Increases enrollee access to and utilization of appropriate SUD treatment services based on the ASAM Criteria;

• Decreases use of medically inappropriate and avoidable high-cost emergency department and hospital services by enrollees with SUD;

• Increases initiation of follow-up after discharge from emergency department for alcohol or other drug dependence; and

• Reduces readmission rates for SUD treatment.

Changes
Resulting changes expected through the demonstration are:

• Greater availability of Medicaid residential service coverage, regardless of Medicaid delivery system.

• Use of data-informed approaches for:
  o Tracking service and provider network adequacy
  o Facilitating data information exchange to promote collaboration and ensure timely care transitions

• Implementation of additional quality monitoring and oversight to ensure providers’ adherence to the most current version of ASAM criteria.

Plan for Testing
Upon approval of the waiver, Delaware will develop a Medicaid 1115 evaluation design plan that includes (for example):

• Analysis of claims, encounter, and public health data to measure changes in:
o Rates of Medicaid overdose episodes or deaths
o Access to SUD services, including MAT
o Hospital emergency department and inpatient services
o Service utilization for SUD and/or mental health treatment across the continuum of care
o Readmission rates for SUD residential and hospital inpatient services

- Development and use of protocols for assessing and reporting on provider/service capacity in order to:
  - Identify high need treatment areas and service gaps
  - Understand barriers to enrollment as an SUD residential treatment provider
  - Encourage MCOs’ use of value-based payment approaches to incentivize provider enrollment and performance

- Design and implementation of data approaches to promote collaboration across systems and levels of care

**Evaluation Indicators**
Delaware will use core quality metrics to evaluate the success of this demonstration. In addition, Delaware will work collaboratively with the provider network and MCOs to prioritize and determine the feasibility of requiring additional performance measures listed in Table 2 of SMD # 17-003 - Strategies to Address the Opioid Epidemic.

**Section VI – Waiver and Expenditure Authorities**

**Delaware requests the following Expenditure Authority:**

Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an IMD.
Section VII – Impact on Expenditures, Enrollment and Budget Neutrality

This amendment would permit Delaware to continue covering SUD treatment services for members in IMDs generally consistent with historical policy of permitting DSHP MCOs to pay for IMD services as a cost-effective alternative setting. The enrollment and expenditures through 2018 reflect the program as currently approved because the SUD amendment is not expected to have a material impact on Medicaid expenditures, enrollment or the current DSHP Waiver budget neutrality.

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Section VIII – Public Notice

1. Delaware provided an open comment period from May 1 through May 30, 2018 on the draft amendment application.

2. Delaware published a Notice of Public Comment in the Delaware Register of Regulations on May 1, 2018, and in the Delaware News Journal and the Delaware State News on April 24, 2018. The publication in the Delaware Register can be found at: http://regulations.delaware.gov/register/may2018/

3. A draft of this Section 1115 Demonstration Waiver amendment application was posted on the Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) website on May 1, 2018 at: http://dhss.delaware.gov/dhss/dmma/medicaid.html

4. Delaware presented to the Medical Care Advisory Committee on May 23, 2018.

5. Delaware conducted three public hearings on this Section 1115 Demonstration Waiver amendment. Individuals were also invited to attend via teleconference. The information for these hearings is as follows:

   a. SUSSEX COUNTY

   Date: May 9, 2018
   Time: 10:00 AM – 11:00 AM
   Location: Thurman Adams State Svc Center
             546 S. Bedford St.
             Georgetown, DE 19947
6. Delaware used an electronic mailing list to notify the public.

7. Hardcopies of the public notice and draft waiver amendment were available by contacting Nicole Cunningham at the address below. Comments and input were also to be submitted in the following ways:

   By email: Nicole.M.Cunningham@state.de.us
   By fax: 302-255-4413 to the attention of Nicole Cunningham
   By mail: Nicole Cunningham
   Division of Medicaid and Medical Assistance
   Planning, Policy & Quality Unit
   1901 North DuPont Highway
   P.O. Box 906
   New Castle, Delaware 19720-0906

8. Delaware received two written comments, both in support of the draft amendment. Delaware also received support for the amendment at the May 23rd MCAC meeting.

Section IX – Demonstration Administration

Name and Title: Glyne Williams, Chief of Policy, Planning, and Quality, DMMA
Telephone Number: (302) 255-9628
Email Address: Glyne.Williams@state.de.us
State of Delaware:

County of Kent:

Before me, a Notary Public, for the County and State aforesaid, Edward Duliu, known to me to be such, who being sworn according to law deposes and says that he is President of Independent Newsmedia Inc. USA, the publisher of the Delaware State News, a daily newspaper published at Dover, County of Kent, and State of Delaware, and that the notice, a copy of which is hereto attached, as published in the Delaware State News in its issue of April 24, 2018.

President
Independent Newsmedia Inc. USA

Sworn to and subscribed before me this 24th Day of April A.D. 2018

Notary Public
STATE OF DELAWARE
PUBLIC NOTICE
DELWARE HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

DELWARE DIAMOND STATE HEALTH PLAN
1115 DEMONSTRATION WAIVER AMENDMENT AND EXTENSION REQUESTS

In compliance with the State’s Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 31 of the Delaware Code, the Division of Medicaid and Medical Assistance (DHSS/DMMA) is submitting a request to the Centers for Medicare and Medicaid Services (CMS) to amend Delaware’s Section 1115 Demonstration Waver which addresses Medicaid coverage of Substance Use Disorder (SUD) services and treatment.

The DHSS/DMMA is requesting the following changes to the current 1115 Demonstration Waiver:

- **Section 3.2.1**: Change to allow for the extension of the demonstration for an additional year.
- **Section 3.2.2**: Change to allow for the inclusion of necessary treatment for mental health conditions.
- **Section 3.2.3**: Change to allow for the inclusion of additional services for individuals with co-occurring disorders.

The DHSS/DMMA requests approval of these changes to better serve the needs of Delaware’s population and to improve access to quality SUD services.

The public is invited to comment on these proposed amendments. Comments must be received by 4:30 PM on May 30, 2018.

Comments may be submitted in the following ways:
- By email: Nicole.Cunningham@state.de.us
- By phone: (302) 255-4413
- By mail: Nicole Cunningham, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, R.D. Box 966, New Castle, Delaware 19720-0965

Public hearings will be held on May 15, 2018, at the Department of Health and Social Services Building, Conference Room A, 770 Market Street, Dover, DE 19901. The public is invited to attend the public hearing and to submit written comments in writing to Nicole Cunningham at the address above.

The proposed amendments will be effective upon approval by CMS and will be posted on the DHSS/DMMA website at: https://dhss.delaware.gov/dhss/dmma/.
State of Delaware
New Castle County

Personally appeared The News Journal

Of the The News Journal Media Group, a newspaper printed, published and circulated in the State of Delaware, who being duly sworn, deposes and saith that the advertisement of which the annexed is a true copy, has been published in the said newspaper 1 times, once in each issue as follows:

04/24/18 A.D 2018

Sworn and subscribed before me, this 24 day of April, 2018

Legal notification printed at larger size for affidavit.
STATE OF DELAWARE
PUBLIC NOTICE
DELWARE HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

DELAWARE DIAMOND STATE HEALTH PLAN
1115 DEMONSTRATION WAIVER AMENDMENT AND EXTENSION REQUESTS

In compliance with the State’s Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 31 of the Delaware Code, Chapter 9, Section 512, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) intends to submit a request to the Centers for Medicare and Medicaid Services (CMS) to immediately amend Delaware’s Section 1115 Demonstration Waiver to address Medicaid coverage of substance use disorder (SUD) treatment services when provided in a setting that qualifies as an institution for mental diseases (IMD).

In compliance with federal public notice requirements of 42 U.S.C. §13215(d) and 42 CFRPart 431, Subpart B, as well as the State’s Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), and under the authority of Title 31 of the Delaware Code, Chapter 9, Section 512, DHSS/DMMA also gives notice of its intent to file an application with CMS to request a five-year extension of the DHSP1115 Demonstration Waiver, which is currently approved through December 31, 2018. The requested extension period is from January 1, 2019 through December 31, 2023. DHSS/DMMA is not currently requesting any changes to the DHSP 1115 Demonstration Waiver for the extension period, with the exception of the amendment described below.

Purpose
The purpose of this posting is to: (1) provide public notice and receive input for consideration regarding Delaware’s DHSP waiver amendment for SUD treatment services and (2) provide public notice and receive public input for consideration regarding Delaware’s DHSP 1115 Waiver five-year extension request. Delaware is proposing an amendment and an extension that will be submitted to CMS at the same time.

Proposed Amendment: Overview and Summary of Proposed 1115 DHSP Waiver Amendment for SUD Services in IMDS

Federal Medicaid rules generally prohibit Medicaid coverage of services for individuals ages 21-64 provided in settings that qualify as IMDS. However, Delaware’s Medicaid managed care program has had a long-standing exception to these rules due to separate policies that govern Medicaid managed care contracts and payment rates, known as Medicaid-in-kind or Miki services. These policies allowed Delaware to provide coverage in settings that qualify as IMDS if an SUD is a cost-effective alternative setting to an allowable Medicaid state plan setting. In 2016, CMS revised the managed care regulations to limit such IMDS stay to no more than 15 days in a month. In recognition of the national opioid SUD epidemic and the need for potentially longer, medically necessary residential treatment stays as part of a comprehensive continuum of care for SUD, CMS is now offering states the opportunity to apply for and receive 1115 waiver authority to include IMDS settings as Medicaid-covered settings for SUD treatment.

If Delaware does not amend the 1115 waiver, Medicaid funding will no longer be available for SUD services provided in settings that qualify as IMDS. This amendment is needed to avoid unnecessarily disrupting Delaware’s substance use continuum of care during the addiction epidemic in Delaware. This amendment will also remove federal Medicaid payment barriers for SUD treatment in IMD settings, regardless of whether the SUD treatment services are delivered through managed care or fee-for-service.

Proposed Extension: Overview and Summary of Proposed DHSP 1115 Waiver Extension

DSHP 1115 Waiver Program Description, Goals and Objectives
Delaware’s DHSP 1115 Demonstration Waiver was initially approved in 1995, and implemented on January 1, 1996. The original goal of the DHSP 1115 Waiver 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.
In order to achieve this goal, the DSHP 1115 Waiver was designed to mandatorily enroll eligible Medicaid recipients into managed care organizations (MCOs) and create efficiencies in the Medicaid program. Initial savings achieved under managed care enabled the expansion of coverage to certain individuals who would otherwise not be eligible for Medicaid, leading up to Medicaid expansion under the Affordable Care Act in 2014. Since 2012, the DSHP 1115 Waiver provides long-term services and support (LTSS) to eligible individuals through DSHP Plus, as well as enhanced behavioral health services and supports for targeted Medicaid beneficiaries through a voluntary program begun in 2015 called Promoting Optimal Mental Health for Individuals Through Support and Empowerment (PROMISE). Most individuals enrolled in the DSHP 1115 Waiver and in MCOs. A limited number of benefits, such as children’s dental and non-emergency transportation, are delivered through fee-for-service. PROMISE benefits are delivered through the fee-for-service PROMISE program administered through the Division of Substance Abuse and Mental Health (DSAMH). A complete description of the current DSHP 1115 Waiver is available at:

http://dhss.delaware.gov/dhss/ddm/medicaid.html

Delaware’s goal today in operating the DSHP 1115 Waiver demonstration is 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 choice;
- 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;
- Expanding coverage to additional low-income Delawareans; and
- Improving overall health status and quality of life of individuals enrolled in PROMISE.

Delaware will continue working towards this goal to improve the health status of low-income Delawareans during the DSHP 1115 Waiver extension. Delaware is not requesting any changes to the DSHP 1115 Demonstration Waiver for the extension period, with the exception of the amendment for SUD services. During the extension, DHSS/DDMA continues to plan and prepare for the future of healthcare in Delaware, including the roles of Medicaid and the Children’s Health Insurance Program (CHIP).

Public Comment Submission Process

As required by 42 CFR Part 441.304, DHSS/DDMA must establish and use a public input process for any changes in the services or operation of the waiver. Per Del Code, Title 29, Ch. 101 §10118(a), the opportunity for public comment shall be held open for a minimum of 30 days after the proposal is published in the Register of Regulations, scheduled for May 1, 2018. The public is invited to review and comment on the proposed amendment for SUD treatment services. Comments must be received by 4:30 p.m. on May 30, 2018 and may be submitted as described below.

As required by 42 CFR Part 431, Subpart G, DHSS/DDMA must provide opportunity for public comment on the DSHP 1115 Waiver extension request. Per Del Code, Title 29, Ch. 101 §10119(a), the opportunity for public comment shall be held open for a minimum of 30 days after the proposal is published in the Register of Regulations, scheduled for May 1, 2018.

The public is invited to review and comment on the proposed DSHP 1115 Waiver extension and amendment as of the date of publication of this public notice. Comments must be received by 4:30 p.m. on May 30, 2018.

Comments on the amendment and the extension may be submitted in the following ways:
This public notice and copies of the draft amendment and extension applications are posted on the DHSS/DMMA website at:

http://dhss.delaware.gov/dhss/dmma/medicaid.html...

Comments and input may be submitted in the following ways:

By email: Nicole.M.Cunningham@state.de.us
By fax: 302-255-4413 to the attention of Nicole Cunningham
By mail: Nicole Cunningham
Division of Medicaid and Medical Assistance
Planning, Policy & Quality Unit
1901 North DuPont Highway
P.O. Box 906
New Castle, Delaware 19720-0906

Hardcopies of the public notice may also be obtained by contacting Nicole Cunningham at the address above.

Public Hearings

DHSS/DMMA will hold three public hearings with opportunity for public comment, as listed below:

1. NEW CASTLE COUNTY
   Date: May 11, 2018
   TIME: 3:00 PM to 4:00 PM
   LOCATION: DDSS Fox Run Center
              Suite 200
              2540 Wrangle Hill Road
              Bear, DE 19701

2. KENT COUNTY
   Date: May 9, 2018
   TIME: 1:30 PM to 2:30 PM
   LOCATION: Thomas Collins Building
              546 S. DuPont HWY
              Dover, DE 19901

SUSSEX COUNTY
   Date: May 9, 2018
   TIME: 10:00 AM to 11:00 AM
   LOCATION: Thurman Adams State Svc Center
              546 S. Bedford St.
              Georgetown, DE 19947

If you are unable to attend the public hearing in person, you may participate by teleconference. To participate via teleconference, on the date and time of the public hearing, call 1-800-351-2545 and enter passcode 46150993.

Any public feedback received will be summarized including any changes that will be made as a result of the public comment to the proposed 1115 DSHP Waiver Extension that will be submitted to CMS.

If you require special assistance or auxiliary aids and/or services to participate in the public hearing (e.g., sign language or wheelchair accessibility), please call the following contact at least ten (10) days prior to the hearing for arrangements:

Lauren Gunton at (302) 255-9561

The prompt submission of requests helps to ensure the availability of qualified individuals and appropriate accommodations in advance.

Stephen M. Groff
Director
Division of Medicaid and Medical Assistance

4/18/2018

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In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) intends to submit a request to the Centers for Medicare and Medicaid Services (CMS) to immediately amend Delaware's Section 1115 Diamond State Health Plan (DSHP) Demonstration Waiver to address Medicaid coverage of substance use disorder (SUD) treatment services when provided in a setting that qualifies as an institution for mental diseases (IMD).

In compliance with federal public notice requirements of 42 U.S.C. §1315(d) and 42 CFR Part 431, Subpart G, as well as the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, DHSS / DMMA also gives notice of its intent to file an application with CMS to request a five year extension of the DSHP 1115 Demonstration Waiver, which is currently approved through December 31, 2018. The requested extension period is from January 1, 2019 through December 31, 2023. DHSS/DMMA is not currently requesting any changes to the DSHP 1115 Demonstration Waiver for the extension period, with the exception of the amendment described below.

**Proposed Amendment: Overview and Summary of Proposed 1115 DSHP Waiver Amendment for SUD Services in IMDs**

Federal Medicaid rules generally prohibit Medicaid coverage of services for individuals ages 21-64 provided in settings that qualify as IMDs. However, Delaware's Medicaid managed care program has had a long-standing exception to these rules due to separate policies that govern Medicaid managed care contracts and payment rates, known as Medicaid "in lieu of" services. These policies allowed Delaware to provide coverage in settings that qualify as IMDs if an IMD is a cost-effective alternative setting to an allowable Medicaid state plan setting. In 2016, CMS revised the managed care regulations to limit such IMD stays to no more than 15 days in a month. In recognition of the national opioid/ SUD epidemic and the need for potentially longer, medically necessary residential treatment stays as part of a comprehensive continuum of care for SUD, CMS is now offering states the opportunity to apply for and receive 1115 waiver authority to include IMD settings as Medicaid-covered settings for SUD treatment.

If Delaware does not amend the 1115 waiver, Medicaid funding will no longer be available for SUD services provided in settings that qualify as IMDs. This amendment is needed to avoid unnecessarily disrupting Delaware's substance use continuum of care during the addiction epidemic in Delaware. This amendment will also remove federal Medicaid payment barriers for SUD treatment in IMD settings, regardless of whether the SUD treatment services are delivered through managed care or fee-for-service.

**Proposed Extension: Overview and Summary of Proposed DSHP 1115 Waiver Extension**

Delaware's DSHP 1115 Demonstration Waiver was initially approved in 1995, and implemented on January 1, 1996. The original goal of DSHP 1115 Waiver 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.

In order to achieve this goal, the DSHP 1115 Waiver was designed to mandatorily enroll eligible Medicaid recipients into managed care organizations (MCOs) and create efficiencies in the Medicaid program. Initial savings achieved under managed care enabled the expansion of coverage to certain individuals who would otherwise not be eligible for Medicaid, leading up to Medicaid expansion under the Affordable Care Act in 2014. Since 2012, the DSHP 1115 Waiver provides long-term services and supports (LTSS) to eligible individuals through DSHP Plus, as well as enhanced behavioral health services and supports for targeted Medicaid beneficiaries through a voluntary program begun in 2015 called Promoting Optimal Mental Health for Individuals through Supports and Empowerment (PROMISE).
A complete description of the current DSHP 1115 Waiver is available at:
http://dhss.delaware.gov/dhss/dmma/medicaid.html

Delaware's goal today in operating the DSHP 1115 Waiver demonstration is 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 home and community based services (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;
- Expanding coverage to additional low-income Delawareans;
- Improving overall health status and quality of life of individuals enrolled in PROMISE; and
- Increasing and strengthening overall coverage of former foster care youth to improve health outcomes for this population.

Delaware will continue working to improve the health status of low-income Delawareans during the DSHP 1115 Waiver extension. During the extension, DHSS/DMMI continues to plan and prepare for the future of healthcare in Delaware, including the roles of Medicaid and the Children’s Health Insurance Program (CHIP).

**DSHP 1115 Waiver Eligibility**

No changes to the DSHP 1115 Waiver eligibility are proposed for the extension period. Most eligibility groups in the DSHP 1115 Waiver are approved in the Medicaid and CHIP State Plan. The 1115 Waiver extends eligibility to additional groups as necessary for their receipt of LTSS through DSHP Plus and behavioral health services through PROMISE. These groups are described in detail as "Demonstration Population Expenditures" in the current approved 1115 Waiver. A waiver amendment was recently approved to add coverage for out-of-state former foster care youth.

**DSHP 1115 Waiver Benefits**

No changes are proposed to the DSHP 1115 Waiver benefits for the extension period. Individuals enrolled in the DSHP 1115 Waiver receive most Medicaid and CHIP State Plan benefits through the DSHP 1115 Waiver delivery system (described below). Individuals eligible for DSHP Plus receive comprehensive, integrated LTSS and individuals eligible for PROMISE services receive an enhanced package of behavioral health services.

**DSHP 1115 Waiver Delivery System**

No changes are currently proposed to the DSHP 1115 waiver delivery system for the extension period. The delivery system for DSHP and DSHP-Plus benefits during the extension period will continue to be mandatory enrollment in MCOs. A limited number of benefits, such as children’s dental and non-emergency transportation, are delivered through fee-for-service. PROMISE benefits will continue to be delivered through the fee-for-service PROMISE program administered through the Division of Substance Abuse and Mental Health (DSAMH). A waiver amendment was recently approved to include DDDS Lifespan Waiver enrollees in MCOs. The SUD amendment proposes to include IMDs as allowable settings for SUD treatment in managed care and fee-for-service.

**DSHP Cost Sharing**

No changes to cost sharing are proposed for the extension period. Cost-sharing will not differ from the approved Medicaid and CHIP State Plans.

**DSHP Waiver Hypotheses and Evaluation**

Once the SUD amendment has been approved by CMS, those hypotheses and evaluation plans will be incorporated into the extension period. The SUD amendment proposes to test whether Delaware 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. Delaware expects to evaluate whether the SUD amendment:
- Increases enrollee access to and utilization of appropriate SUD treatment services based on the American Society of Addiction Medicine (ASAM) Criteria;
- Decreases the use of medically inappropriate and avoidable high-cost emergency department and hospital services by enrollees with SUD;
• Increases initiation of follow-up after discharge from emergency department for alcohol or other drug dependence; and
• Reduces readmission rates for SUD treatment.
Details on the SUD amendment can be found in the draft application for public comment.
No other changes to the DSHP 1115 waiver proposed hypotheses and evaluation parameters are planned for the extension period. Delaware’s proposed hypotheses and evaluation approach is in its draft Waiver Evaluation Plan pending before CMS. Delaware has proposed various methodologies to evaluate the impact of the 1115 Waiver on access to care, quality of care, cost-containment/cost-effectiveness, and the impact of rebalancing LTC in favor of HCBS. For example, Delaware has proposed to evaluate the following questions:

**Access to Care**
- Is access to primary care providers sufficient?
- Has access to specialists increased under the 1115 Waiver?
- Is access to HCBS providers sufficient in the community?
- Are the members satisfied with the services received under DSHP Plus?
- Has there been a shift in where services are being received from Nursing Home to community based care?
- What is the Nursing Home admission rate in the DSHP Plus population?
- What is the Nursing Home discharge rate (other than death) in the DSHP Plus population?

**Quality of Care**
- Has the health status of waiver enrollees improved?
- Has the quality of care improved for select performance measures?
- What is the level of enrollee satisfaction with MCOs?

**Cost Containment/Cost Effectiveness**
- Are actual expenditures less than the per member per month projections for the 1115 waiver?
- Did emergency room care utilization and expenditures decrease for select populations?
- Is there a decrease in nursing home utilization?

The proposed evaluation will use data from a variety of sources as follows:
- Provider Satisfaction Surveys
- Member Satisfaction Survey
- MCO member surveys
- External Quality Review Reports
- Enrollment files and reports.
- Fee-for-service claims and encounter data as applicable.
- Data submitted to the State for review such as contracts, quality management plans; select utilization reports.

An interim evaluation report will be submitted to CMS on ten of the eleven goals in place during the most recent waiver period. (The eleventh goal related to foster-care youth is too new to evaluate.) Overall, this interim evaluation concludes that Delaware has been successful in meeting the DSHP Waiver’s goals, but additional efforts may be needed with respect to PROMISE behavioral health services and improving coordination for full-benefit dual eligibles. A summary of this interim evaluation is included in the draft application for public comment.

**Waiver and Expenditure Authorities**
Expenditure authority for the proposed SUD amendment is the only change proposed for the extension period. No other changes to the DSHP 1115 waiver and expenditure authorities are proposed for the extension period. DHSS/DMMA is requesting the same waiver and expenditure authorities as approved in the current DSHP 1115 Waiver. These include:

**Waiver authorities:**
1. **Amount, duration and scope of services (Section 1902(a)(10)(B) and 1902(a)(17)).** To permit benefit packages for DSHP and DSHP Plus enrollees that vary from the State Plan and permit the provision of additional benefits under DSHP Plus and PROMISE.
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 permit mandatory enrollment in MCOs and selective contracting for certain HCBS and transportation providers.

4. Retroactive Eligibility Section 1902(a)(34): To permit 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 workers with disabilities who buy-in for Medicaid coverage.

Current Expenditure authorities:
Expenditures for the following 1115 Demonstration Populations receiving LTSS or PROMISE services:

1. 217-Like Elderly and Disabled Home and Community Based Services (HCBS) Group
2. 217-Like HIV/AIDS HCBS Group
3. "At-risk" for Nursing Facility Group
4. TEFRA-Like Group
5. Continuing Receipt of Nursing Facility Care Group
6. Continuing Receipt of Home and Community-Based Services Group
8. PROMISE Services Group

SUD Expenditure authority requested for amendment and extension periods:
Expenditures for otherwise covered services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an IMD.

DSHP 1115 Waiver Estimate of Expected Increase/Decrease in Annual Enrollment and Annual Aggregate Expenditures
The expected increase in enrollment and expenditures through the extension period reflect the program as currently approved. The estimated enrollment and expenditures for 2018-2023 also reflect the proposed SUD amendment. The SUD amendment is not expected to have a material impact on Medicaid expenditures. No other changes are currently proposed for the extension period.

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<tr>
<th>Historical Data (Current Waiver Period)</th>
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<tbody>
<tr>
<td>2014</td>
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<tr>
<td>Enrollment</td>
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<td>Expenditures</td>
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<th>Demonstration Extension Period</th>
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<tr>
<td>2019</td>
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Public Comment Submission Process
As required by 42 CFR Part 441.304, DHSS/DMMA must establish and use a public input process for any changes in the services or operation of the waiver. Per Del. Code, Title 29, Ch. 101 §10118 (a), The opportunity for public comment shall be held open for a minimum of 30 days after the proposal is published in the Register of Regulations, scheduled for May 1, 2018. The public is invited to review and comment on the proposed amendment for SUD treatment services. Comments must be received by 4:30 p.m. on May 31, 2018 and may be submitted as described below.

As required by 42 CFR Part 431, Subpart G, DHSS/DMMA must provide opportunity for public comment on the DSHP 1115 Waiver extension request. Per Del. Code, Title 29, Ch. 101 §10118(a), the opportunity for public comment shall be
DSHP 1115 Waiver Amendment Application for Substance Use Disorder Services

held open for a minimum of 30 days after the proposal is published in the Register of Regulations, scheduled for May 1, 2018.

The public is invited to review and comment on the proposed DSHP 1115 Waiver extension and amendment as of the date of publication of this public notice. Comments must be received by 4:30 p.m., on May 31, 2018.

Comments on the amendment and the extension may be submitted in the following ways:

This public notice and copies of the draft amendment and extension applications are posted on the DHSS/DMMA website at: http://dhss.delaware.gov/dhss/dmma/medicaid.html

Comments and input may be submitted in the following ways:

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Hardcopies of the public notice may also be obtained by contacting Nicole Cunningham at the address above. Any public feedback received will be summarized including any changes that will be made as a result of the public comment to the proposed 1115 DSHP Waiver amendment or extension that will be submitted to CMS.

Stephen M. Groff 4/15/2018
Director
Division of Medicaid and Medical Assistance

21 DE Reg. 917 (05/01/18) (Gen. Notice)