

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Medication-Assisted Treatment (MAT)

BEFORE DELAWARE HEALTH AND SOCIAL SERVICES
IN THE MATTER OF)

REVISION OF THE REGULATION)
OF DELAWARE'S)
TITLE XIX MEDICAID STATE PLAN)
Attachment 3.I-A Page 2A, 4-19-B Page 18)

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Title XIX Medicaid State Plan regarding Medication-Assisted Treatment (MAT) *to move coverage of MAT benefit from the optional services sections of the Medicaid State Plan to the mandatory services section of the Medicaid State Plan for categorically needy populations, per federal requirements.* The Department's proceedings to amend its regulations were initiated pursuant to 29 *Del. C.* § 10114 and its authority as prescribed by 31 *Del. C.* § 512.

The Department published its notice of proposed regulation changes pursuant to 29 *Del. C.* § 10115 in the March 2021 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by March 31, 2021 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

Summary of Proposed Changes

Effective for services provided on and after October 1, 2020 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend Attachment 3.I-A Page 2A and Attachment 4-19-B Page 18 of Title XIX Medicaid State Plan regarding Medication-Assisted Treatment (MAT) to move coverage of MAT benefit from the optional services sections of the Medicaid State Plan to the mandatory services section of the Medicaid State Plan for categorically needy populations, per federal requirements.

Background

Section 1006(b) of the SUPPORT Act, signed into law on October 24, 2018, amends section 1902(a)(10)(A) of the Social Security Act (the Act) to require state Medicaid plans to include coverage of MAT for all eligible to enroll in the state plan or waiver of state plan. States are also required to cover counseling services and behavioral therapies associated with provision of the required drug and biological coverage.

States that already use existing Medicaid authorities to cover items and services that will now be covered under the new mandatory MAT benefit, including FDA-approved or licensed drugs and biologicals used for MAT to treat OUD, and associated counseling services and behavioral therapies, are expected to submit a SPA to move their coverage of these items and services to a new page in their Medicaid state plans for the new mandatory benefit at section 1905(a)(29) of the Act. Delaware currently covers Medication-Assisted Treatment (MAT) as an optional benefit and is publishing this regulation so as to move this coverage from an optional benefit to a mandatory benefit.

Upon receipt of the State Health Official dated December 30, 2020, issuing guidance about the requirements of section 1006(b), Delaware submitted a modification request of SPA submission requirements at 42 C.F.R. 430.20 in order to submit a SPA implementing section 1905(a)(29) of the Act by March 31, 2021 that would take effect on October 1, 2020. Pursuant to section 1135(b) of the Act, Delaware requested modification of the public notice time frames set forth at 42 C.F.R. 447.205 in order to obtain an effective date of October 1, 2020.

Statutory Authority

- Section 1905(a)(29) of the Social Security Act
- Section 1006(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act
- Section 1135(b) of the Social Security Act

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 440.386 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, DHSS/DMMA gives public notice and provides an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been received by 4:30 p.m. on March 31, 2021.

Centers for Medicare and Medicaid Services Review and Approval

The provisions of this state plan amendment (SPA) are subject to approval by the Centers for Medicare and Medicaid Services (CMS). The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manuals and Communications Update

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

Fiscal Impact Statement

There is no anticipated fiscal impact as Delaware currently covers Medication-Assisted Treatment (MAT).

Summary of Comments Received with Agency Response and Explanation of Changes

The following summarized comments were received:

Comment: There was one endorsement of the regulation.

Agency Response: DMMA appreciates the support.

DMMA is pleased to provide the opportunity to receive public comments and greatly appreciates the thoughtful input given by:

- Governor's Advisory Council for Exceptional Citizens

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the March 2021 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Medication-Assisted Treatment (MAT) to move coverage of MAT benefit from the optional services sections of the Medicaid State Plan to the mandatory services section of the Medicaid State Plan for categorically needy populations, per federal requirements, is adopted and shall be final effective August 11, 2021.

7/14/2021

Date of Signature

Molly K. Magarik, MS
DHSS Cabinet Secretary

Attachment 3.1-A
Page 2A

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE

AMOUNT, DURATION, AND SCOPE OF MEDICAL
AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

1905(a)(29) Medication-Assisted Treatment (MAT)

i. **General Assurance**

MAT is covered under the Delaware Medicaid state plan for all Medicaid beneficiaries who meet the

medical necessity criteria for receipt of the service for the period beginning October 1, 2020, and ending September 30, 2025.

- ii. Assurances
 - a. The state assures coverage of Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).
 - b. The state assures that Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 C.F.R. Part 8.

- iii. Service Package
The state covers the following counseling services and behavioral health therapies as part of MAT.

Outpatient Addiction Services

MAT may be provided as part of outpatient addiction services which are community-based addiction services not provided in an outpatient hospital setting and include individual-centered activities consistent with the beneficiary's assessed treatment needs with a rehabilitation and recovery focus designed to promote skills for coping with and managing symptoms and behaviors associated with substance use disorders (SUD). These activities are designed to help beneficiaries achieve and maintain recovery from SUDs. Outpatient SUD services include medically necessary care according to assessed needs including the four (4) component activities: (1) Assessment and clinical treatment plan development - The purpose of the assessment is to provide sufficient information for problem identification, SUD treatment or referral for the beneficiary to gain access to other needed Medicaid SUD or mental health services. The treatment plan for Medicaid SUD or mental health services must be patient centered and developed in collaboration with the patient; (2) Skill development for coping with and managing symptoms and behaviors associated with substance use disorders (SUD) such as the participant's perspective and lack of impulse control or signs and symptoms of withdrawal; (3) Counseling to address a beneficiary's major lifestyle, attitudinal, and behavioral problems. Counseling includes highly structured psychosocial therapy to address issues that have the potential to undermine the goals of treatment; (4) Medication Assisted Therapies (MAT), when clinically appropriate and desired by the patient, including the direct administration of medication.

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Outpatient activities are delivered on an individual or group basis in a wide variety of settings including site-based facility, in the community or in the beneficiary's place of residence. These services may be provided on site or on a mobile basis as defined by Delaware Health and Social Services (DHSS) or its designee. The setting will be determined by the goal which is identified to be achieved in the beneficiary's written treatment plan. Outpatient services may be indicated as an initial modality of care for a beneficiary whose severity of illness warrants this level of treatment, or when a beneficiary's progress warrants a less intensive modality of service than they are currently receiving. The intensity of the services will be driven by medical necessity. Medication Assisted Therapies (MAT) should only be utilized when a beneficiary has an established SUD (e.g., opiate or alcohol dependence condition) that is clinically appropriate for MAT.

Provider qualifications: Outpatient addiction services are provided by licensed and unlicensed professional staff, who are at least eighteen (18) years of age with a high school or equivalent diploma, according to their areas of competence as determined by degree, required levels of experience as defined by state law and regulations and approved program guidelines and certifications approved by

DHSS or its designee. All outpatient substance use disorder (SUD) programs are licensed or certified under state law. Licensed practitioners under Delaware state regulation are licensed by Delaware and include Licensed Clinical Social Workers (LCSWs), Licensed Professional Counselors of Mental Health (LPCMH), Licensed Marriage and Family Therapists (LMFTs), nurse practitioners (NPs), advanced practice nurses (APNs), medical doctors (MD and DO), Licensed Chemical Dependency Professionals (LCDPs), and psychologists.

Residential Addiction Services

MAT may be provided as part of residential services which include individual-centered residential services consistent with the beneficiary's assessed treatment needs, with a rehabilitation and recovery focus designed to promote skills for coping with and managing substance use disorder symptoms and behaviors. These services are designed to help beneficiaries achieve changes in their substance use disorder behaviors. Services should address the beneficiary's major lifestyle, attitudinal, and behavioral problems that have the potential to undermine the goals of treatment. Residential SUD services include medically necessary care according to assessed needs including the four (4) component activities: (1) Assessment and clinical treatment plan development – The purpose of the assessment is to provide sufficient information for problem identification, SUD treatment or referral for the beneficiary to gain access to other needed Medicaid SUD or mental health services. The treatment plan for Medicaid SUD or mental health services must be patient-centered and developed in collaboration with the patient; (2) Skill development for coping with and managing symptoms and behaviors associated with substance use disorders (SUD) such as the participant's perspective and lack of impulse control or signs and symptoms of withdrawal; (3) Counseling to address a beneficiary's major lifestyle, attitudinal, and behavioral problems. Counseling includes highly structured psychosocial therapy to address issues that have the potential to undermine the goals of treatment; (4) Medication Assisted Therapies (MAT) when clinically appropriate and desired by the patient, including the direct administration of medication. Residential services are delivered on an individual or group basis in a wide variety of settings including treatment in residential settings of sixteen (16) beds or less designed to help beneficiaries achieve changes in their substance use disorder behaviors.

Provider qualifications: Services are provided by licensed and unlicensed professional staff, who are at least eighteen (18) years of age with a high school or equivalent diploma, according to their areas of competence as determined by degree, required levels of experience as defined by state law and regulations and departmentally approved program guidelines and certifications. All residential programs are licensed or certified under state law per Delaware Administrative Code Title 16.6001. The licensure applies to all programs providing services to beneficiaries in need of programs and

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services for diagnosed substance use and/or mental disorders. The licensure at a minimum requires documentation of all insurance coverage required in regulation; the maximum client capacity requested; and a copy of the agency's Delaware business license and home state license, when applicable. The licensure or certification also requires a description of the services to be provided by the program, including a statement of the program philosophy, goals and objectives, and a description of the methodology for each service element; and organization charts of showing incumbent names, positions, degrees and credentials (e.g., license, certification); all vacant positions; and illustrating direct and indirect reporting and supervisory relationships. Licensed practitioners under Delaware State regulation are licensed by Delaware and include Licensed Clinical Social Workers (LCSWs), Licensed Professional Counselors of Mental Health (LPCMH), Licensed Marriage and Family Therapists (LMFTs), nurse practitioners (NPs); advanced practice nurses (APNs), medical doctors (MD and DO), Licensed Chemical

Dependency Professionals (LCDPs), and psychologists. Any staff who is unlicensed and providing addiction services must be credentialed by DHSS or its designee and/or the credentialing board or, if a Recovery Coach or Credentialed Behavioral Health Technician, be under the supervision of a qualified health professional (QHP) or Clinical Supervisor.

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Attachment 3.1-A
Page 2D

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

iv. Utilization Controls

The state has drug utilization controls in place. (Check each of the following that apply)

- Generic first policy
- X Preferred drug lists
- X Clinical criteria
- X Quantity limits

The state does not have drug utilization controls in place.

v. Limitations

Describe the state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT.

- : BUPRENORPHINE-NALOXONE limited to 2 (tabs or films) per day unless a prior authorization is approved.

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Attachment 4.19-B
Page 18

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: **DELAWARE**
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –
OTHER TYPES OF CARE

Payments for Medication Assisted Treatment

Effective October 1, 2020, the Medicaid agency will continue to pay qualified providers for evaluation and management (E/M) or HCPCS Code as applicable when Medication Assisted Treatment (MAT) is part of a visit.

The reimbursement for the MAT drugs that meet the definition of a covered outpatient drug in section 1927(k) of the Social Security Act will continue to follow the same reimbursement provided in the table on page Attachment 4.19-B Page 14a related to generic and brand drugs.

TN No. SPA
Supersedes
TN No. SPA 13-018

Approval Date

Effective Date **[October 1, 2020]**

25 DE Reg. 184 (08/01/21) (Final)