

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

Drug Utilization Review (DUR)

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 the DUR, specifically, to update provisions included in section 1004 of the SUPPORT Act. The Department's proceedings to amend its regulations were initiated pursuant to 29 Delaware Code Section 10114 and its authority as prescribed by 31 Delaware Code Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 Delaware Code Section 10115 in the December 2019 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 31, 2019 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

Effective for services provided on and after October 1, 2019 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend Section 4.26 of Title XIX Medicaid State Plan regarding the DUR, specifically, to update provisions included in section 1004 of the SUPPORT Act.

Background

All states, with a Medicaid program that include a drug benefit are required to have a Drug Utilization Review (DUR) program. New provisions for the DUR were included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for patients and Communities Act (P.P. 115-271) as requirements of the state plan. States were required to describe how they met the requirements for claim review limitations, programs to monitor antipsychotic medications to children and fraud and abuse identification.

Statutory Authority

- 42 CFR. §456.703
- SUPPORT Act (P.P. 115-271)

Public Notice

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 447.205 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (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 December 31, 2019.

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 associated with this policy change.

Summary of Comments Received with Agency Response and Explanation of Changes

The following summarized comments were received:

Comment: Two commenters expressed support.

Agency Response: DMMA appreciates the support.

Comment: One commenter expressed concern that the proposed regulation could create processes that require increased oversight and prior approvals for initial or continuing prescriptions of buprenorphine.

Agency Response: To address the Opioid Epidemic, in July 2017 Delaware Medicaid removed restrictions, such as prior authorization, from buprenorphine products to ensure access to treatment at point of sale (POS) and Medication-Assisted Treatment (MAT) (methadone, buprenorphine, and extended-release naltrexone drugs). With open access to SUD treatment, Delaware continues to monitor drug use information against predetermined standards.

Comment: One commenter recommended that a board certified physician be appointed to the Drug Utilization Review (DUR) board.

Agency Response: The Drug Utilization Review board consist of three physicians who are licensed and actively practicing in Delaware. The complete board composition can be found at <https://dhss.delaware.gov/dhss/dmma/drugutilizationreviewboard.html>

Comment: Two commenters inquired about the removal of section (d) "Managed Care Organization (MCO) Requirements," which appeared in the version of the regulation published 23 DE Reg. 184 (09/01/19) (Prop.) and was not included in the regulation published in 23 DE Reg. 427 (12/01/19).

Agency Response: The section was removed due to CMS clarification which indicated that specifications regarding MCO SUPPORT Act compliance should not be included on the state FFS plan pharmacy DUR pages.

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

- Christiana Care Health System
- Governor's Advisory Council for Exceptional Citizens (GACEC)
- State Council for Persons with Disabilities (SCPD)

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the December 2019 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding the DUR, specifically, to update provisions included in section 1004 of the SUPPORT Act, is adopted and shall be final effective February 11, 2020.

1/14/2020

Date of Signature

Kara Odom Walker, MD, MPH, MSHS,
Secretary, DHSS

***Please Note: Due to the formatting requirements of the regulation, it is being attached here as a PDF document:**

<http://regulations.delaware.gov/register/february2020/final/DMMA DUR Final.pdf>

23 DE Reg. 657 (02/01/20) (Final)