DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

PROPOSED

PUBLIC NOTICE

Drug Utilization Review (DUR)

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 CFR §447.205, 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) is proposing to amend Title XIX Medicaid State Plan regarding the DUR, specifically, to update provisions included in section 1004 of the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for patients and Communities Act* (P.L. 115-271).

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to, Planning, Policy and Quality Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, by email to Nicole.M.Cunningham@delaware.gov, or by fax to 302-255-4413 by 4:30 p.m. on October 1, 2019. Please identify in the subject line: Drug Utilization Review (DUR)

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend Title XIX Medicaid State Plan regarding the DUR, specifically, to update provisions included in section 1004 of the SUPPORT Act.

Statutory Authority

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

Background

All states with a Medicaid program that includes 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.L. 115-271) as requirements of the state plan.

Summary of Proposal

Summary of Proposed Changes

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 Attachment 3.1-A Page 5 Addendum of Title XIX Medicaid State Plan regarding the DUR, specifically, to update provisions included in section 1004 of the SUPPORT 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 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 must be received by 4:30 p.m. on October 1, 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

There is no anticipated fiscal impact associated with this policy change.

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

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

12.a. Prescribed Drugs Continued:

Drug Utilization Review (DUR) Board

Drug Utilization Review (DUR) Board is comprised of pharmacists, physicians, and community members, appointed by the Secretary, Delaware Health & Social Services. The makeup and membership authority for the DUR Board complies with 42 U.S.C. s1396r-8. The DUR assures that prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results.

The Board assesses data on drug use in accordance with predetermined standards. The predetermined standards shall be:

- monitoring for therapeutic appropriateness
- overutilization and underutilization
- appropriate use of generic products
- therapeutic duplication
- drug-disease contraindications
- drug-drug interactions
- incorrect drug dosage or duration of drug treatment
- clinical efficacy
- safety
- medical necessity
- potential for abuse, misuse and diversion
- experimental use opportunity, and
- cost effectiveness relative to similar therapies

Drug Utilization Review Board makes recommendation for:

1) Status on the Preferred Drug List
2) Guidelines to be used in the determination of medical necessity and clinical appropriateness of prescribed drugs
3) Safety edits including limits on quantity and duration
4) Concurrent utilization alerts
5) Provisions of Section 1004 of the SUPPORT ACT
   a. Claim Review Limitations
      i. Safety Edits Including Early and Duplicate Fill, and Quantity Limits: Long acting opioids are on review for clinical appropriateness. Short acting agents have a maximum of two per day for short acting low potency agents.
      ii. Maximum Daily Morphine Milligram Equivalents (MME) Safety Edits: A maximum dosing limit on opioids limits the daily morphine milequivalents to 90 or less.
      iii. Concurrent Utilization Alerts: A prospective drug-to-drug interaction alert will require a response from the pharmacy if an opioid and benzodiazepine are being dispensed with an overlapping period. All requests for long acting agents are reviewed for concomitant utilization of a benzodiazepine. Practitioners are asked to create a titration plan for these members. A prospective drug-to-drug interaction for opioid to antipsychotic agents will alert the pharmacist. These claims will require a response before the claim is adjudicated as paid.
   b. Programs to monitor antipsychotic medications to children
      i. Antipsychotic agents are reviewed for age based on the FDA product approval. The Division of Services for Children, Youth, and Families (DSCYF) employs a pharmacist consultant that reviews all foster children

profiles that include behavioral health drugs. DMMA data are provided to the pharmacist for the monthly review and consultation with the prescribing practitioner.

c. Fraud and abuse identification

i. DMMA receive monthly data from the Prescription Monitoring Program. Analysis is done at the prescriber and client level. Additional steps are taken, such as audits or client lock-in to a specific pharmacy, when outliers are identified.

d. Managed Care Organization (MCO) Requirements

i. Effective October 2019, DMMA contracts require MCOs to comply with the drug reviews included in the SUPPORT Act. Our MCO partners are employing the same review processes and limits as our fee-for-service program.

TN No. SPA#	Approval Date _____
Supersedes	
TN No. NEW	Effective Date October 1, 2019