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) - Opioid Provisions

BEFORE DELAWARE HEALTH AND SOCIAL SERVICES
IN THE MATTER OF

	)
REVISION OF THE REGULATION	)
OF DELAWARE'S	)
TITLE XIX MEDICAID STATE PLAN	)
SECTION 4.26	)

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend Title XIX Medicaid State Plan regarding the DUR, specifically, to update policy to comply with the published Final Rule. 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 May 2021 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by June 1, 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

Effective for services provided on and after August 11, 2021, 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 policy to comply with the published Final Rule.

Background

On December 21, 2020, Centers for Medicare & Medicaid Services (CMS) published the final rule Establishing Minimum Standards in Medicaid Drug Utilization Review (DUR) and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate And Third Party Liability Requirements (Rule). This Rule contains opioid-related DUR provisions with which a state must comply and a state must include its compliance plan in the State Plan.

Statutory Authority

42 CFR. § 456.703
42 U.S. Code § 1396a(a)(85)

Purpose

The purpose of this proposed regulation is to update policy to comply with the published Final Rule.

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 June 1, 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.

Summary of Comments Received with Agency Response and Explanation of Changes

No comments were received during the public comment period.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the May 2021 *Register of Regulation*s should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding the DUR, specifically, to update policy to comply with the published Final Rule, is adopted and shall be final effective August 11, 2021.

7/14/2021
Date of Signature

Molly K. Magarik, MS
DHSS Cabinet Secretary

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

ELIGIBILITY CONDITIONS AND REQUIREMENTS

Citation	4.26	Drug Utilization Review Program

1927(g)
42 CFR 456.700

A. (1) The Medicaid agency meets the requirements of Section 1927(g) of the Act for a drug use review (DUR) program for outpatient drug claims.

1927(g)(1)(A)

(2) The DUR program assures that prescriptions for outpatient drugs are:

- Appropriate
- Medically necessary
- Are not likely to result in adverse medical results.

1927(g)(1)(a)
42 CFR 456.705 (b) and 456.709(b)

B. The DUR program is designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs as well as:

- Potential and actual adverse drug reactions
- 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
- Drug-allergy interactions
- Clinical abuse/misuse

1927(g)(1)(B) 42 CFR 456.703 (d) and (f)

C. The DUR program shall assess data use against predetermined standards whose source materials for their development are consistent with peer- reviewed medical literature which has been critically reviewed by unbiased independent experts and the following compendia:

- American Hospital Formulary Service Drug Information
- United States Pharmacopeia-Drug Information
- American Medical Association Drug Evaluations

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

ELIGIBILITY CONDITIONS AND REQUIREMENTS

Citation	4.26	Drug Utilization Review Program

1927(g)(1)(D)
42 CFR 456.703(b)

D. DUR is not required for drugs dispensed to residents of nursing facilities that are in compliance with drug regimen review procedures set forth in 42 CFR 483.60. The State has never-the-less chosen to include nursing home drugs in:

☒ Prospective DUR
☒ Retrospective DUR.

1927(g)(2)(A)
42 CFR 456.705(b)

E. 1. The DUR program includes prospective review of drug therapy at the point of sale or point of distribution before each prescription is filled or delivered to the Medicaid recipient.

1927(g)(2)(A)(i)
42 CFR 456.705 (b), (1)-(7))

2. Prospective DUR includes screening each prescription filled or delivered to an individual receiving benefits for potential drug therapy problems due to:

- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions
- Drug-interactions with non-prescription or over-the-counter drugs
- Incorrect drug dosage or duration of drug treatment
- Drug allergy interactions
- Clinical abuse/misuse

1927(g)(2)(A) (ii)
42 CFR 456.705 (c) and (d)

3. Prospective DUR includes counseling for Medicaid recipients based on standards established by State law and maintenance of patient profiles.

1927(g)(2)(B)
42 CFR 456.709 (a)

F. 1. The DUR program includes retrospective DUR through its mechanized drug claims processing and information retrieval system or otherwise which undertakes ongoing periodic examination of claims data and other records to identify:

- Patterns of fraud and abuse
- Gross overuse
- Inappropriate or medically unnecessary care among physicians, pharmacists, Medicaid recipients, or associated with specific drugs or groups of drugs.

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

ELIGIBILITY CONDITIONS AND REQUIREMENTS

Citation 4.26 Drug Utilization Review Program

927(g)(2)(C)
42 CFR 456.709 (b)

F. 2. The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:

- Therapeutic appropriateness
- overutilization and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage/duration of drug treatment
- Clinical abuse/misuse

1927(g)(2)(D)
42 CFR 456.711

3. The DUR program through its State DUR Board, using data provided by the Board, provides for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems to improve prescribing and dispensing practices.

1927(g)(3)(A)
42 CFR 456.716(a)

G. 1. The DUR program has established a state DUR Board either:

☒ Directly,
☐ or Under contract with a private organization

1927(g)(3)(B)
42 CFR 456.716
(A) and (B)

2. The DUR Board membership includes health professionals (one-third licensed actively practicing pharmacists and one"', third but no more than 51 percent licensed and actively practicing physicians) with knowledge and experience in one or more of the following:

- Clinically appropriate prescribing of covered outpatient drugs.
- Clinically appropriate dispensing and monitoring of covered outpatient drugs .
- Drug use review, evaluation and intervention.
- Medical quality assurance.

927(g)(3)(c)
42 CFR 456.716 (d)

3. The activities of the DUR Board include:

- Retrospective DUR,
- Application of Standards as defined in section 1927(g)(2)(C), and
- Ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR.

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

ELIGIBILITY CONDITIONS AND REQUIREMENTS

Citation	4.26	Drug Utilization Review Program

1927(g)(3)(C)
42 CFR 456.711
(a)-(d)

G. 4. The interventions include in appropriate instances:

- Information dissemination
- Written, oral, and electronic reminders
- Face-to-Face discussions
- Intensified monitoring/review of prescribers/dispensers

1927(g)(3)(D)
CFR 456.712
(A) and (B)

H. The State assures that it will prepare and submit an annual report to the Secretary, which incorporates a report from the State DUR Board, and that the State will adhere to plans, steps, procedures as described in the report.

1927 (h)(1)
42 CFR 456.722

☒ I. 1. The State establishes, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system to perform on-line:

- real time eligibility verification
- claims data capture
- adjudication of claims
- assistance to pharmacists, etc. applying for and receiving payment.

1927(g)(2)(A)(i)
42 CFR 456.705(b)

☒ 2. Prospective DUR is performed using an electronic point-of-sale drug claims processing system.

1927 (j)(2)

J. Hospitals which dispense covered outpatient drugs are exempted from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs.

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

ELIGIBILITY CONDITIONS AND REQUIREMENTS

Citation 4.26 Drug Utilization Review Program

1902(a)(85) K. Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

a. Claim Review Limitations
   i. Prospective Safety Edits on opioids including days' supply, early refills, duplicate fills, and quantity limits for clinical appropriateness.
   ii. Maximum Daily Morphine Milligram Equivalents (MME) Safety Edits: A maximum dosing limit on opioids limits the daily morphine milliequivalent (as recommended by clinical guidelines) and regularly reviewed by the state.
   iii. Concurrent Utilization Alerts: Prospective drug-to-drug interaction alerts require a response from the pharmacy if an opioid and benzodiazepine or opioid and antipsychotic are being dispensed within an overlapping period. Retrospective reviews are performed on an ongoing periodic basis to alert prescribers of these alerts.
   iv. Comprehensive Retrospective DUR is performed on opioid prescriptions on an ongoing periodic basis.

b. Programs to monitor antipsychotic medications to children
   i. Antipsychotic agents are reviewed for age appropriateness, duplicate therapy, and adverse effects in children based on the FDA product approval and clinical guidelines.

c. Fraud and abuse identification
   i. DMMA receives monthly data of recipient prescriptions from the Prescription Monitoring Program for review, analysis and investigation for additional steps to be taken, such as audits or client lock-in to a specific pharmacy, when clinical concerns are established.

d. <u>Other Requirements</u>
   i. <u>Prospective safety edits if an opioid is prescribed after a beneficiary has been prescribed drugs used for Medication Assisted Treatment [within an overlapping period.]</u>
   ii. <u>Allowance of a pharmacist to prescribe naloxone to beneficiaries at high risk of opioid overdose including those prescribed 90 MME or more.</u>