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State Name: Delaware

State Plan Amendment (SPA) #19-006

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

February 6, 2020

Stephen M. Groff, Director
Division of Medicaid and Medical Assistance
Delaware Health and Social Services
P.O. Box 906
New Castle, DE 19720-0906

Dear Mr. Stephen Groff:

We have reviewed Delaware's State Plan Amendment (SPA) 19-0006, Drug utilization Review, received in the Philadelphia Regional Operations Group on December 20, 2019. This SPA proposes to amend the Title XIX Medicaid State Plan regarding DUR provisions included in section 1004 of the SUPPORT for Patients and Communities Act with the effective date of October 1, 2019.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that DE SPA 19-0006 is approved with an effective date of October 1, 2019. If changes are subsequently made to the DUR pages, a new SPA and any required documents should be submitted to CMS for review and authorization.

A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Delaware's state plan will be forwarded by the Philadelphia Regional Operations Group.

If you have any questions regarding this amendment, please contact Whitney Swears at (410) 786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,

[redacted]

John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy

cc: Nicole Cunningham, State Plan Coordinator
Kimberly Xavier, State Senior Policy Administrator
Glyne Williams, State Chief Policy, Planning and Quality
Christiana Ogunremi, State Pharmacy Director
Frances McCullough, CMS, Director, Philadelphia Regional Operations Group
Michael Cleary, CMS, Philadelphia Regional Operations Group

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 19 — 0 0 6

2. STATE: Delaware

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: October 1, 2019

5. TYPE OF PLAN MATERIAL *(Check One)*

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☑ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: Title XIX Medicaid State Plan

7. FEDERAL BUDGET IMPACT
a. FFY 2020 $ 0
b. FFY 2021 $ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Section 4.26

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Section 4.26

10. SUBJECT OF AMENDMENT: Drug Utilization Review (DUR)

11. GOVERNOR'S REVIEW *(Check One)*

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☑ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]

13. TYPED NAME: Stephen M. Groff

14. TITLE: Director

15. DATE SUBMITTED: December 20, 2019

16. RETURN TO: Stephen M. Groff, Director, DMMA, P.O. Box 906 New Castle, DE19720

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: December 20, 2019

18. DATE APPROVED: February 6, 2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: October 1, 2019

20. [redacted]

21. TYPED NAME: James G. Scott

22. TITLE: Director, Division of Program Operations

23. REMARKS

FORM CMS-179 (07/92)

Instructions on Back

Distinction

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.