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State/Territory Name: Maine

State Plan Amendment (SPA) #: 19-021

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

Michelle Probert, Director
MaineCare Services
Maine Department of Health and Human Services
11 State House Station
Augusta, Maine 04333-0011

Dear Ms. Probert:

The CMS Division of Pharmacy team has reviewed Maine State Plan Amendment (SPA) 19-0021 received in the Boston Regional Operations Group on December 27, 2019. This SPA proposes to allow the state to comply with the Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271).

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0021 is approved with an effective date of October 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Maine's state plan will be forwarded by the Boston Regional Operations Group.

If you have any questions regarding this request, please contact Lisa Shochet at (410) 786-5445 or Lisa.Shochet@cms.hhs.gov.

Sincerely,

/s/

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: Thomas Leet, Policy Director, MaineCare Services
James G. Scott, Division Director, CMS Division of Program Operations
Nancy E. Grano, Boston Regional Operations Group
Gilson DaSilva, Boston 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: **19-0021**

2. STATE: **Maine**

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: **10/01/2019**

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

☐ NEW STATE ☐ 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
1902(a)(85) and Section 1004 of the SUPPORT Act

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

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
74, 74(a), 74(b), 74(c), 74(d)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
74, 74(a), 74(b), 74(c)

10. SUBJECT OF AMENDMENT
Clarifying provisions required by 1902(a)(85) and Section 1004 of the SUPPORT Act

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:
Michelle Probert, Director, MaineCare Services

12. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

13. TYPED NAME
Michelle Probert

14. TITLE
Director, MaineCare Services

15. DATE SUBMITTED
12/27/2019

16. RETURN TO:
Michelle Probert
Director, MaineCare Services
#11 State House Station
109 Capitol Street
Augusta, Maine 04333-0011

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED
12/27/2019

18. DATE APPROVED
2/6/2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
10/1/2019

20. SIGNATURE OF REGIONAL OFFICIAL
/s/

21. TYPED NAME
James G. Scott

22. TITLE
Director, Division of Program Operations

23. REMARKS

FORM CMS-179 (07/92)

Instructions on Back

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Revision: HCFA-PM- (MB)

State/Territory: Maine

Citation

1927(g)
42 CFR 456.700

4.26 Drug Utilization Review Program

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:

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

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Revision: HCFA-PM- (MB)

State/Territory: Maine

Citation	
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 483.30. The State has never-the-less chosen to include nursing home drugs in: X Prospective DUR X 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-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: -Patters 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.

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Citation	
1927(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 456.716(a)	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: X 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 processionals (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.
1927(g)(3)(C) 42CFR 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.

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Citation	
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) 42 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 the plans, steps, procedures as described in the report.
1927(h)(1) 42 CFR 456.722	___I.1. The State established, 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) 42 CFR 456.703(c)	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.

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Revision: HCFA-PM- (MB)

State/Territory: Maine

Citation

1902(a)(85) and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)	**Claim Review Limitations** • Prospective safety edits on opioid prescriptions to address days' supply, early refills, duplicate fills and quantity limitations for clinical appropriateness. • Prospective safety edits on maximum daily morphine milligram equivalents (MME) on opioids prescriptions to limit the daily morphine milligram equivalent (as recommended by clinical guidelines). • Retrospective reviews on opioid prescriptions exceeding these above limitations on an ongoing basis. • Retrospective reviews on concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics on an ongoing periodic basis. **Programs to monitor antipsychotic medications to children:** Antipsychotic agents are reviewed for appropriateness for all children including foster children based on approved indications and clinical guidelines. **Fraud and abuse identification:** The DUR program has established a process that identifies potential fraud or abuse of controlled substances by enrolled individuals, health care providers and pharmacies.