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State/Territory Name: Ohio

State Plan Amendment (SPA) #: 19-0027

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

February 6, 2020

Maureen M. Corcoran, State Medicaid Director
Ohio Department of Medicaid
P.O. Box 182709
Columbus, OH 43218

Dear Ms. Corcoran,

The CMS Division of Pharmacy team has reviewed Ohio State Plan Amendment (SPA) 19-0027 received in the Chicago Regional Operations Group on November 25, 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 19-0027 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 Ohio's state plan will be forwarded by the Chicago Regional Operations Group.

If you have any questions regarding this request, please contact Réna McClain at (410) 786-3975 or Rena.McClain1@cms.hhs.gov.

Sincerely,

/s/

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

cc: Carolyn Humphrey, Ohio Medicaid State Plan Team
Rebecca Jackson, Ohio Medicaid State Plan Team
James Scott, Director, Division of Program Operations
Christine Davidson, Division of Program Operations

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	1. TRANSMITTAL NUMBER: **19-027**	2. STATE **OHIO**
	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 01, 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: Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (**P.L 115-271)**	7. FEDERAL BUDGET IMPACT: a. FFY 2020 $ 0 b. FFY 2021 $ 0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Section 4.26, pages 74, 74a, 74b, 74c Section 4.26, page 74d (new)	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Section 4.26, pages 74, 74a, 74b, 74c (TN 93-10)

10. SUBJECT OF AMENDMENT: Drug Utilization Review Provisions in SUPPORT Act of 2019

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:
The State Medicaid Director is the Governor's designee

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO:
13. TYPED NAME: **MAUREEN M. CORCORAN**	**Carolyn Humphrey** **Ohio Department of Medicaid** **P.O. BOX 182709** **Columbus, Ohio 43218**
14. TITLE: **STATE MEDICAID DIRECTOR**	
15. DATE SUBMITTED: Nov. 25, 2019	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: November 25, 2019	18. DATE APPROVED: February 6, 2020
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: October 1, 2019	20. SIGNATURE OF REGIONAL OFFICIAL: [redacted] Digitally signed by James G. Scott -S Date: 2020.02.19 09:44:50 -06'00'
21. TYPED NAME: James G. Scott	22. TITLE: Director, Division of Program Operations

23. REMARKS:

Instructions on Back

FORM CMS-179 (07-92)

State/Territory: OHIO

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)(l)(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 or groups of drugs, as well as: -Potential and actual severe 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 -The DRUGDEX Information System

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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 483.60. 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 -Serious 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.

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Citation		
1927(g)(2)(C) 42 CFR 456.709(b)	F.2.	The DUR program, on an ongoing basis, 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 _X_ 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 expertise 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) 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.

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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, or 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 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 in 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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Citation

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

K.1. Claims Review Limitations

-Day supply limits in the prospective point-of-sale system for new starts on short-acting opioids.
-Morphine Equivalent Dose (MED) limits in the prospective point of sale system.
-Early refill thresholds for opioid prescriptions in the point of sale system that are more restrictive than non-controlled medication refill thresholds.
-Periodic retrospective claims review which monitors for concerning opioid therapy treatment. Interventions applied as deemed appropriate.
-Periodic retrospective claims review which monitors for concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics.
-Duplicate fill safety edits in the point of sale system for opioid prescriptions.

2. Program to Monitor Antipsychotic Medications by Children

-Periodic retrospective claims review which monitors for concerning use of antipsychotic medications in children including foster children.

3. Fraud and Abuse Identification

-Enrollment in the Coordinated Services Program, also known as the Lock-in-Program.
-Periodic retrospective claims review which monitors for potential fraud and abuse of controlled medications by individuals, health care providers and pharmacies. Interventions applied and referrals made as deemed appropriate.