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State Name: Virginia

State Plan Amendment (SPA) #: 19-017

This file contains the following documents in the order listed:

1) Approval Letter
2) CMS-179
3) Approved SPA Pages

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

March 4, 2020

Ms. Karen Kimsey, Director
Department of Medical Assistance Services
600 East Broad Street, #1300
Richmond, Virginia 23219

Dear Ms. Kimsey:

The CMS Division of Pharmacy team has reviewed Virginia's State Plan Amendment (SPA) 19-0017 received in the Philadelphia Regional Operations Group on December 17, 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 19-0017 is approved with an effective date of December 31, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Commonwealth of Virginia'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,

/s/

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

cc: Emily McClellan, Virginia Regulatory Supervisor
Donna Proffitt, Virginia Pharmacy Director
Nicole McKnight, CMS Division of Program Operations Branch East Manager
Margaret Kosherzenko, CMS Division of Program Operations - East Branch

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: 19-017

2. STATE: Virginia

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: 12/31/2019

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: 42 CFR 456

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

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Revised pages 74. 74a, 74b, 74c, 74d
New pages 74e, 74f

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Same as box 8.

10. SUBJECT OF AMENDMENT
Revisions to Drug Utilization Review Program

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
Secretary of Health and Human Resources

12. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted] /S/

13. TYPED NAME: Karen Kimsey

14. TITLE: Director

15. DATE SUBMITTED: 12-6-19

16. RETURN TO
Dept. of Medical Assistance Services
600 East Broad Street, #1300
Richmond VA 23219

Attn: Regulatory Coordinator

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: December 17, 2019

18. DATE APPROVED: March 4, 2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: December 31, 2019

20. SIGNATURE OF REGIONAL OFFICIAL
/S/ [redacted]
Digitally signed by James G. Scott -S
Date: 2020.03.16 16:28:27 -05'00'

21. TYPED NAME: James G. Scott

22. TITLE: Director, Division of Program Operations

23. REMARKS

FORM CMS-179 (07/92)

Instructions on Back

Save

Revision: HCFA-PM-93-3 (MB)
March, 1992

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State of VIRGINIA

Citation

4.26 Drug Utilization Review Program

1927(g) (a) (1) The Medicaid agency meets the requirements of
42 CFR 456.700 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

(b) The DUR program is designed to educate physicians and pharmacists to identify and to 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
- Over-utilization 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
- Provisions of Section 1004 of the SUPPORT ACT (below)

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

SUPPORT ACT Provisions

a. Claim Review Limitations

i. Prospective safety edits including early, duplicate fill, and quantity limits for clinical appropriateness for opioids.

ii. Maximum daily Morphine Milligram Equivalents (MME) safety edits: A maximum dosing limit on opioids limits the daily morphine milliequivalents (as recommended by clinical guidelines)

iii. Concurrent Utilization Alerts: Prospective drug-to-drug interaction alerts will require a response from the pharmacy if an opioid and benzodiazepine or opioid and antipsychotics are being dispensed within an overlapping period with retrospective reviews performed on an ongoing periodic basis.

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. The Client Medical Management (CMM) program for fee-for-service (FFS) beneficiaries that may require restriction to physician, pharmacy or both limiting the beneficiary's access to services identified as not medically necessary, excessive or both. The beneficiary's designated physician is responsible for supervising, coordinating, and providing initial and primary medical care; initiating written referrals for specialist care and for maintaining the continuity of patient care.

1927(g)(1)(B)
42 CFR 456.703

(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
MICROMEDICS (as updated monthly)
Drug Facts and Comparisons (as updated monthly)
Drug Information Handbook (2003, 2004 as amended)

1927(g)(1)(D)

(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)(i)

(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.

Citation		
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 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.
		(4) Prospective DUR may also include electronic messages as well as rejection of claims at point-of-sale pending appropriate designated interventions by the dispensing pharmacist or prescribing physician.
		(5) Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.
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.

Citation

1927(g)(2)(C)
42 CFR
456.709(b)

(2) The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:
- Therapeutic appropriateness
- Over-utilization and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug disease contraindications
- Drug-drug interactions
- Incorrect 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 and pharmacists on common drug therapy problems to improve prescribing and dispensing practices.

(4) In situations of conflict with these criteria, DMAS, pursuant to the DUR Board's criteria and requirements, shall reject or deny presented claims and require the dispensing pharmacist to intervene as specified through electronic messages in the point-of-sale system before the claim will be approved for payment2

(5) Designated interventions may include provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers

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

(g) (1) The DUR program has established a State DUR Board either:

☒ Directly

☐ Contract with a private organization

Citation		
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.
1927(g)(3)(C) 42 CFR 456.716(d)		(3) The activities of the DUR Board include: - Prospective DUR - Retrospective DUR - Application of Standards as defined in §1927(g)(2)(C), and - Ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR
1927(g)(3)(C) 42 CFR 456.711 (a)-(d)		(4) The interventions include in appropriate instances: - Information dissemination - Written, oral, and electronic reminders - Face-to-Face and telephonic discussions - Intensified monitoring/review of prescribers/dispensers - Rejected or denied claims, as appropriate, to prevent the violation of the DUR Board's predetermined criteria - Provider override, obtaining prior authorization via communication to a call center staffed with appropriate clinicians, or written communication to prescribers.
1927(g)(3)(D) 42 CFR 456.712	(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, and procedures as described in the report.

Citation		
		The Medicaid agency ensures that predetermined criteria and standards have been recommended by the DUR Board and approved by either BMAS or the director, acting on behalf of the BMAS, . pursuant to Virginia Code § 32.1-324 and that they are based upon documentary evidence of the DUR Board. The activities of the DUR Board and the Medicaid fraud control programs are and shall be . maintained as separate. The DUR Board shall refer suspected cases of fraud or abuse to the appropriate fraud and abuse control unit with the Medicaid agency.
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 online: - real time eligibility verification - claims data capture - adjudication of claims. Such adjudication may include the rejection or denial of claims found to be in conflict with DUR criteria. Should such rejection or denial occur during the adjudication process, the dispensing pharmacist shall have the opportunity to resolve the conflict and re-submit the claim for re-adjudication. - Assistance to pharmacists, etc., applying for and - receiving payment
Citation		
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 pursuant to federal law 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.