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State/Territory Name: Virginia

State Plan Amendment (SPA)#: 21-0014

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179 Form
- 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

August 18, 2021

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

Dear Ms. Kimsey,

The CMS Division of Pharmacy team has reviewed Virginia's State Plan Amendment (SPA) 21-0014 received in the CMS Medicaid & CHIP Operations Group on June 14, 2021. This SPA proposes to allow for 12-Month Contraception Dispensing and Participation in the National Medicaid Pooling Initiative (NMPI).

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that VA-21-0014 is approved with an effective date of July 1, 2021. We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into Virginia's state plan.

If you have any questions regarding this request, please contact Michael Forman at 410-786-2666 or michael.forman@cms.hhs.gov.

Sincerely,

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

Cc: Daniel Carey, MD, Virginia Secretary of Health and Human Services
Emily McClellan, Virginia Department of Medical Assistance Services
Mary Ann McNeil, Virginia Department of Medical Assistance Services
Janetta Emmelhainz, Virginia Department of Medical Assistance Services
Margaret H. Kosherzenko, CMS, Medicaid & CHIP Operations Group

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER
2 1 — 0 1 4

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
7/1/2021

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 440

7. FEDERAL BUDGET IMPACT

a. FFY 2021 \$ 332,324
b. FFY 2022 \$ (6,375,320)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1A&B Supplement 1, pages 20, 21, and 22

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Same as box #8.

10. SUBJECT OF AMENDMENT

12-Month Contraception and Participation in the National Rebate Pool

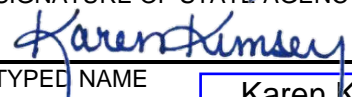
11. GOVERNOR'S REVIEW (Check One)

- GOVERNOR'S OFFICE REPORTED NO COMMENT
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED

Secretary of Health and Human Resources

12. SIGNATURE OF STATE AGENCY OFFICIAL



13. TYPED NAME

Karen Kimsey

14. TITLE

Director

15. DATE SUBMITTED

6/14/2021

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

June 14, 2021

18. DATE APPROVED

August 18, 2021

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

July 1, 2021

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

John M. Coster, Ph.D., R.Ph

22. TITLE

Director, Division of Pharmacy

23. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

**AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED TO THE CATEGORICALLY NEEDY and MEDICALLY NEEDY**

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of §1927 of the Social Security Act (OBRA '90 §4401), shall not be covered.
2. Non-legend drugs shall be covered by Medicaid in the following situations:
 - a. Insulin, syringes, and needles for diabetic patients;
 - b. Diabetic test strips for Medicaid recipients under 21 years of age;
 - c. Family planning supplies;
 - d. Designated categories of non-legend drugs for Medicaid recipients in nursing homes;
 - e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs.
3. Contraceptives may be covered for up to a 12-month supply.
4. Select maintenance legend and non-legend drugs may be covered for a maximum of a 90-day supply per prescription per patient after two 34-day or shorter duration fills. The drugs or classes of drugs identified in Supplement 5 to Attachment 3.1 A&B and all other covered drugs are covered for a maximum of a 34-day supply per prescription. FDA- approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with the Department of Medical Assistance Services' medical necessity requirements, by the treating physician.
5. Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioner so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written or unless the drug class is subject to the Preferred Drug List.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

**AMOUNT, DURATION, AND SCOPE OF MEDICAL
AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY
and MEDICALLY NEEDY**

- 6. New drugs shall be covered pursuant to the Social Security Act of §1927(d) (OBRA '90 §4401).
- 7. The number of refills shall be limited pursuant to the Drug Control Act, Code of Virginia Title 54.1, §54.1-3411.
- 8. Drug Prior Authorization.
 - a. Definitions. The following words and terms, when used in these regulations, shall have the following meaning, unless the context clearly indicates otherwise:

“Clinical data” means drug monographs as well as any pertinent clinical studies, including peer review literature.

“Complex drug regimen” means treatment or course of therapy that typically includes multiple medications, co-morbidities and or caregivers.

“Department” means the Department of Medical Assistance Services.

“Drug” shall have the same meaning, unless the context otherwise dictates or the Board otherwise provides by regulation, as provided in the Drug Control Act (§54.1-3400 et seq.).

“Drug Utilization Review” means the process for the retrospective and prospective review and approval of drug use based on criteria and standards employed by the agency to evaluate the medical necessity of reimbursing for covered outpatient drugs.

“Emergency supply” means 72-hour supplies of the prescribed medication that is dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist, including after hours, weekends, holidays and the pharmacist, in his professional judgment consistent with current standards of practice, feels that the patient’s health would be compromised without the benefit of the drug, or other criteria defined by the P & T Committee and DMAS.

“Non-preferred drugs” means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs may be prescribed but require prior authorization prior to dispensing to the patient.

“Pharmacy and Therapeutics Committee (P&T Committee)” or “Committee” means the Committee formulated to review therapeutic classes, conduct clinical

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reviews of specific drugs, recommend additions or deletions to the preferred drug list, and perform other functions as required by the Department.

“Polypharmacy program” means a retrospective review program for recipients receiving a set number of unique prescriptions (refills and OTC excluded) in a period of one calendar quarter. These outlier reviews are initiated based upon standard clinical and medical utilization practices.

“Preferred drug list (PDL)” means the list of drugs that meet the safety, clinical efficacy, and pricing standards employed by the P&T Committee and adopted by the Department for the Virginia Medicaid fee-for-service program. Most drugs on the PDL may be prescribed and dispensed in the Virginia Medicaid fee-for-service program and Managed Care Plans without prior authorization; however, some drugs as recommended by the Pharmacy and Therapeutics Committee may require authorization prior to dispensing to the patient.

“Prior authorization” as it relates to the PDL, means the process of review by a clinical pharmacist or pharmacy technician of legend and non-legend drugs that are not on the preferred drug list or other drugs as recommended by the Pharmacy and Therapeutics Committee, to determine if medically justified.

“State supplemental rebate” means any cash rebate that offsets Virginia Medicaid expenditure and that supplements the Federal rebate. State supplemental rebate amounts shall be calculated in accordance with the National Medicaid Pooling Initiative (NMPI).

“Therapeutic class” means a grouping of medications sharing the same Specific Therapeutic Class Code (GC3) within the Federal Drug Data File published by First Data Bank, Inc.