COMMONWEALTH of VIRGINIA

Office of the Governor

Daniel Carey, MD
Secretary of Health and Human Resources

May 24, 2021

Francis McCullough, Associate Regional Administrator
Centers for Medicare &Medicaid Services
801 Market Street, Suite 9400
Philadelphia, PA 19107-3134

Dear Mr. McCullough:

Attached for your review and approval is amendment 21-014, entitled "12-Month Contraception and Participation in the National Rebate Pool" to the Plan for Medical Assistance for the Commonwealth. I request that your office approve this change as quickly as possible.

Sincerely,

Daniel Carey, MD, MHCM

Attachment

cc: Karen Kimsey, Director, Department of Medical Assistance Services

Transmittal Summary

SPA 21-014

I. IDENTIFICATION INFORMATION

Title of Amendment: 12-Month Contraception and Participation in National Rebate Pool

II. SYNOPSIS

Basis and Authority: The Code of Virginia (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended, § 32.1-324, authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the Board's requirements.

Item 313.YYYYY of the 2021 Appropriations Act states that DMAS "…shall amend the Medicaid and CHIP State Plans to authorize prescriptions of contraceptives up to a 12 month supply for eligible beneficiaries in the Medicaid and CHIP programs. The department shall have the authority to promulgate emergency regulations to implement these amendments within 280 days or less from the enactment of this Act."

This SPA contains the changes related to the Medicaid State Plan. The changes will also be made in the CHIP state plan, but that will be submitted to CMS at a later date.

Purpose: This SPA contains two elements. First, in accordance with the 2020 Special Session, Item 313.YYYYY, DMAS will authorize prescriptions of contraceptives up to a 12 month supply. Second, DMAS will begin to calculate state supplemental pharmacy rebate amounts in accordance with the National Medical Pooling Initiative (NMPI) instead of the Virginia Supplemental Rebate Agreement and Addenda. This change will allow Virginia to receive additional rebate amounts and generate savings for the state.

Substance and Analysis: The section of the State Plan that is affected by this amendment is "Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy and Medically Needy."

Impact: The expected increase in aggregate annual expenditures due to the 12-month contraceptive change is $34,133 in state general funds, $332,324 in federal funds, and $12,850 in special funds in federal fiscal year 2021.

There is no expected increase or decrease in aggregate annual expenditures due to the rebate change in federal fiscal year 2021.

Tribal Notice: Please see Attachments A-1 and A-2.

Prior Public Notice: N/A

Public Comments and Agency Analysis: N/A

ATTACMENT A-1

Commonwealth of Virginia

Mcclellan, Emily <emily.mcclellan@dmas.virginia.gov>

Tribal Notice re: two pharmacy changes in Medicaid

1 message

Mcclellan, Emily <emily.mcclellan@dmas.virginia.gov> Tue, May 11, 2021 at 12:00 PM
To: Dean Branham <TribalOffice@monacannation.com>, "G. Anne Richardson" <chiefannerich@aol.com>, Gerald Stewart <wasandson@cox.net>, Pam Thompson <Pamelathompson4@yahoo.com>, Rappahannock Tribe <rappahannocktrib@aol.com>, Reginald Stewart <regstew007@gmail.com>, Robert Gray <robert.gray@pamunkey.org>, Rufus Elliott <tribaladmin@monacannation.com>, Samuel Bass <samflyingeagle48@yahoo.com>, Stephen Adkins <chiefstephenadkins@gmail.com>, "W. Frank Adams" <WFrankAdams@verizon.net>, "bradbybrown@gmail.com" <bradbybrown@gmail.com>, heather.hendrix@ihs.gov, "Garrett, Tabitha (IHS/NAS/RIC)" <tabitha.garrett@ihs.gov>

Dear Tribal Leaders and Indian Health Programs:

Attached is a Tribal Notice letter from Virginia Medicaid Director Karen Kimsey indicating that the Dept. of Medical Assistance Services (DMAS) plans to submit a State Plan Amendment (SPA) to the federal Centers for Medicare and Medicaid Services. This SPA makes two changes related to Medicaid pharmacy coverage: 1) it will authorize prescriptions of contraceptives for up to a 12 month supply at a time; and 2) it will allow DMAS to calculate state supplemental pharmacy rebate amounts in accordance with the National Medicaid Pooling Initiative.

If you would like a copy of the SPA documents or proposed text changes, or if you have any questions, please let us know.

Thank you! -- Emily McClellan

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Emily McClellan
Regulatory Supervisor
Policy Planning and Innovation Division
Virginia Department of Medical Assistance Services
600 East Broad Street
Richmond, VA 23219
(804) 371-4300
www.dmas.virginia.gov

VIRGINIA'S MEDICAID PROGRAM DMAS *Improving the health and well-being of Virginians through access to high quality health care coverage*

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Tribal_Notice_letter (signed) 5-11-21.pdf
284K

ATTACHMENT A-2

COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

KAREN KIMSEY
DIRECTOR

SUITE 1300
600 EAST BROAD STREET
RICHMOND, VA 23219
804/786-7933
800/343-0634 (TDD)
www.dmas.virginia.gov

May 11, 2021

SUBJECT: Notice of Opportunity for Tribal Comment – State Plan Amendment related to 12-month contraception and Participation in National Rebate Pool

Dear Tribal Leader and Indian Health Programs:

This letter is to notify you that the Department of Medical Assistance Services (DMAS) is planning to amend the Virginia State Plan for Medical Assistance with the Centers for Medicare and Medicaid Services (CMS). Specifically, DMAS is providing you notice about a State Plan Amendment (SPA) that the Agency will file with CMS in order to make two changes related to pharmacy. First, in accordance with the 2020 Special Session, Item 313.YYYYY, DMAS will authorize prescriptions of contraceptives for up to a 12 month supply. Second, DMAS will begin to calculate state supplemental pharmacy rebate amounts in accordance with the National Medicaid Pooling Initiative (NMPI) instead of the Virginia Supplemental Rebate Agreement and Addenda. This change will allow Virginia to receive additional rebate amounts and generate savings for the state.

The tribal comment period for this SPA is open through June 10, 2021. You may submit your comments directly to Emily McClellan, DMAS Policy Division, by phone (804) 371-4300, or via email: Emily.McClellan.dmas.virginia.gov Finally, if you prefer regular mail you may send your comments or questions to:

Virginia Department of Medical Assistance Services
Attn: Emily McClellan
600 East Broad Street
Richmond, VA 23219

Please forward this information to any interested party.

Sincerely,

Karen Kimsey

Karen Kimsey

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. (12 VAC 30-50-210)

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.

~~3.~~ 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 12 VAC 30-50-520 (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.

~~4.~~ 5. Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332shall 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.

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~~5.~~ 6. New drugs shall be covered pursuant to the Social Security Act of §1927(d) (OBRA '90 §4401).

~~6.~~ 7. The number of refills shall be limited pursuant to the Drug Control Act, Code of Virginia Title 54.1, §54.1-3411.

~~7.~~ 8. Drug Prior Authorization.

a. Definitions. The following words and terms, when used in these regulations, shallhave 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 theP & 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 drugsmay 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

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 calendarquarter. 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 ~~Virginia Supplemental Rebate Agreement and Addenda.~~ 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.

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: 21-0014

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: Karen Kimsey

13. TYPED NAME: Karen Kimsey

14. TITLE: Director

15. DATE SUBMITTED: 5/11/2021

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

18. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

22. TITLE

23. REMARKS

FORM CMS-179 (07/92)

Instructions on Back

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