



COMMONWEALTH of VIRGINIA
Office of the Governor

John E. Littel
Secretary of Health and Human Resources

April 3, 2023

James G. Scott, Director
Division of Program Operations
Medicaid & CHIP Operations Group
Centers for Medicare and Medicaid Services
601 E. 12th St., Room 355
Kansas City, MO 64106

Dear Mr. Scott:

Attached for your review and approval is amendment 23-006, entitled "OTC Drugs" to the Plan for Medical Assistance for the Commonwealth. I request that your office approve this change as quickly as possible.

Sincerely,

A handwritten signature in blue ink that reads "John E. Littel".

John E. Littel

Attachment

cc: Cheryl J. Roberts, Director, Department of Medical Assistance Services

Transmittal Summary

SPA 23-006

I. IDENTIFICATION INFORMATION

Title of Amendment: OTC Drugs

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.

Purpose: The state plan is being revised in response to a CMS request to change the language related to over-the-counter (OTC) drugs. CMS asked DMAS to include the new, underlined language in order to indicate where a list of OTC drugs could be located. The new language includes all of the items that had been shown in (a) through (d) and as a result, this text was removed.

During the course of this review, CMS also asked that Virginia remove language related to home infusion therapy from the pharmacy section of the state plan. That language is already in the durable medical equipment section of the state plan, so removing the language from the pharmacy section has no practical effect.

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."

Impact: None.

Tribal Notice: Please see attached.

Prior Public Notice: N/A

Public Comments and Agency Analysis: N/A

Tribal Notice – Over-the-Counter (OTC) Drugs

Lee, Meredith (DMAS) <Meredith.Lee@dmas.virginia.gov>

Fri 3/24/2023 11:44 AM

To: TribalOffice@MonacanNation.com <TribalOffice@MonacanNation.com>; Ann Richardson <chiefannerich@aol.com>; Gerald Stewart <jerry.stewart@cit-ed.org>; pamelathompson4@yahoo.com (pamelathompson4@yahoo.com) <pamelathompson4@yahoo.com>; rappahannocktrib@aol.com (rappahannocktrib@aol.com) <rappahannocktrib@aol.com>; Reggie Stewart <regstew007@gmail.com>; Gray, Robert <robert.gray@pamunkey.org>; tribaladmin <tribaladmin@monacannation.com>; Sam Bass (samflyingeagle48@yahoo.com) <samflyingeagle48@yahoo.com>; chiefstephenadkins@gmail.com (chiefstephenadkins@gmail.com) <chiefstephenadkins@gmail.com>; Frank Adams <Board.R1D@DGIF.VIRGINIA.GOV>; bradbybrown@gmail.com (bradbybrown@gmail.com) <bradbybrown@gmail.com>; tabitha.garrett@ihs.gov (tabitha.garrett@ihs.gov) <tabitha.garrett@ihs.gov>; kara.kearns@ihs.gov (kara.kearns@ihs.gov) <kara.kearns@ihs.gov>; Mia Eubank (mia.eubank@ihs.gov) <mia.eubank@ihs.gov>

📎 1 attachments (169 KB)

Tribal Notice Letter OTC, signed.pdf;

Dear Tribal Leaders and Indian Health Programs:

Attached is a Tribal Notice letter from Virginia Medicaid Director, Cheryl Roberts, indicating that the Department of Medical Assistance Services (DMAS) plans to submit a State Plan Amendment (SPA) to the federal Centers for Medicare and Medicaid Services. This SPA is in response to a CMS request to change the language related to over-the-counter (OTC) drugs. CMS asked DMAS to include the following sentence to indicate where a list of OTC drugs could be located: "A list of specific covered drug categories is published in Chapter 4 of the Pharmacy Provider Manual." With this new language, DMAS no longer needs, and proposes deleting the following language: "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..." (These items will remain covered, but they will be stated with specificity in the Pharmacy Manual and do not need to be repeated in the state plan.)

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! -- Meredith Lee

Meredith Lee
Division of Policy, Regulation, and Member Engagement
Policy, Regulations, and Manuals Supervisor
Department of Medical Assistance Services
Hours: 6:00 am - 4:30 pm (Monday-Thursday); out of the office on Fridays
meredith.lee@dmas.virginia.gov
(804) 371-0552





COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

CHERYL J. ROBERTS
DIRECTOR

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

March 24, 2023

SUBJECT: Notice of Opportunity for Tribal Comment – State Plan Amendment related to Over-the-Counter (OTC) Drugs.

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 to update language in the pharmacy section of the state plan.

CMS has asked Virginia to change the language related to over-the-counter (OTC) drugs. CMS asked DMAS to include the following sentence in order to indicate where a list of OTC drugs could be located: "A list of specific covered drug categories is published in Chapter 4 of the Pharmacy Provider Manual." With this new language, DMAS no longer needs, and proposes deleting the following language: "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..." (These items will remain covered, but they will be stated with specificity in the Pharmacy Manual and do not need to be repeated in the state plan.)

CMS also asked that Virginia remove language related to home infusion therapy from the pharmacy section of the state plan. That language is already in the durable medical equipment section of the state plan, so removing the language from the pharmacy section has no practical effect.

The tribal comment period for this SPA is open through April 23, 2023. You may submit your comments directly to Meredith Lee, DMAS Policy, Regulation, and Member Engagement Division, by phone (804) 371-0552, or via email: Meredith.Lee@dmas.virginia.gov. If you prefer regular mail you may send your comments or questions to: Virginia Department of Medical Assistance Services, Attn: Meredith Lee, 600 East Broad Street Richmond, VA 23219.

Please forward this information to any interested party.

Sincerely,

A handwritten signature in black ink, appearing to read "Cheryl J. Roberts".

Cheryl J. Roberts, Director

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. A list of specific covered drug categories is published in Chapter 4 of the Pharmacy Provider Manual.
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.

TN No. 21-014
Supersedes
TN No. 20-018

Approval Date 8-18-21

Effective Date 7-1-2021

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- e. State supplemental rebates. The Department has the authority to seek supplemental rebates from pharmaceutical manufacturers. In addition to collecting supplemental rebates for fee-for-service claims, the Department may, at its option, also collect supplemental rebates for Medicaid Member utilization through MCOs under an agreement. Supplemental rebate agreements shall be separate from the federal rebates and in compliance with federal law, §§ 1927(a)(1) and 1927(a)(4) of the *Social Security Act* (Act). All rebates collected on behalf of the Commonwealth shall be collected for the sole benefit of the state share of the costs.
 - f. Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D), information disclosed to the Department or to the Committee by a pharmaceutical manufacturer or wholesaler which discloses the identity of a specific manufacturer or wholesaler and the pricing information regarding the drugs by such manufacturer or wholesaler is confidential and shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§[2.2-3700](#) *et seq.* of the Code of Virginia).
 - g. Appeals for denials of prior authorization shall be addressed pursuant to 12VAC30-110, Part I, Client Appeals.
- ~~8. Coverage of home infusion therapy. This service shall be covered consistent with the limits and requirements set out within home health services (12 VAC 30-50-160). Multiple applications of the same therapy (e.g. two antibiotics on the same day) shall be covered under one service day rate of reimbursement. Multiple applications of different therapies (e.g. chemotherapy, hydration, and pain management on the same day) shall be covered under a full service day rate methodology as provided in pharmacy services reimbursement.~~
- 12b. Dentures.
- A. Provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

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

1. TRANSMITTAL NUMBER

2. STATE

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT

XIX

XXI

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

5. FEDERAL STATUTE/REGULATION CITATION

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY _____ \$ _____

b. FFY _____ \$ _____

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

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

9. SUBJECT OF AMENDMENT

10. 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

11. SIGNATURE OF STATE AGENCY OFFICIAL

Cheryl Roberts

15. RETURN TO

12. TYPED NAME

13. TITLE

14. DATE SUBMITTED

FOR CMS USE ONLY

16. DATE RECEIVED

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

21. TITLE OF APPROVING OFFICIAL

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

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