Table of Contents

State Name: Virginia

State Plan Amendment (SPA) #: 12-05

This file contains the following documents in the order listed:

1) Approval Letters
2) CMS 179 Form/Summary Form (with 179-like data)
3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
150 S. Independence Mall West
Suite 216, The Public Ledger Building
Philadelphia, Pennsylvania 19106-3499

Region III/Division of Medicaid and Children's Health Operations

SWIFT #121420124029

DEC 17 2012

Cynthia B. Jones, Director
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, VA 23219

Re: Approval-VA SPA 12-05, 2012 Pharmacy Changes

Dear Ms. Jones:

The Centers for Medicare & Medicaid Services (CMS) would like to inform you of the approval of Virginia's State Plan Amendment (SPA) 12-05 entitled 2012 Pharmacy Changes. The Pharmacy Team at CMS approved this SPA on December 12, 2012 and you were duly notified. This SPA proposes to remove text from the State Plan that is procedural in nature, to remove the provision of an additional unit dose dispensing fee of $5.00 per recipient per month, and to remove text related to the prescription threshold limits that will be a function of the preauthorization process. In addition, the SPA will make non-substantive changes to the supplemental rebate agreement (SRA), and will streamline the State Plan text regarding the SRA requirements.

The effective date of this amendment is April 1, 2012. Enclosed are the approved State Plan pages and a copy of the signed Form CMS-179.

If you have any questions about this SPA, please contact Margaret Kosherzenko of my staff at 215-861-4288.

Sincerely,

/S/

Francis McCullough
Associate Regional Administrator

Enclosures

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

December 12, 2012

Cynthia B. Jones
Director, Department of Medical Assistance Services
600 East Broad Street, #1300
Richmond VA 23219

Dear Ms. Jones:

We have reviewed Virginia's State Plan Amendment (SPA) 12-05 submitted to the Philadelphia Regional Office on May 15, 2012. This amendment proposes to remove text from the state plan that is procedural in nature, to remove the provision of an additional unit dose dispensing fee of $5.00 per recipient per month, to remove text related to the prescription threshold limits that will be a function of the preauthorization process, to make non-substantive changes to the supplemental rebate agreement (SRA), and to streamline the state plan text regarding the SRA requirements.
Based on the information provided, we are pleased to inform you that SPA 12-05 is approved with an effective date of April 1, 2012.

A copy of the CMS-179 form, as well as the pages approved for incorporation into Virginia's state plan, will be forwarded by the Philadelphia Regional Office. If you have any questions regarding this amendment, please contact Madlyn Kruh at (410) 786-3239.

Sincerely,

/ s /

Larry Reed
Director
Division of Pharmacy

cc: Francis McCullough, ARA, Philadelphia Regional Office
Margaret Kosherzenko, Philadelphia Regional Office
Lois Grey, Virginia Department of Medical Assistance Services

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

R: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 12 — 05

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: April 1, 2012

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 Part 447

7. FEDERAL BUDGET IMPACT
a. FFY 2012 $ (324,000)
b. FFY $

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attach. 4.19-B, Pages 7.5 and 8.1 of 15, and Attach. 3.1-A&B, Suppl. 1, Pages 22 & 25 of 41

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

10. SUBJECT OF AMENDMENT: 2012 Pharmacy Changes

GOVERNOR'S REVIEW (Check One)

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT 2012
☐ 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: /S/

13. TYPED NAME: Cynthia B. Jones

14. TITLE: Director

15. DATE SUBMITTED: 5/15/12

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: MAY 15, 2012

18. DATE APPROVED: DEC 12 2012

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: APRIL 1, 2012

20. SIGNATURE OF REGIONAL OFFICIAL: /S/

21. TYPED NAME: FRANCIS McCullough

22. TITLE: Associate Regional Administrator/DMCHO

23. REMARKS

FORM CMS-179 (07/92)

Instructions on Back

Save

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

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 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.

"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.

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

(1) Prior authorization shall consist of prescription review by a licensed pharmacist or pharmacy technician to ensure that all predetermined clinically appropriate criteria, as established by the P&T Committee relative to each therapeutic class, have been met before the prescription may be dispensed. Prior authorization shall be obtained through a call center staffed with appropriate clinicians, or through written or electronic communications (e.g., faxes, mail). Responses by telephone or other telecommunications device within 24 hours of a request for prior authorization shall be provided. The dispensing of 72-hour emergency supplies of the prescribed drug shall be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.

(2) The preferred drug list program shall include: (i) provisions for an expedited review process of denials of requested prior authorization by the Department; (ii) consumer and provider education, (iii) training and information regarding the preferred drug list both prior to implementation as well as ongoing communications, to include computer and website access to information and multilingual material.

(3) Exclusion of protected groups from pharmacy preferred drug list prior authorization requirements. The following groups of Medicaid eligibles shall be excluded from pharmacy prior authorization requirements: individuals enrolled in hospice care, services through PACE or pre-PACE programs; persons having comprehensive third party insurance coverage; minor children who are the responsibility of the juvenile justice system; and refugees who are not otherwise eligible in a Medicaid covered group.

d. (Repealed with SPA 12-05, effective 4/1/2012)

NEXT PAGE IS 26.1 OF 41

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATE-
OTHER TYPES OF CARE

---

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

5. MAC methodology for specialty drugs. Payment for drug products designated by DMAS as specialty drugs shall be the lesser of subdivisions 1 through 4 of this section or the following method, whichever is least:

a. The methodology used to reimburse for designated specialty drug products shall be the WAC price plus the WAC percentage. The WAC percentage is a constant percentage set at 4.75%.

b. Designated specialty drug products are certain products used to treat chronic, high-cost, or rare diseases; the drugs subject to this pricing methodology and their current reimbursement rates are listed on the DMAS website at the following internet address:

http://www.dmas.virginia.gov/downloads/pdfs/pharm-special_mac_list.pdf.

c. The MAC reimbursement methodology for specialty drugs shall be subject to the pricing review and dispute resolution procedures described in subdivisions 2 C (i) and 2 C (ii) of this section.

6. Payment for pharmacy services will be as described above; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee for brand name and generic drugs is $3.75.

7. *RESERVED.*

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATE-
OTHER TYPES OF CARE

---

10. Supplemental rebate agreement. The Commonwealth complies with the requirements of § 1927 of the *Social Security Act* and 42 CFR 447.500 et seq. with regard to supplemental drug rebates. In addition, the following requirements are also met:

a. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for legend drugs provided to Medicaid recipients, entitled Virginia Supplemental Drug-Rebate Agreement Contract and Addendum A, have been authorized by CMS to be effective April 1, 2012. All amendments to the Supplemental Drug-Rebate Agreement Contract shall also be authorized by CMS.

b. Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

c. Prior authorization requirements found in § 1927(d)(5) of the *Social Security Act* have been met.

d. Non-preferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs will be made available to Medicaid beneficiaries through prior authorization.

e. Payment of supplemental rebates may result in a product's inclusion on the PDL.

End of Pharmacy Reimbursement Methodology

FINAL