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State Name: Virginia

State Plan Amendment (SPA) #: 10-01

This file contains the following documents in the order listed:

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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

APR 2 1 2010

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

Dear Ms. Jones:

We have reviewed State Plan Amendment (SPA) 10-01, in which you propose two technical changes to your state plan: 1) recalibrate your resource based relative value system physician reimbursement rates by implementing a site of service differential payment policy, and 2) complete the implementation of a method of reimbursement for specialty drugs.

This SPA, as modified by your email notes dated March 30, April 7, and April 13, 2010, is acceptable. Therefore, we are approving SPA 10-10 with an effective date of January 1, 2010. Enclosed are the approved SPA page and signed CMS-179 form.

If you have further questions about this SPA, please contact Jake Hubik at (215) 861-4181.

Sincerely,

/S/

Ted Gallagher
Associate Regional Administrator

Enclosures

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: 10-01

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: January 1, 2010

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 2010 $ 0.00
b. FFY 2011 $ 0.00

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attach. 4.19-B, pp. 7.3-7.6 of 15; Attach. 4.19-B, Suppl. 4, pp. 1-3 of 3.
Attach 4.19B p 8-8.2 of 15

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Same pages

10. SUBJECT OF AMENDMENT: Physician Reimbursement for Site of Service; Pharmacy Specialty MAC

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: /S/

13. TYPED NAME: Patrick W. Finnerty

14. TITLE: Acting Director

15. DATE SUBMITTED: 1/21/10

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: 1/21/10

18. DATE APPROVED: APR 21 2010

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 1/1/10

20. SIGNATURE OF REGIONAL OFFICIAL: /S/

21. TYPED NAME: Ted Gallagher

22. TITLE: Associate Regional Administrator

23. REMARKS

FORM CMS-179 (07/92)

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§7. Fee-for-service providers: pharmacy. (12VAC30-80-40)

Payment for pharmacy services shall be the lowest of items 1 through 5 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in the longstanding provisions formerly at 42 CFR 447.331(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to the longstanding provisions formerly at 42 CFR 447.331 and 447.332, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the CMS Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The methodology used to reimburse for generic drug products shall be the higher of either (i) the lowest Wholesale Acquisition Cost (WAC) plus 10% or (ii) the second lowest WAC plus 6.0%. This methodology shall reimburse for products' costs based on a Maximum Allowable Cost (VMAC) list to be established by the single state agency.

A. In developing the maximum allowable reimbursement rate for generic pharmaceuticals, the department or its designated contractor shall:

(i) Identify three different suppliers, including manufacturers that are able to supply pharmaceutical products in sufficient quantities. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmaceutical products that are not available from three different suppliers, including manufacturers, shall not be subject to the VMAC list.

(ii) Identify that the use of a VMAC rate is lower than the Federal Upper Limit (FUL) for the drug. The FUL is a known, widely published price provided by CMS; and

(iii) Distribute the list of state VMAC rates to pharmacy providers in a timely manner prior to the implementation of VMAC rates and subsequent modifications. DMAS shall publish on its website, each month, the information used to set the Commonwealth's prospective VMAC rates, including, but not necessarily limited to:

(a) The identity of applicable reference products used to set the VMAC rates;

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(b) The Generic Code Number (GCN) or National Drug Code (NDC), as may be appropriate, of reference products;

(c) The difference by which the VMAC rate exceeds the appropriate WAC price; and

(d) The identity and date of the published compendia used to determine reference products and set the VMAC rate. The difference by which the VMAC rate exceeds the appropriate WAC price shall be at least or equal to 10% above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.

B. Development of a VMAC rate that does not have a FUL rate shall not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program.

C. DMAS or its designated contractor shall:

(i) Implement and maintain a procedure to add or eliminate products from the list, or modify VMAC rates, consistent with changes in the fluctuating marketplace. DMAS or its designated contractor will regularly review manufacturers' pricing and monitor drug availability in the marketplace to determine the inclusion or exclusion of drugs on the VMAC list; and

(ii) Provide a pricing dispute resolution procedure to allow a dispensing provider to contest a listed VMAC rate. DMAS or its designated contractor shall confirm receipt of pricing disputes within 24 hours, via telephone or facsimile, with the appropriate documentation of relevant information, e.g., invoices. Disputes shall be resolved within three business days of confirmation. The pricing dispute resolution process will include DMAS' or the contractor's verification of accurate pricing to ensure consistency with marketplace pricing and drug availability. Providers will be reimbursed, as appropriate, based on findings. Providers shall be required to use this dispute resolution process prior to exercising any applicable appeal rights.

3. The provider's usual and customary charge to the public, as identified by the claim charge.

4. The Estimated Acquisition Cost (EAC), which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 8 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c of this subdivision;

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

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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. The Program pays additional reimbursement for unit dose dispensing systems of dispensing drugs. DMAS defines its unit dose dispensing system coverage consistent with that of the Virginia Board of Pharmacy of the Department of Health Professions (18 VAC 110-20-420). This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose per capita fee to be calculated by DMAS' fiscal agent based on monthly per nursing home resident service per pharmacy provider. Only one service fee per month may be paid to the pharmacy for each patient receiving unit dose dispensing services. Multisource drugs will be reimbursed at the maximum allowed drug cost for specific multiple source drugs as identified by the state agency or CMS' upper limits as applicable. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency. The original per capita fee shall be determined by a DMAS analysis of costs related to such dispensing, and shall be reevaluated at periodic intervals for appropriate adjustment. The unit dose dispensing fee is $5.00 per recipient per month per pharmacy provider.

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8. Determination of EAC was the result of a report by the Office of the Inspector General that focused on appropriate Medicaid marketplace pricing of pharmaceuticals based on the documented costs to the pharmacy. An EAC of AWP minus 10.25% shall become effective July 1, 2002.

The dispensing fee for brand name and generic drugs of $3.75 shall remain in effect, creating a payment methodology based on the previous algorithm (least of subdivisions of this section) plus a dispensing fee where applicable.

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9. Home infusion therapy.

a. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the CMS 1500 claim form.

b. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

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10. Supplemental rebate agreement. Based on the requirements in § 1927 of the Social Security Act, the Commonwealth of Virginia has the following policies for the supplemental drug rebate program for Medicaid recipients:

a. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for legend drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract A and Amendment #2 to Contract A has been authorized by CMS.

b. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract B and Amendment #2 to Contract B has been authorized by CMS.

c. The model supplemental rebate agreement between the Commonwealth and pharmaceutical manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract C, and Amendments #1 and #2 to Contract C has been authorized by CMS.

d. 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.

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

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

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

End of Pharmacy Reimbursement Methodology

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11. All reasonable measures will be taken to ascertain the legal liability of third parties to pay for authorized care and services provided to eligible recipients including those measures specified under 42 USC 1396a(a)(25).

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The State Agency Fee Schedule

A. Reimbursement of fee-for-service providers. Effective for dates of service on or after July 1, 1995, the Department of Medical Assistance Services (DMAS) shall reimburse fee-for-service providers, with the exception of Home Health services (see Supplement 3), and durable medical equipment services (see 12VAC30-80-30), using a fee schedule that is based on a Resource Based Relative Value Scale (RBRVS). The RBRVS fees shall be the same for both public and private providers. One goal of this methodology is to prevent the total cost of reimbursement for physicians to increase or decrease solely as a result of changes in the Medicare conversion factor.

B. Fee schedule.

1. For those services or procedures which are included in the RBRVS published by the Centers for Medicare and Medicaid Services (CMS) as amended from time to time, DMAS' fee schedule shall employ the Relative Value Units (RVUs) developed by CMS as periodically updated.

a. Effective for dates of service on or after July 1, 2008, DMAS shall implement site of service differentials and employ both non-facility and facility RVUs. The implementation shall be budget-neutral using the methodology in subsection 2 below.

b. The implementation of site-of-service shall be transitioned over a four-year period.
(1) Effective for dates of service on or after July 1, 2008, DMAS shall calculate the transitioned facility RVU by adding 75 percent of the difference between the non-facility RVU and non-facility RVU to the facility RVU.
(2) Effective for dates of service on or after July 1, 2009, DMAS shall calculate the transitioned facility RVU by adding 50 percent of the difference between the non-facility RVU and non-facility RVU to the facility RVU.
(3) Effective for dates of service on or after July 1, 2010, DMAS shall calculate the transitioned facility RVU by adding 25 percent of the difference between the non-facility RVU and non-facility RVU to the facility RVU.
(4) Effective for dates of service on or after July 1, 2011, DMAS shall use the unadjusted Medicare facility RVU.

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2. DMAS shall calculate the RBRVS-based fees using conversion factors (CFs) published from time to time by CMS. DMAS shall adjust CMS's CFs by additional factors so that no change in expenditure will result solely from the implementation of the RBRVS-based fee schedule. DMAS may revise the additional factors when CMS updates its RVUs or CFs so that no change in expenditure will result solely from such updates. Except for this adjustment, DMAS' CFs shall be the same as those published from time to time by CMS. The calculation of the additional factor shall be based on the assumption that no change in services provided will occur as a result of these changes to the fee schedule. The determination of the additional factors required above shall be accomplished by means of the following calculation:

a. The estimated amount of DMAS expenditures if DMAS were to use Medicare's RVUs and CFs without modification, is equal to the sum, across all relevant procedure codes, of the RVU value published by the CMS, multiplied by the applicable conversion factor published by the CMS, multiplied by the number of occurrences of the procedure code in DMAS patient claims in the most recent period of time (at least six months).
b. The estimated amount of DMAS expenditures, if DMAS were not to calculate new fees based on the new CMS RVUs and CFs is equal to the sum, across all relevant procedure codes, of the existing DMAS fee multiplied by the number of occurrences of the procedure codes in DMAS patient claims in the period of time used in subdivision 2a of this subsection.
c. The relevant additional factor is equal to the ratio of the expenditure estimate (based on DMAS fees in subdivision 2b of this subsection) to the expenditure estimate based on unmodified CMS values in subdivision 2a of this subsection.
d. During the transition to "site of service" described in subsection B.1.b. above, the additional factors will be adjusted by the same percentage so as to spend any estimated savings from the implementation of "site of service".

e. DMAS shall calculate a separate additional factor for:
(1) Emergency Room Services (defined as the American Medical Association's (AMA) annual publication of the Current Procedural Terminology (CPT) codes 99281, 99282, 99283, 99284, and 99285);
(2) Obstetrical/Gynecological Services (defined as Maternity Care and Delivery procedures, Female Genital System procedures, Obstetrical/Gynecological-related radiological procedures, and mammography procedures, as defined by the American Medical Association's (AMA) annual publication of the Current Procedural Terminology (CPT) manual);

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(3) Pediatric preventive services (defined as Evaluation and Management (E&M) procedures, excluding those listed in 2(e)(1) of this subsection, as defined by the AMA's annual publication of the CPT manual, in effect at the time the service is provided, for recipients under age 21;

(4) Pediatric primary services (defined as evaluation and management (E&M) procedures, excluding those listed in subdivisions 2e(1) and 2e(3) of this subsection, as defined by the AMA's publication of the CPR manual, in effect at the time the service is provided, for recipients under age 21;
(5) Adult primary and preventive services (defined as E&M procedures, excluding those listed in 2e(1) of this subsection, as defined by the AMA's annual publication of the CPT manual, in effect at the time the service is provided, for recipients age 21 and over); and,
(6). All other procedures set through the RBRVS process combined.

3. For those services or procedures for which there are no established RVUs DMAS shall approximate a reasonable relative value payment level by looking to similar existing relative value fees. If DMAS is unable to establish a relative value payment level for any service or procedure, the fee shall not be based on a RBRVS, but shall instead be based on the previous fee-for-service methodology.

The Fee Schedule is published in the DMAS website, and may be found at:
http://www.dmas.virginia.gov/pr-fee_files.htm