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MEMORANDUM

TO: **EMILY MCCLELLAN**
Regulatory Supervisor
Department of Medical Assistance Services

FROM: **JENNIFER L. GOBBLE**
Assistant Attorney General

DATE: **May 3, 2017**

SUBJECT: **Emergency Regulations – Fee-For-Service Pharmacy Reimbursement Methodology**

I have reviewed the attached emergency regulations that would revise the pharmacy reimbursement methodology for the Medicaid fee-for-service program to meet the requirements of recent federal regulations and comply with the directive in the 2016 *Acts of Assembly*, Chapter 780, Item 306.OO. The language implementing the revisions required by federal regulations was approved by the Centers for Medicare and Medicaid Services.

Based on my review, it is this Office's view that the Director of the Department of Medical Assistance Services, acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code § 32.1-324, has the authority to promulgate these regulations, subject to compliance with the provisions of Article 2 of the Virginia Administrative Process Act (VAPA), and has not exceeded that authority.

The authority for this emergency action is found in Virginia Code § 2.2-4011(B), which provides that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment and the regulation is not exempt under the provisions of subdivision A.4 of Virginia Code § 2.2-4006.

Pursuant to § 2.2-4012, the attached emergency regulations shall become effective upon approval by the Governor and filing with the Registrar of Regulations. In addition, the emergency regulations shall be effective for no more than 18 months. If the

Department intends to continue regulating the subject matter governed by these emergency regulations beyond 18 months, it will be necessary to replace these emergency regulations with regulations duly promulgated under Article 2 of the VAPA. A Notice of Intended Regulatory Action relating to the proposed replacement regulations must be filed with the Registrar within 60 days of the effective date of the emergency regulations. The proposed regulations must be filed with the Registrar within 180 days after the effective date of the emergency regulations. Va. Code § 2.2-4011(C).

If you have any questions or need any additional information, please feel free to contact me at 786-4905.

cc: Kim F. Piner
Senior Assistant Attorney General

Emergency Text

Action:
Pharmacy Fee-for-Service Reimbursement
Stage: Emergency/NOIRA
5/3/17 2:57 PM [latest]

12VAC30-80-40. Fee-for-service providers: pharmacy.

~~Payment for pharmacy services shall be the lowest of subdivisions 1 through 5 of this section (except that subdivisions 1 and 2 of this section will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.512(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 42 CFR 447.512 and 447.514, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA 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:~~

~~(1) 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.~~

~~(2) 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~~

~~(3) 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;~~

~~(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:~~

~~(1) 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~~

~~(2) 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 (U&C) 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 7 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.~~

~~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 identified each year for all GCNs.~~

~~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 (1) and 2 c (2) 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. An EAC of AWP minus 13.1% shall become effective July 1, 2011. 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.~~

A. Payment for covered outpatient legend and non-legend drugs dispensed by a retail community pharmacy will include the drug ingredient cost plus a $10.65 professional dispensing fee. The drug ingredient cost reimbursement shall be the lowest of:

1. The National Average Drug Acquisition Cost (NADAC) of the drug, the Federal Upper Limit (FUL), or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge;

2. When no NADAC is available, DMAS shall reimburse at the lowest of the Wholesale Acquisition Cost (WAC) + 0%, the Federal Upper Limit (FUL), or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

B. Payment for specialty drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail will include the drug ingredient cost plus a $10.65 professional dispensing fee. The drug ingredient cost reimbursement shall be the lowest of:

1. The National Average Drug Acquisition Cost (NADAC) of the drug; the Federal Upper Limit (FUL); or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

2. When no NADAC is available, DMAS shall reimburse at the lowest of the Wholesale Acquisition Cost (WAC) + 0%; the Federal Upper Limit (FUL); or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

C. Payment for drugs not dispensed by a retail community pharmacy (i.e., institutional or long-term care facility pharmacies) will include the drug ingredient cost plus a $10.65 professional dispensing fee. The drug ingredient cost reimbursement shall be the lowest of:

1. The National Average Drug Acquisition Cost (NADAC) of the drug; the Federal Upper Limit (FUL); or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

2. When no NADAC is available, DMAS shall reimburse at the lowest of the Wholesale Acquisition Cost (WAC) + 0%; the Federal Upper Limit (FUL); or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

D. Payment for clotting factor from specialty pharmacies, hemophilia treatment centers (HTC) and Centers of Excellence will include the drug ingredient cost plus a $10.65 professional dispensing fee. The drug ingredient cost reimbursement shall be the lowest of:

1. The National Average Drug Acquisition Cost (NADAC) of the drug; or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge;

2. When no NADAC is available, DMAS shall reimburse at the lowest of the Wholesale Acquisition Cost (WAC) + 0%; or the provider's usual and customary (U & C) charge to the public, as identified by the claim charge.

E. 340B covered entities and Federally Qualified Health Centers (FQHCs) that fill Medicaid member prescriptions with drugs purchased at the prices authorized under section 340 B of the Public Health Services Act will be reimbursed no more than the actual acquisition cost for the drug plus a $10.65 professional dispensing fee. 340B covered entities that fill Medicaid member prescriptions with drugs not purchased under Section 340B of the Public Health Services Act will be reimbursed in accordance with paragraph (A) of this section plus the $10.65 professional dispensing fee as described in paragraph (I) of this section.

F. Drugs acquired through the federal 340B drug price program and dispensed by 340B contract pharmacies are not covered.

G. Facilities purchasing drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. § 1826, 42 U.S.C. § 256b, or 42 U.S.C. §1396-8, other than the 340B drug pricing program will be reimbursed no more than the actual acquisition cost for the drug plus a $10.65 professional dispensing fee.

H. Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a $10.65 professional dispensing fee. Nominal Price as defined in 42 CFR §447.502 means that a price is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

I. Payment for pharmacy services will be as described in paragraphs (A) through (H) of this section; however, shall include the allowed cost of the drug plus only one professional dispensing fee, as defined at 42 CFR 447.502, per member 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 professional dispensing fee for all covered outpatient drugs shall be $10.65. The professional dispensing fee shall be determined by a cost of dispensing survey conducted at least every five (5) years.

J. Physician administered drugs (PADs) submitted under the medical benefit will be reimbursed at 106 percent of the Average Sales Price (ASP) as published by CMS. PADs without an ASP on the CMS reference file will be reimbursed at the provider's actual acquisition cost. Covered entities using drugs purchased at the prices authorized under Section 340B of the Public Health Services Act for Medicaid members shall bill Medicaid their actual acquisition cost.

K. Payment to Indian Health Service, tribal, and urban Indian pharmacies. DMAS does not have any Indian Health Service, tribal, or urban Indian pharmacies enrolled at this time. Payment for pharmacy services will be defined in a state plan amendment if such entity enrolls with DMAS.

L. Investigational drugs are not a covered service under the DMAS pharmacy program.

~~8.~~ M. Home infusion therapy.

~~a.~~ 1. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, and 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.~~ 2. 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.

~~9.~~ N. Supplemental rebate agreement. The Commonwealth complies with the requirements of § 1927 of the Social Security Act and Subpart I (42 CFR 447.500 et seq.) of 42 CFR Part 447 with regard to supplemental drug rebates. In addition, the following requirements are also met:

~~a.~~ 1. 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.

~~b.~~ 2. Prior authorization requirements found in § 1927(d)(5) of the Social Security Act have been met.

~~c.~~ 3. 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.

~~d.~~ 4. Payment of supplemental rebates may result in a product's inclusion on the PDL.