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

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 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 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 HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. ~~The Virginia Maximum Allowable Cost (VMAC) established by the Virginia Department of Medical Assistance Services to be inclusive of appropriate multiple source and specific high cost drugs plus a dispensing fee. The VMAC methodology shall be defined as the 75th percentile cost level, or the 60th percentile cost level for unit dose drugs, of the aggregate for each generic manufacturer's drug for each Generic Code Number (GCN). Manufacturers' costs are supplied by the most current First Data Bank file. Multiple source drugs may include but are not limited to Food and Drug Administration-rated products such as drugs established by a Virginia Voluntary Formulary (VVF) drugs, Federal Upper Limit Drugs and any other state or federally~~

~~approved listing. "Multisource drugs" means covered outpatient drugs for which there are two or more drug products that:~~

~~a. Are included in the Centers for Medicare and Medicaid Services' state drug rebate program;~~

~~b. Have been approved by the Federal Food and Drug Administration (FDA);~~

~~c. Are included in the Approved Products with Therapeutic Equivalence Evaluations as generically equivalent; and~~

~~d. Are sold or marketed in Virginia.~~

The methodology used to reimburse for generic drug products shall be the higher of either: (i) the lowest Wholesale Acquisition Cost (WAC) plus 10 percent, OR (ii) the second lowest WAC plus six percent. This methodology shall reimburse for products' costs based on a Maximum Allowable Cost (VMAC) list to be established by the single state agency. In developing the maximum allowable reimbursement rate for generic pharmaceuticals, the department or its designated contractor shall:

a. Identify three different suppliers, including [~~either~~] manufacturers [~~or wholesalers~~], that are able to supply, in sufficient quantities, pharmaceutical products. 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"), updated quarterly. Pharmaceutical products that are not available from three different suppliers, including [~~either~~] manufacturers [~~or wholesalers~~], shall not be subject to the VMAC list.

b. 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

c. 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:

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

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

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

(iv) 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 percent above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.

d. 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.

e. 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 below.

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. 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 of $3.75 (effective July 1, 2003) for brand name drugs shall remain in effect. The dispensing fee for generic drugs is $4.00.

6. 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 Board of Pharmacy of the Department of Health Professions (18VAC110-20-420). 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. ~~The maximum allowed drug cost for specific multiple source drugs will be the lesser of subdivisions 1 through 4 of this section as applicable.~~ Multi-source 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.

7. 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 generic drugs of $4.00, and the dispensing fee for brand name drugs of $3.75 (effective July 1, 2003) shall remain in effect, creating a payment methodology based on the previous algorithm (least of 1 through 5 of this subsection above) plus a dispensing fee where applicable.

8. 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.

9. 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.

CERTIFIED: I hereby certify that these regulations are full, true, and correctly dated.

_____ _____

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services