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TO: **BRIAN MCCORMICK**
Regulatory Supervisor
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FROM: **ELIZABETH M. GUGGENHEIM**
Assistant Attorney General

DATE: **April 3, 2015**

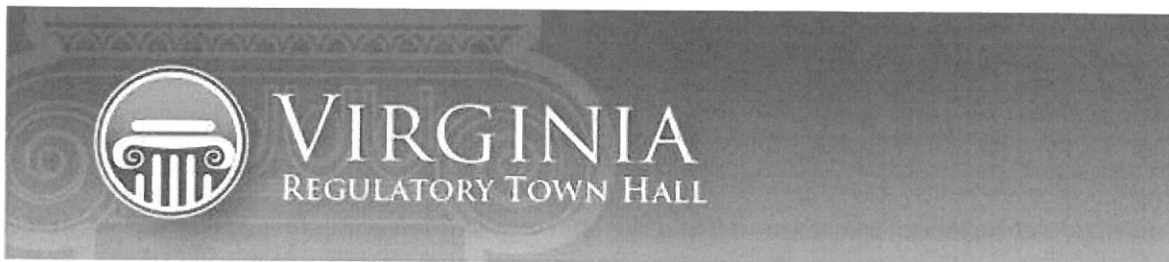
SUBJECT: **Final regulations regarding outpatient hospital reimbursement methodology.**

I have reviewed the attached final regulations that would implement a prospective payment methodology for outpatient hospital services. You have asked the Office of the Attorney General to review and determine if DMAS has the legal authority to promulgate the final regulations and if they comport with state and federal law. The 2013 Acts of Assembly, Chapter 806, Item 307 XX, gave the agency the authority to "amend the State Plan for Medical Assistance to convert the current cost-based reimbursement methodology for outpatient hospitals to an Enhanced Ambulatory Patient Group (EAPG) methodology. Reimbursement for laboratory services shall be included in the new outpatient hospital reimbursement methodology."

It is my view that the Director, acting on behalf of the Board of Medical Assistance Services, pursuant to Virginia Code § 32.1-324, has the authority to promulgate these changes to the regulations and has not exceeded that authority. If you have any questions or need any additional information, please call me at 786-2071.

Attachments

cc: Kim F. Piner
Senior Assistant Attorney General/Section Chief



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12 VAC 30-80-20, 80-36, and 80-40
Regulation title(s)	Methods and Standards for Establishing Payment Rates; Other Types of Care
Action title	Enhanced Ambulatory Patient Group Outpatient Hospital Reimbursement Methodology
Date this document prepared	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This action implements a prospective payment methodology for outpatient hospital services. The current cost-based methodology is out-of-date, inefficient and costly. The Enhanced Ambulatory Patient Group (EAPG) methodology assigns outpatient procedures and ancillary services that reflect similar patient characteristics and resource utilization to EAPG codes. DMAS converted inpatient hospital services to a similar prospective reimbursement methodology, Diagnosis-Related Groups, in the 1990s. DMAS proposes to implement the EAPG methodology that is a more efficient and predictable reimbursement methodology to pay hospitals that furnish services to Medicaid recipients in an outpatient hospital setting.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory 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 DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

The 2013 *Acts of the Assembly*, Chapter 806, Item 307 XX gave the agency the authority to implement the Enhanced Ambulatory Patient Group (EAPG) reimbursement methodology for outpatient hospital services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this action is to produce a permanent regulation from the emergency authority provided in the previous regulatory action. That emergency regulation proposed to implement a prospective payment methodology for outpatient hospital services. The current cost-based methodology is out-of-date, inefficient and costly. DMAS is proposing to implement the EAPG methodology that is a more efficient and predictable reimbursement methodology for hospitals that furnish services to Medicaid recipients in an outpatient hospital setting.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The section of the regulations that is affected by this action is the Methods and Standards for Establishing Payment Rates-Other Types of Care (12 VAC 30-80-20, 36, and 40).

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

This action increases the efficiency and predictability of reimbursement for outpatient hospital services. It also reduces the costs of settlement of reimbursement for outpatient hospital services. This regulatory action poses no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

This action does not contain any requirements that are more restrictive than applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

This action does not produce any material impact on any particular locality as it will apply statewide.

Family Impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC 30-80-20		Describes reimbursement for outpatient hospital services on a cost basis.	End dates cost-based reimbursement for outpatient hospital services but maintains cost reporting requirements and the definition of emergency room triage services for transition purposes.
	12VAC 30-80-36		Implements the EAPG methodology for outpatient hospital reimbursement in a budget neutral manner.
12VAC 30-80-40		Describes reimbursement for pharmacy services.	Defines drug reimbursement under the new EAPG methodology so that drug payments will still be eligible for drug rebates.



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Final Text

Action: Enhanced Ambulatory Patient Group Out Patient Hospital ...**Stage:** Final

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12VAC30-80-20. Services that are reimbursed on a cost basis.

A. Payments for services listed below in this section shall be on the basis of reasonable cost following the standards and principles applicable to the Title XVIII Program with the exception provided for in subdivision D 1 d e of this section. The upper limit for reimbursement shall be no higher than payments for Medicare patients on a facility by facility basis in accordance with 42 CFR 447.321 and 42 CFR 447.325. In no instance, however, shall charges for beneficiaries of the program be in excess of charges for private patients receiving services from the provider. The professional component for emergency room physicians shall continue to be uncovered as a component of the payment to the facility.

B. Reasonable costs will be determined from the filing of a uniform cost report by participating providers. The cost reports are due not later than 150 days after the provider's fiscal year end. If a complete cost report is not received within 150 days after the end of the provider's fiscal year, the Program shall take action in accordance with its policies to assure that an overpayment is not being made. The cost report will be judged complete when DMAS has all of the following:

1. Completed cost reporting form(s) provided by DMAS, with signed certification (s);
2. The provider's trial balance showing adjusting journal entries;
3. The provider's financial statements including, but not limited to, a balance sheet, a statement of income and expenses, a statement of retained earnings (or fund balance), and a statement of changes in financial position;
4. Schedules that reconcile financial statements and trial balance to expenses claimed in the cost report;
5. Depreciation schedule or summary;
6. Home office cost report, if applicable; and
7. Such other analytical information or supporting documents requested by DMAS when the cost reporting forms are sent to the provider.

C. Item 398 D of the 1987 Appropriation Act (as amended), effective April 8, 1987, eliminated reimbursement of return on equity capital to proprietary providers.

D. The services that are cost reimbursed are:

1. ~~Outpatient~~ For dates of service prior to January 1, 2014, outpatient hospital services, including rehabilitation hospital outpatient services and excluding laboratory services.

a. Definitions. The following words and terms when used in this regulation shall have the following meanings when applied to emergency services unless the context clearly indicates otherwise:

"All-inclusive" means all emergency department and ancillary service charges claimed in association with the emergency room visit, with the exception of laboratory services.

"DMAS" means the Department of Medical Assistance Services consistent with Chapter 10 (§ 32.1-323 et seq.) of Title 32.1 of the Code of Virginia.

"Emergency hospital services" means services that are necessary to prevent the death or serious impairment of the health of the recipient. The threat to the life or health of the recipient necessitates the use of the most accessible hospital available that is equipped to furnish the services.

"Recent injury" means an injury that has occurred less than 72 hours prior to the emergency department visit.

b. Scope. DMAS shall differentiate, as determined by the attending physician's diagnosis, the kinds of care routinely rendered in emergency departments and reimburse for nonemergency care rendered in emergency departments at a reduced rate.

(1) With the exception of laboratory services, DMAS shall reimburse at a reduced and all-inclusive reimbursement rate for all services rendered in emergency departments that DMAS determines were nonemergency care.

(2) Services determined by the attending physician to be emergencies shall be reimbursed under the existing methodologies and at the existing rates.

(3) Services performed by the attending physician that may be emergencies shall be manually reviewed. If such services meet certain criteria, they shall be paid under the methodology for subdivision 1 b (2) of this subsection. Services not meeting certain criteria shall be paid under the methodology of subdivision 1 b (1) of this subsection. Such criteria shall include, but not be limited to:

(a) The initial treatment following a recent obvious injury.

(b) Treatment related to an injury sustained more than 72 hours prior to the visit with the deterioration of the symptoms to the point of requiring medical treatment for stabilization.

(c) The initial treatment for medical emergencies including indications of severe chest pain, dyspnea, gastrointestinal hemorrhage, spontaneous abortion, loss of consciousness, status epilepticus, or other conditions considered life threatening.

(d) A visit in which the recipient's condition requires immediate hospital admission or the transfer to another facility for further treatment or a visit in which the recipient dies.

(e) Services provided for acute vital sign changes as specified in the provider manual.

(f) Services provided for severe pain when combined with one or more of the other guidelines.

(4) Payment shall be determined based on ICD diagnosis codes and necessary supporting documentation. As used here, the term "ICD" is defined in 12VAC30-95-5.

(5) DMAS shall review on an ongoing basis the effectiveness of this program in achieving its objectives and for its effect on recipients, physicians, and hospitals. Program components may be revised subject to achieving program intent, the accuracy and effectiveness of the ICD code designations, and the impact on recipients and providers. As used here, the term "ICD" is defined in 12VAC30-95-5.

c. Limitation of allowable cost. Effective for services on and after July 1, 2003, reimbursement of Type Two hospitals for outpatient services shall be at various percentages as noted in subdivisions 1 c (1) and 1 c(2) of this subsection of allowable cost, with cost to be determined as provided in subsections A, B, and C of this section. For hospitals with fiscal years that do not begin on July 1, outpatient costs, both operating and capital, for the fiscal year in progress on that date shall be apportioned between the time period before and the time period after that date, based on the number of calendar months in the cost reporting period, falling before and after that date.

(1) Type One hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating reimbursement shall be at 91.2% of allowable cost and capital reimbursement shall be at 87% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating reimbursement shall be at 90.2% of allowable cost and capital reimbursement shall be at 86% of allowable cost.

(2) Type Two hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating and capital reimbursement shall be 77% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating and capital reimbursement shall be 76% of allowable cost.

d. The last cost report with a fiscal year end on or after December 31, 2013, shall be used for reimbursement for dates of service through December 31, 2013, based on this section. Reimbursement shall be based on charges reported for dates of service prior to January 1, 2014. Settlement will be based on four months of runout from the end of the provider's fiscal year. Claims for services paid after the cost report runout period will not be settled.

e. Payment for direct medical education costs of nursing schools, paramedical programs and graduate medical education for interns and residents.

(1) Direct medical education costs of nursing schools and paramedical programs shall continue to be paid on an allowable cost basis.

(2) Effective with cost reporting periods beginning on or after July 1, 2002, direct graduate medical education (GME) costs for interns and residents shall be reimbursed on a per-resident prospective basis. See 12VAC30-70-281 for prospective payment methodology for graduate medical education for interns and residents.

2. Rehabilitation agencies or comprehensive outpatient rehabilitation.

- a. Effective July 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities that are operated by community services boards or state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see 12VAC30-80-200.
- b. Effective October 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities operated by state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see 12VAC30-80-200.

12VAC30-80-36. Fee-for-service providers: outpatient hospitals.

A. Definitions. The following words and terms when used in this section shall have the following meanings unless the context clearly indicates otherwise:

"Enhanced ambulatory patient group" or "EAPG" means a defined group of outpatient procedures, encounters, or ancillary services that incorporates International Classification of Diseases (ICD) diagnosis codes, Current Procedural Terminology (CPT) codes, and Healthcare Common Procedure Coding System (HCPCS) codes.

"EAPG relative weight" means the expected average costs for each EAPG divided by the relative expected average costs for visits assigned to all EAPGs.

"Base year" means the state fiscal year for which data is used to establish the EAPG base rate. The base year will change when the EAPG payment system is rebased and recalibrated. In subsequent rebasings, [the Commonwealth DMAS] shall notify affected providers of the base year to be used in this calculation.

"Cost" means the reported cost as described in 12VAC30-80-20 A and B.

"Cost-to-charge ratio" equals the hospital's total costs divided by the hospital's total charges. The Cost-to-charge ratio shall be calculated using data from cost reports from hospital fiscal years ending in the state fiscal year used as the base year.

"Medicare wage index" means the Medicare wage index published annually in the Federal Register by the Centers for Medicare and Medicaid Services. The indices used in this section shall be those in effect in the base year.

B. Effective January 1, 2014, the prospective enhanced ambulatory patient group (EAPG) based payment system described in this subsection shall apply to reimbursement for outpatient hospital services (with the exception of laboratory services referred to the hospital but not associated with an outpatient hospital visit, which will be reimbursed according to the laboratory fee schedule).

1. The payments for outpatient hospital visits shall be determined on the basis of a hospital-specific base rate per visit multiplied by the relative weight of the EAPG (and the payment action) assigned for each of the services performed during a hospital visit.

2. The EAPG relative weights shall be the weights determined and published periodically by DMAS and shall be consistent with applicable Medicaid reimbursement limits and policies. The weights shall be updated at least every three years.

3. The statewide base rate shall be equal to the total costs described in this subdivision divided by the wage-adjusted sum of the EAPG weights for each facility. The wage-adjusted sum of the EAPG weights shall equal the sum of the EAPG weights multiplied by the labor percentage times the hospital's Medicare wage index plus the sum of the EAPG weights multiplied by the nonlabor

percentage. The base rate shall be determined for outpatient hospital services at least every three years so that total expenditures will equal the following:

a. When using base years prior to January 1, 2014, for all services, excluding all laboratory services and emergency services described in subdivision 3 c of this subsection, a percentage of costs as reported in the available cost reports for the base period for each type of hospital as defined in 12VAC30-70-221.

(1) Type One hospitals. Effective January 1, 2014, hospital outpatient operating reimbursement shall be calculated at 90.2% of cost, and capital reimbursement shall be at 86% of cost inflated to the rate year.

(2) Type Two hospitals. Effective January 1, 2014, hospital outpatient operating and capital reimbursement shall be calculated at 76% of cost inflated to the rate year.

When using base years after January 1, 2014, the percentages described in subdivision 3 a of this subsection shall be adjusted according to subdivision 3 c of this subsection.

b. Laboratory services, excluding laboratory services referred to the hospital but not associated with a hospital visit, are calculated at the fee schedule in effect for the rate year.

c. Services rendered in emergency departments determined to be nonemergencies as prescribed in 12VAC30-80-20 D 1 b shall be calculated at the nonemergency reduced rate reported in the base year for base years prior to January 1, 2014. For base years after January 1, 2014, the cost percentages in subdivision 3 a of this subsection shall be adjusted to reflect services paid at the nonemergency reduced rate in the last [base] year prior to January 1, 2014.

4. Inflation adjustment to base year costs. Each July, the Virginia moving average values as compiled and published by Global Insight (or its successor), under contract with DMAS, shall be used to update the base year costs to the midpoint of the rate year. The most current table available prior to the effective date of the new rates shall be used to inflate base year amounts to the upcoming rate year. Thus, corrections made by Global Insight (or its successor) in the moving averages that were used to update rates for previous state fiscal years shall be automatically incorporated into the moving averages that are being used to update rates for the upcoming state fiscal year. Inflation shall be applied to the costs identified in subdivision 3 a of this subsection.

5. Hospital-specific base rate. The hospital-specific base rate per case shall be adjusted for geographic variation. The hospital-specific base rate shall be equal to the labor portion of the statewide base rate multiplied by the hospital's Medicare wage index plus the nonlabor percentage of the statewide base rate. The labor percentage shall be determined at each rebasing based on the most recently reliable data. For rural hospitals, the hospital's Medicare wage index used to calculate the base rate shall be the Medicare wage index of the nearest metropolitan wage area or the effective Medicare wage index, whichever is higher. A base rate differential of 5.0% shall be established for freestanding Type Two children's hospitals. The base rate for noncost-reporting hospitals shall be the average of the hospital-specific base rates of in-state Type Two hospitals.

6. The total payment shall represent the total allowable amount for a visit including ancillary services and capital.

7. The transition from cost-based reimbursement to EAPG reimbursement shall be transitioned over a four-year period. DMAS shall calculate a cost-based base rate at January 1, 2014, and at each rebasing during the transition.

a. Effective for dates of service on or after January 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 75% of the cost-based base rate and 25% of the EAPG base rate.

b. Effective for dates of service on or after July 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 50% of the cost-based base rate and 50% of the EAPG base rate.

c. Effective for dates of service on or after July 1, 2015, DMAS shall calculate the hospital-specific base rate as the sum of 25% of the cost-based base rate and 75% of the EAPG base rate.

d. Effective for dates of service on or after July 1, 2016, DMAS shall calculate the hospital-specific base rate as the EAPG base rate.

8. To maintain budget neutrality during the first six years of the transition to EAPG reimbursement, DMAS shall compare the total reimbursement of hospital claims based on the parameters in subdivision 3 of this subsection to EAPG reimbursement every six months based on the six months of claims ending three months prior to the potential adjustment. If the percentage difference between the reimbursement target in subdivision 3 of this subsection and EAPG reimbursement is greater than 1.0%, plus or minus, DMAS shall adjust the statewide base rate by the percentage difference the following July 1 or January 1. The first possible adjustment would be January 1, 2015, using reimbursement between January 1, 2014, and October 31, 2014.

C. The enhanced ambulatory patient group (EAPG) grouper version used for outpatient hospital services shall be determined by DMAS. Providers or provider representatives shall be given notice prior to implementing a new grouper.

D. The primary data sources used in the development of the EAPG payment methodology are the DMAS hospital computerized claims history file and the cost report file. The claims history file captures available claims data from all enrolled, cost-reporting general acute care hospitals. The cost report file captures audited cost and charge data from all enrolled general acute care hospitals. The following table identifies key data elements that are used to develop the EAPG payment methodology. DMAS may supplement this data with similar data for Medicaid services furnished by managed care organizations if DMAS determines that it is reliable.

<u>Data Elements for EAPG Payment Methodology</u>	
<u>Data Elements</u>	<u>Source</u>
<u>Total charges for each outpatient hospital visit</u>	<u>Claims history file</u>
<u>Number of groupable claims lines in each EAPG</u>	<u>Claims history file</u>
<u>Total number of groupable claim lines</u>	<u>Claims history file</u>
<u>Total charges for each outpatient hospital revenue line</u>	<u>Claims history file</u>
<u>Total number of EAPG assignments</u>	<u>Claims history file</u>
<u>Cost-to-charge ratio for each hospital</u>	<u>Cost report file</u>
<u>Medicare wage index for each hospital</u>	<u>Federal Register</u>

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

Payment for pharmacy services (excluding outpatient hospital) 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. for example, 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 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 <http://www.dmas.virginia.gov/Content/pgs/pharm-home.aspx>.

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~~ in subdivisions 1 through 5 of this section; 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.

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

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

10. Each drug administered in an outpatient hospital setting and reimbursed based on the enhanced ambulatory patient group methodology, as described in 12VAC30-80-36, shall be reimbursed separately at a rate greater than zero to be eligible for drug rebate claiming.