Virginia Regulatory Town Hall

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30-80
Regulation title	Methods and Standards for Establishing Payment Rates—Other Types of Care Pharmacy Reimbursement
Action title	MAC Reimbursement Methodology for Specialty Drugs
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 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

This final action completes the implementation of a method of reimbursement for specialty drugs, which are covered by the Virginia Medicaid program, based on the Wholesale Acquisition Cost of the drug. Specialty drug products are those which are used to treat chronic, high-cost or rare diseases, including drugs for the treatment of Hepatitis-C and Multiple Sclerosis, as well as drugs such as growth hormone agents and interferon. These drugs tend to be much higher in cost than standard pharmaceutical products, can sometimes require special handling techniques and typically also require unique patient education and monitoring. This action implements a new methodology to help contain the higher costs associated with these drugs. In the near future, DMAS will be designing and implementing a system of care management for the Medicaid recipients who require these medications. The only change being made in this final stage from the proposed stage is the correction of an internal citation.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background document with the attached amended State Plan pages MAC Reimbursement Methodology for Specialty Drugs (12VAC 30-80-40) and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012, of the Administrative Process Act. I hereby certify that these regulations are full, true, and correctly dated.

_____ _____

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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.

Chapter 879 of the *2008 Acts of the Assembly*, Item 306 CC directed DMAS to promulgate emergency regulations to provide for this new specialty drug reimbursement methodology. DMAS complied with that mandate and is currently reimbursing for the drug products affected by this action under that new reimbursement methodology.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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.

This is the final step in the regulatory process in which the Department is promulgating this regulation to create a specialty drug reimbursement methodology based upon the Wholesale Acquisition Cost (WAC) of designated specialty drugs. Specialty drug products are products used to treat chronic, high-cost or rare diseases, including drugs for the treatment of Hepatitis-C and Multiple Sclerosis, as well as drugs such as growth hormone agents and interferon. These drugs tend to be much higher in cost than standard pharmaceutical products and also tend to have significantly higher per patient costs. This action finalizes a new methodology to help contain the higher costs associated with these drugs. This action is not expected to affect the health, safety, or welfare of citizens of the Commonwealth as it is a reimbursement methodology change. DMAS paid for these drugs prior to the current emergency regulations but with a methodology that was not as well controlled and lacked the care management component.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The section of the State Plan for Medical Assistance that is affected by this action is Methods and Standards for Establishing Payment Rates—Other Types of Care: Pharmacy Services (12 VAC 30-80-40).

Prior to the emergency regulation, DMAS' regulations contained no specific provisions for the reimbursement of specialty drugs. These drugs were paid for, along with all other covered pharmaceuticals, under the existing reimbursement methodology set out in 12VAC30-80-40. The payment algorithm pays for drugs at the lowest of either: (i) the Federal Upper Limit, (ii) the higher of either the lowest Wholesale Acquisition Cost (WAC) plus 10%, or the second lowest WAC plus 6%, (iii) the provider's usual and customary charge to the public OR (iv) the Estimated Acquisition Cost. Generally, these drugs are being reimbursed at the rate of the Wholesale Acquisition Cost plus 4.75%. Due to advances in pharmaceutical technology which typically produce even more expensive and complex pharmaceutical products, DMAS has determined that it would be appropriate to separate out this particular group of drugs for a unique payment and care management methodology.

Specialty (or 'biotechnology') drugs are a category of drugs resulting from advances in drug development research, technology, and design. These drugs are used to treat specific chronic or genetic conditions. Specialty drugs include biological drugs, blood-derived products, complex molecules, and select oral, injectable and infused medications. They also typically include

tailored patient education for safe and cost-effective use, patient-specific dosing, close patient monitoring, and can require special handling (such as refrigeration). Examples of some conditions that specialty drugs address include Acromegaly, Cancer, Chronic Granulomatous Disease, Cystic Fibrosis, HIV/AIDS, Multiple Sclerosis, Psoriasis, Rheumatoid Arthritis, Hepatitis C, and Respiratory Syncytial Virus (RSV).

Specialty drugs have a direct impact on any health benefit program's prescription drug expenditures. A 2004 DMAS analysis revealed that nationwide, total population spending on specialty medications grew 26.6 percent in 2003 with surges in treatments for Rheumatoid Arthritis and Cancer. According to the 2004 analysis, annual per patient costs of specialty drug therapies can range from $6,000 to $350,000 annually. Total public and private sector spending reached $54 billion by the end of 2007 and is expected to reach $100 billion by 2010. In Virginia, it is estimated that within the fee-for-service component of the Medicaid program, about $18 million annually is expended on specialty drugs related to only five chronic or genetic conditions. This point-of-sale data represented 9,000 claims and affected only 2,700 individual recipients.

Recipients who receive care through managed care organizations (MCOs) currently get their prescriptions through the MCO's network of providers. MCOs, via the capitation payments received from Medicaid, provide all required prescription drugs and assume the risk that one of their members will require such specialty prescriptions. No additional payments are made to MCOs in such instances. A 2005 article from a Cigna Pharmacy Management newsletter indicates that the cost of specialty drugs is increasing up to 30% annually, and utilization of these medications is increasing at a rate near 20%. Furthermore, at any given time approximately 800 new specialty drugs are under development; these new specialty drugs drive significant increases in medical expenditures. The rapid expansion of biotechnology drugs makes it the fastest growing segment for drug costs in America.

In an effort to control the growing costs of specialty drugs and improve the health outcomes of these affected recipients, DMAS proposed the development of a specialty drug program. Appropriations Act language was included in the 2006-2008 budget language during the 2006 General Assembly to support the funding of a specialty drug program. In implementing a specialty drug program, DMAS has focused on (i) implementing an appropriate care management model for those patients who require specialty drug therapy and (ii) establishing a discounted pricing model. In achieving these objectives, DMAS is working to limit disruption in the specialty drug market, maintain patient access to specialty drugs, and minimize administrative requirements.

This action makes final and permanent a new methodology for the reimbursement of designated specialty drugs. The new methodology, described in the new subsection 5 of 12 VAC 30-80-40, is a formula based upon the Wholesale Acquisition Cost (WAC) of these specialty drugs. The methodology computes a price above a given percentage of the WAC for each specified drug. The current percentage value is 4.75%. In addition to the formula, the new subsection also references the location of the list of designated drugs subject to the new methodology on the DMAS website, and states that the new pricing methodology is reviewed and subject to the same

dispute resolution and appeal rights as the standard Maximum Allowable Cost pricing methodology. Lowering the percentage of Average Wholesale Price (AWP) that DMAS pays for the specified specialty drugs will help limit some of the rising costs associated with specialty drugs.

Presently, both physicians and pharmacies are permitted to obtain these specialty drugs from manufacturers and bill their costs to the Medicaid program for Medicaid recipients. As a result of federal statutory requirements in the Deficit Reduction Act of 2005, DMAS is now securing rebates from the pharmaceutical manufacturers for these drugs. This open access by all such providers will not be affected by this regulatory action.

Specialty drugs are a dynamic group of emerging medications, and different strategies will have to be employed to better manage these expenditures, and coordinate patient care. The Department is working with its Pharmacy Liaison Committee and other interested parties to develop appropriate care coordination models as part of the later phase of the specialty drug program. Through this process, DMAS and its partners will further identify additional disease conditions that lend themselves to improved outcomes when under specialty drug management and develop a program design that will most effectively manage these conditions.

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.

Specialty pharmaceuticals represent the fastest growing segment of the prescription drug market in the U.S. Industry projections estimate the growth rate at 20% per year. Typically, these products are used to treat complex chronic and/or rare diseases, are high-cost, and can be administered by injection, infusion inhalation, or orally. DMAS implemented this regulation in an effort to help contain the costs of these complex and expensive drugs and to improve care management for these affected recipients. Pharmacy reimbursement is one of the highest dollar expenditures in the Medicaid budget.

The primary advantage to the Commonwealth of this regulatory action is expected to be improved health outcomes for these affected recipients as well as some cost savings for the agency and Commonwealth. The disadvantage to the pharmaceutical industry will be reduced profits due to reduced payments for these drugs.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

The only change being made in this final stage from the proposed stage is the correction of an internal citation.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC 30-80-40 (4)	This VAC section references subdivision 9	The methodology for the Estimated Acquisition Cost (EAC) is referenced in subdivision 8 instead of 9.	This action corrects an internal citation relative to number 4 changing the reference from subdivision 9 to subdivision 8.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

DMAS' proposed regulations were published in the June 8, 2009, *Virginia Register* for their public comment period from June 8, 2009, through August 7, 2009. There were no comments received during the public comment period.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 30-80-40	12 VAC 30-80-40(5)	This VAC section currently does not provide for unique reimbursement for specialty drugs as such drugs were covered by	This action creates a separate provision for the reimbursement of specialty drugs. The previous emergency regulation stage placed this provision at item 10. This proposed text is moved up to item 5 for inclusion with the existing 4-part

		the existing four part algorithm.	payment algorithm. The text is modified from the current emergency stage to show that the lowest rate of reimbursement will be paid regardless of by which methodology it is obtained.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

With this regulatory action, DMAS is not creating any new regulatory requirements that will affect small businesses. There is no compliance or reporting requirements, nor will any operational changes be required for small businesses as a consequence of this regulatory action.

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.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or 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. It does not strengthen or erode the marital commitment, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.