Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES (DMAS)
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

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

This proposed action creates 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.

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 number(s), if applicable, and (2) promulgating entity, i.e., the 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 by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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 implements 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" 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).

Currently, DMAS' regulations contain no specific provisions for the reimbursement of specialty drugs. These drugs are currently 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 Drug 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 ever 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 M annually is expended on specialty drugs related to only five chronic or genetic conditions. This point-of-sale data represented 9000 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 has 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 implements 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 will work 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.

DMAS may contract with a vendor to create a care management program for recipients with selected conditions requiring specialty drugs. Care management is expected to provide monitoring of patients' utilization of services and relevant clinical data specific to each condition. The patient would be contacted directly and care coordination would be provided, when necessary. This program would be similar to the current disease management model being used by DMAS to manage selected health conditions (e.g., asthma, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and diabetes). Some recipients of specialty drugs already receive care management services from their specialty pharmacy providers, such as confidential counseling, compliance monitoring, educational information, and health care coordination. DMAS will continue to research opportunities to improve care management for recipients with hemophilia and implement services directly and/or through coordination with specialty pharmacies.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so 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 is promulgating 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.

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.

There are no federal requirements applicable to this policy issue.

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.

There are no localities that will be uniquely affected by this regulatory action as these policies will apply statewide.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

To better understand specialty drug programs, DMAS staff conducted an analysis of specialty drugs programs to ascertain which model would be best suited for Virginia's Medicaid program. As part of the analysis, DMAS met with experts from (i) specialty pharmacy vendors; (ii) pharmaceutical manufacturers; (iii) other states, and; (iv) the federal funding agency, the Centers for Medicare and Medicaid Services (CMS).

DMAS determined, in its meetings with industry representatives, that only two states, Pennsylvania and Maine, have recently implemented specialty drug methodologies for their Medicaid recipients. Moreover, there is little information available from private sector models focusing on care management strategies for recipients who have chronic or genetic conditions that are treated with specialty drugs.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Keith Hayashi, R.Ph., Pharmacy Services, Division of Healthcare Services, DMAS, 600 East Broad Street, Suite 1300, Richmond, VA 23219, (804-225-2773; 804-786-5799 FAX, email Keith.Hayashi@DMAS.virginia.gov)**.** Written comments must include the name and address of the commenter. In order to be considered, comments must be received by close of business on the last date of the advertised public comment period. Written comments may also be submitted via the Virginia Regulatory Town Hall website (www.townhall.virginia.gov).

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	Initial cost of $63,750. Ongoing maintenance costs of not more than $75,000 per year through 2010.
Projected cost of the regulation on localities	None.
Description of the individuals, businesses or other entities likely to be affected by the regulation	All physician and pharmacy enrolled providers that currently provide specialty drugs will be affected by this action. Some of these providers will likely meet the definition of a small business. This regulatory action imposes no new requirements beyond those currently in place for these enrolled providers.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	A total of 1,750 pharmacies in Virginia, of which approximately 28% (500) are small businesses.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There are no additional costs to affected entities beyond those already incurred in billing DMAS for prescription drugs.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There were several approaches available to DMAS to accomplish the goal of controlling expenditures for specialty drugs. DMAS has chosen a hybrid approach in order to maximize available savings while not compromising clinical management of the complex conditions associated with the use of these drugs. To gain experience in this new area, DMAS is approaching the specialty drug program through a phased-in implementation. To date, specialty drugs have been addressed through a collection of rebates for physician-administered specialty drugs and the introduction of two specialty drug classes on Virginia Medicaid's Preferred Drug List, which achieves both clinical management and cost savings (via supplemental rebates) for these two classes. Finally, DMAS has determined that not all specialty drug classes should be subject to the program due to the complexities of clinical management and market conditions related to the drugs.

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 are no compliance or reporting requirements, nor will any operational changes be required for small businesses as a consequence of this regulatory action.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

DMAS' Notice of Intended Regulatory Action (NOIRA) was published in the August 18, 2008, *Virginia Register* (VR 24:25) for its public comment period from August 18, 2008, to October 1, 2008. No comments were received during the NOIRA comment period

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.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

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 the existing four part algorithm.	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 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.