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Proposed Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12 VAC 30-80-40
Regulation title(s)	Fee-for-service providers: pharmacy
Action title	Pharmacy fee-for-service reimbursement
Date this document prepared	October 23, 2017

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 (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

DMAS proposes to revise its pharmacy reimbursement methodology for the Medicaid fee-for-service program from the current methodology (set out in 12VAC30-80-40) to one that meets the drug pricing definition described in a CMS final rule that was published in the Federal Register on February 1, 2016. The rule requires states to pay pharmacies based on the drug's ingredient cost, defined as the actual acquisition cost (AAC) plus a "professional dispensing fee". Before an emergency regulation on this topic went into place, DMAS utilized an estimated acquisition cost (EAC) methodology to pay pharmacies that is based on "lesser of" logic that reimburses pharmacies using the federal upper payment limit (FUL), Virginia's maximum allowable cost (MAC), Virginia specialty maximum allowable cost (SMAC), the estimated acquisition cost (EAC) or the provider's usual and customary (U&C) amount plus a dispensing fee, whichever is

less. Virginia's EAC was based on the published Average Wholesale Price (AWP) minus a percentage discount established by the Virginia General Assembly (12 VAC30-80-40). This methodology did not meet the requirements of the new federal rule and the DMAS dispensing fee of $3.75 did not reflect actual dispensing costs and does not meet the CMS proposed definition of a "professional dispensing fee". DMAS issued an emergency regulation to meet the new federal requirements. This proposed stage regulation follows the emergency regulation. CMS has reviewed and approved the revised language.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

AAC = Actual Acquisition Cost
AWP = Average Wholesale Price
CMS = Centers for Medicare and Medicaid Services
DMAS = Department of Medical Assistance Services
EAC = Estimated Acquisition Cost
FUL = Federal Upper Payment Limit
NADAC = National Average Drug Acquisition Cost
SMAC = Specialty Maximum Allowable Cost
U & C = Usual and Customary

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 2016 *Acts of the Assembly*, Chapter 780, Item 306.OO, and the 2017 *Acts of Assembly*, Chapter 836, Item 306.OO, directed the agency to promulgate emergency regulations to implement to implement a pricing methodology to modify or replace the current pricing methodology for pharmaceutical products as defined in 12 VAC 30-80-40 within 280 days or less from the enactment of the Act.

These proposed stage regulations follow the emergency regulations, which are already in place.

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.

DMAS is proposing this regulatory change to 12VAC30-80-40 in order to meet the requirements of the CMS final rule (available at https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf) as well as to comply with Virginia budget appropriations language that requires DMAS to implement a pricing methodology that is cost neutral or creates cost savings.

In order to develop a pricing methodology that meets both the requirements of the new rule and that is cost neutral or creates cost savings, DMAS proposes to utilize the CMS National Average Drug Acquisition Cost (NADAC), which is offered by CMS to meet, in part, their definition of AAC. NADAC is based on a comprehensive national survey carried out on behalf of CMS that provides wholesale purchase prices of all covered drugs by retail community pharmacies in the United States and published weekly by CMS.

In order to establish a reasonable dispensing fee that meets the CMS definition of AAC and a "professional dispensing fee" referenced in their proposed rule, DMAS, in collaboration with Myers and Stauffer (a nationally recognized leader in developing pricing) carried out a cost of dispensing survey in 2014. Myers and Stauffer determined that the weighted average cost of dispensing prescriptions to Virginia Medicaid members is $10.65. DMAS then carried out a fiscal impact analysis using the most recent 9 months of prior pharmacy claims data and a spread of dispensing fees ranging from $10 to $10.75. This fiscal impact analysis concluded that DMAS would obtain cost savings ranging between $0.2 and $1.3 million dollars per year, in addition to saving $88,000 per year with the elimination of the MAC program by using the NADAC.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

DMAS proposes to change its fee-for-service pricing methodology in 12VAC30-80-40 from the lessor of payment logic that reimburses Medicaid-enrolled pharmacies for drug ingredients based on the lowest of the FUL, MAC, SMAS, EAC or the U&C and the dispensing fee of $3.75 with a new pricing methodology using the NADAC and a dispensing fee that reflects the actual costs of dispensing by Virginia Medicaid pharmacies. The new pricing methodology will reimburse pharmacies for drug ingredients based on the lowest of NADAC, WAC or U&C plus a dispensing fee of $10.65. This dispensing fee was obtained utilizing a methodologically sound cost of dispensing survey carried out by a national leader in determining cost of dispensing, Myers and Stauffer.

CURRENT POLICY

In current state regulation (12VAC30-80-40) DMAS utilizes an estimated acquisition cost (EAC) methodology to pay pharmacies that is based on a "lessor of" logic that reimburses pharmacies using either FUL, MAC, SMAC, EAC or the provider's U&C amount plus a dispensing fee, whichever is less. Virginia's current EAC is based on the published Average Wholesale Price (AWP) minus a percentage discount established by the Virginia General Assembly (12 VAC30-80-40). The current DMAS dispensing fee is $3.75, which does not reflect actual dispensing costs and does not meet the CMS proposed definition of a "professional dispensing fee".

ISSUES

Current state regulations governing Virginia Medicaid fee-for-service prescription drug pricing methodology under 12VAC30-80-40 no longer comply with Federal regulations. In order for the Commonwealth to comply with Federal regulations that govern how states reimburse drug ingredient costs under its Medicaid fee-for-service programs, DMAS is required to change its drug ingredient cost pricing methodology and dispensing fee reimbursement rate to meet the new definition of "AAC" and "professional dispensing fee".

RECOMMENDATIONS

DMAS is proposing regulatory changes to 12VAC30-80-40 that eliminate the lessor of pricing logic described earlier in this document, replacing it with the NADAC wholesale price survey and reimbursing Medicaid enrolled Virginia pharmacies a professional dispensing fee based on the actual cost of dispensing, which is based on a methodologically sound, state wide survey of pharmacies carried out by Myers and Stauffer. This proposed methodology meets both the Federal regulatory requirements and the current Virginia appropriations language, which requires DMAS to develop a drug pricing methodology that is cost neutral or produces cost savings.

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.

The primary advantage of this regulatory action is that it will allow DMAS to comply with federal regulations. There are no disadvantages to the public, the agency, 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.

There are no requirements more restrictive than federal requirements in these regulations.

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.

No localities will be particularly affected because these regulations 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.

In addition to any other comments, the [insert either: Board or 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 for the public comment file may do so by mail, email or fax to [insert: staff contact person's name, mailing address, phone number, fax number and email address]. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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	The new reimbursement methodology is expected to be cost neutral.
Projected cost of the new regulations or	There are no costs to localities.

changes to existing regulations on localities.	
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Pharmacies that participate in Medicaid and CHIP will be affected.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	1400 pharmacies participate with DMAS, and some of these are small businesses.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no reporting, recordkeeping, or other administrative costs associated with this regulation. There are no costs related to the development of real estate.
Beneficial impact the regulation is designed to produce.	The regulation will allow DMAS to comply with federal requirements.

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.

No alternatives will meet the federal regulatory requirements.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

No alternatives will meet the federal regulatory requirements.

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; nor 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.

Public comment

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

No comments were received during the public comment period.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

There are no changes since the emergency regulation.

The changes that were included in the emergency regulation are as follows.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC30-80-40		DMAS utilizes an estimated acquisition cost	DMAS is proposing regulatory changes to 12VAC30-80-40 that

		(EAC) methodology to pay pharmacies that is based on a "lessor of" methodology that reimburses pharmacies using either FUL, MAC, SMAC, EAC or the provider's U&C amount plus a dispensing fee, whichever is less. Virginia's current EAC is based on the published Average Wholesale Price (AWP) minus a percentage discount established by the Virginia General Assembly (12 VAC30-80-40). The current DMAS dispensing fee is $3.75	replaces the current lessor of pricing logic with the lesser of NADAC, WAC or U&C and reimbursing Medicaid enrolled Virginia pharmacies a professional dispensing fee based on the actual cost of dispensing which is based on a methodologically sound, state wide survey of pharmacies carried out by Myers and Stauffer. This proposed methodology meets both the Federal regulatory requirement and the current Virginia appropriations language which requires DMAS to develop a drug pricing methodology that is cost neutral or produces cost savings.