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Final Regulation
Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12 VA 30-80-40
Regulation title(s)	Fee-for-service providers: pharmacy
Action title	Pharmacy fee-for-service reimbursement
Date this document prepared	2/8/19

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

These regulations revise the DMAS pharmacy reimbursement methodology for the Medicaid fee-for-service program 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 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 final 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

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 Regulatory Review Summary entitled Pharmacy Fee-for-Service Reimbursement 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.

2/8/19
Date

/signature/
Jennifer S. Lee, M.D., Director
Dept. of Medical Assistance Services

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

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 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 final regulations follow the emergency regulations that are already in place.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must 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 or promulgating entity'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 and to promulgate regulations. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance and to promulgate regulations 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.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's 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, FUL, 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.

In the old version of the state regulation (12VAC30-80-40) DMAS utilized an estimated acquisition cost (EAC) methodology to pay pharmacies that was 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 was less. Virginia's EAC was based on the published Average Wholesale Price (AWP) minus a percentage discount established by the Virginia General Assembly. The DMAS dispensing fee was $3.75, which did not reflect actual dispensing costs and did not meet the CMS proposed definition of a "professional dispensing fee".

The state regulations governing Virginia Medicaid fee-for-service prescription drug pricing methodology under 12VAC30-80-40 did not comply with Federal regulations. In order to comply with Federal regulations that govern how states reimburse drug ingredient costs under its Medicaid fee-for-service programs, DMAS was 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".

DMAS proposed 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 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 regulatory change, 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, include a specific statement to that effect.

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 list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

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

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

No localities or other state agencies or entities will be particularly affected.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Individual	The commenter is concerned that by using the most recent 9 months of prior pharmacy claims using a spread of dispensing fees ranging	DMAS is complying with new federal regulations that require a pharmacy reimbursement methodology based on average acquisition cost (AAC) and a

	from $10 to $10.75, DMAS may not be adequate to predict the effect of long-term pharmaceutical market volatility. Observing analysis of similar NADAC implementation plans in other states, and seeing differences in policy and economic impact outcomes, the commenter notes that a small frame of data collection may be misleading. In addition, the commenter is concerned about rapid increases in market costs that undermine expected NADAC cost models, and is concerned about high-priced specialty products like biologics. The commenter notes that there are lags in NADAC pricing, and these prices do not include rebates and discounts.	professional dispensing fee. DMAS understands the concerns of the commenter, and will evaluate the dispensing fee on an ongoing basis to ensure that it is appropriate. If circumstances require a change in the dispensing fee, DMAS will submit the proposed change to CMS for review.

Detail of Changes Made Since the Previous Stage

*Please list all changes that made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

No changes have been made since the proposed stage.