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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	New Fee-for-service pharmacy reimbursement methodology
Date this document prepared	November 27, 2016

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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". DMAS currently utilizes 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 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). This methodology does not meet the requirements of the new rule. Additionally, the current DMAS dispensing fee of $3.75 does not reflect actual dispensing costs and does not meet the CMS proposed definition of a "professional dispensing fee".

DMAS has rewritten its regulations to conform to the CMS final rule, and CMS has approved the revised language.

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

Section 2.2-4011 of the *Code of Virginia* states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006(A)(4). The 2016 *Acts of the Assembly*, Chapter 780, 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.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled (Pharmacy Fee-for-Service Reimbursement; 12 VAC 30-80-40) and also authorize the initiation of the promulgation process provided for in § 2.2-4007.

Legal basis

Other than the emergency authority described above, 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) the promulgating entity, i.e., agency, board, or person.

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 "make, adopt, promulgate, and enforce" regulations to implement the state plan. 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.

In addition, Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

The 2016 *Acts of the Assembly*, Chapter 780, 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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 current 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 a "professional dispensing fee" referenced in their proposed rule, DMAS contracted with Myers and Stauffer (a nationally recognized leader in developing pricing) to carry 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 and a dispensing fee of $10.65.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

This proposed regulatory change is needed in order to comply with Federal regulations. In addition, DMAS is required by the Virginia General Assembly to develop a drug pricing methodology that either generates cost savings or is cost neutral. The proposed changes in this regulatory action meet the new definition of AAC as defined by the Federal rule, and will generate additional cost savings to the Commonwealth. Additionally, the proposed regulatory change will reimburse Medicaid enrolled pharmacies a reasonable dispensing fee based on a sound survey methodology. This action protects the health, safety, and welfare of citizens by ensuring that Virginia's Medicaid reimbursement rules for pharmacy services comply with federal law and that Virginia Medicaid can continue to provide pharmacy services.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

DMAS proposes to change its fee-for-service pricing methodology in 12VAC30-80-40 from the current 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 current 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 regulation governing Virginia Medicaid fee-for-service prescription drug pricing methodology under 12VAC30-80-40 will 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 will be 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 eliminates 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, statewide 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.

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

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

DMAS will be out of compliance with new Federal regulations if changes are not made to state regulations at 12VAC30-80-40. Alternative drug pricing methodologies to determine AWP do

exist and are utilized by other Medicaid states and private payors, although the number of these states using these methods have declined significantly. The continued use of AWP pricing compendia provided by companies such as Medispan or First Data Bank as a pricing source is not feasible as a reimbursement methodology for DMAS in the near term. AWP has been discredited and delegitimized by the United States General Accounting Office (GAO), the Federal Appeals Court, the Department of Health and Human Services Office of the Inspector General (HHS OIG), CMS, the National Association of Chain Drug Stores and others. In its July 2011 report, "Replacing Average Wholesale Price: Medicaid Drug Policy", the HHS OIG stated,

> "Numerous reports by the Office of the Inspector General have found that the fundamentally flawed nature of AWP based reimbursement has caused Medicaid to pay too much for certain drugs. AWP is not defined in law or regulation and fails to account for prompt pay or other discounts, rebates or reductions."

Both Medispan and FDB AWP were equally cited as flawed pricing methodologies by the judge that ruled in the AWP class action law suit settled in 2006, Judge Sarris. In the settlement agreement Judge Sarris stated the following:

> "pharmacies reliance on AWP is a trap for unwary and unsophisticated third party payors and results in consumers paying unwarranted co-payments. Not only do FDB and Medi-Span have the right to make these changes, but in my view, after eight years on this multi-district legislation rolling back AWPs or phasing them out as a pricing benchmark is in the public interest and to the benefit of the class."

Pricing methods offered by companies such as First Data Bank, Medispan and others also require states to purchase a subscription, while the use of NADAC is free to states.

CMS developed NADAC to provide states with a free, viable, non-biased and sound method for determining the ingredient costs of drugs paid by retail pharmacies and is strongly encouraging its use by state Medicaid programs by its actual development and including a reference in the methodology in its proposed rule. Additionally, NADAC removes acquisition costs from dispensing fees, requiring states to reimburse pharmacies at a reasonable cost of dispensing based on sound survey methodology. Because the flawed nature of private pricing compendia, current state dispensing fees, such as the current DMAS dispensing fee of $3.75, bear no relation to the actual cost of dispensing as demonstrated in the Myers and Stauffer survey. Utilizing the NADAC and a dispensing fee established by Myers and Stauffer is an attempt to decouple ingredient costs from dispensing fees, reimburse retail pharmacies a fair price for both components and maintain the cost neutrality or cost savings required in state appropriations language.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated

Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, phone, or email, to Donna Proffitt, Pharmacy Division, 600 E. Broad Street, Richmond, Virginia 23219, phone 804-371-0428, or email Donna.Proffitt@dmas.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage 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; 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.