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Fast-Track Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 30-50-210
VAC Chapter title(s)	Prescribed Drugs, Dentures, and Prosthetic Devices, and Eyeglasses Prescribed by a Physician Skilled in Diseases of the Eye or by an Optometrist.
Action title	Update to State Supplemental Drug Rebate Agreement
Date this document prepared	2/13/2020

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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.

This regulation updates the text related to supplemental drug rebates in accordance with text changes requested by the Centers for Medicare and Medicaid Services (CMS). There are no changes in practice related to drug rebates, and there are no costs associated with these changes. These changes match the CMS-approved language in the state plan to the language in the Virginia Administrative Code.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

CMS = Centers for Medicare and Medicaid Services
DMAS = Department of Medical Assistance Services

Statement of Final Agency Action

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 "Update to Supplemental Drug Rebate Agreement" 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.

February 13, 2020
Date

/signature/
Karen Kimsey, Director
Dept. of Medical Assistance Services

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The Code of Virginia § 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 § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

These regulatory changes are expected to be non-controversial because they do not represent changes in practice, and do not involve any costs to Medicaid providers or to the Commonwealth. Instead, they match the language in the Virginia Administrative Code to language that was approved by CMS in the Virginia State Plan.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the

promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The Code of Virginia § 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 § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

Purpose

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.

The regulation is essential to protect the health, safety, and welfare of citizens in that it ensures that DMAS can continue to obtain state supplemental drug rebates, and that the rules for such rebates are transparent to all parties.

Substance

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.

This regulation updates the text related to supplemental drug rebates in accordance with text changes requested by CMS. There are no changes in practice related to drug rebates, and there are no costs associated with these changes. These changes match the CMS-approved language in the state plan to the language in the Virginia Administrative Code.

Issues

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 provides clarity on the CMS-approved rules relating to supplemental drug rebate agreements. There are no disadvantages to the public or to the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no requirements in this regulation that are more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

No state agencies, localities, or other entities are particularly affected by this change.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	None
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	This regulatory action provides clarity on the CMS-approved rules relating to supplemental drug rebate agreements.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	This regulatory action provides clarity on the CMS-approved rules relating to supplemental drug rebate agreements.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The Agency's Pharmacy Benefit Management Services contractor, Magellan, currently negotiates Virginia specific supplemental rebate agreements with manufacturers. The regulatory change will allow DMAS to participate in the future, at no additional cost, in one of Magellan's multi-state supplemental rebate agreement pools. (DMAS would need additional approval from CMS before implementing any multi-state supplemental rebate agreements.)
Agency's best estimate of the number of such entities that will be affected. 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.	This regulatory change should not impact small businesses since the supplemental rebate agreements are with national pharmaceutical manufacturers.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no changes related to reporting, recordkeeping, fees, equipment, or the developmental of real estate.
Benefits the regulatory change is designed to produce.	This regulatory action provides clarity on the CMS-approved rules relating to supplemental drug rebate agreements.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

In order to maintain transparency and to ensure that the rules in the state plan are followed effectively, DMAS had no alternative but to update its regulatory language to match the CMS - approved language in the state plan.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

This regulatory change has no effect on small business.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

DMAS is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Emily McClellan at DMAS, 600 E. Broad Street, Richmond, VA 23219, by email at Emily.McClellan@dmas.virginia.gov or by phone at 804-371-4300. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
30-50-			Text changes are made to match the

210 A 7 d			CMS-approved language in the state plan.