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Fast-Track Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation(s)	12 VAC 30-50-210
Regulation 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	Supplemental Drug Rebates and MCOs
Date this document prepared	February 12, 2018

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 has the authority to seek supplemental rebates from pharmaceutical manufacturers under the State Plan. This action will update the Virginia Administrative Code to clarify that DMAS has the option to collect supplemental payments for Medicaid member utilization through managed care organizations (MCOs). The rebates through MCOs will occur in the same manner in which fee-for-service rebates are collected.

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 "Supplemental Drug Rebates and MCOs" with the attached amended regulations (12 VAC 30-50-210) and adopt the action stated therein. I certify that this fast track regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012.1, of the Administrative Process Act.

February 12, 2018
Date

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

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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.

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.*

The purpose of this action is to allow DMAS to align drug formularies across fee-for-service and Medicaid managed care health plans allowing DMAS to collect supplemental rebates for Medicaid member drug utilization through MCOs. This will protect the health, safety, and welfare of citizens in that it will allow recipients to continue their medications in the event they change from fee-for-service to managed care and will minimize potential disruptions in the recipient's drug therapy.

Rationale for using fast-track process

*Please **explain the rationale for using the fast-track process** in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

This regulatory action is being promulgated as a fast track action because it is expected to be non-controversial. The 2010 Affordable Care Act expanded the collection of federal rebates for drugs administered to Medicaid recipients enrolled with Medicaid managed care plans. The Department has been collecting federal rebates for this population since 2010. Effective, August 1, 2017 with the implementation of the Commonwealth Coordinated Care program, Medicaid managed health plans are contractually required to cover all "preferred" drugs on Virginia Medicaid's fee-for-service Preferred Drug List (PDL). DMAS will be soliciting drug rebates for select "preferred" drugs for recipients enrolled with Medicaid managed care health plans. Contractually, the health plans are required to cover these drugs; therefore, no opposition is anticipated from the managed care health plans or pharmaceutical manufacturers.

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.

This regulatory action permits allow DMAS to collect supplemental payments for Medicaid member utilization through MCOs.

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 to the Commonwealth and the public from these regulatory changes is collection of additional supplemental drug rebates from pharmaceutical manufacturers for drugs dispensed to Medicaid recipients enrolled in a Medicaid managed care health plan.

There are no disadvantages to the Commonwealth or the public as a result of this regulatory action.

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 contained in these recommendations.

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 will be no localities that are more affected than others as these requirements will apply statewide.

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.

This regulatory action is not expected to affect small businesses as it does not impose compliance or reporting requirements, nor deadlines for reporting, nor does it establish performance standards to replace design or operational standards.

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**	None.
Projected cost of the new regulations or changes to existing regulations on localities.	None.
Description of the individuals, businesses, or	Existing pharmaceutical manufacturers who have

other entities likely to be affected by the new regulations or changes to existing regulations.	supplemental rebate agreements. Any new pharmaceutical manufacturer who wish to participate in the supplemental drug rebate program and meet the regulatory requirements. Contracted Medicaid managed care health plans participating the Commonwealth Coordinated Care and Medallion 4.0 programs.
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.	6 Medicaid Managed Care Health plans 35-40 pharmaceutical manufacturers No 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.	None.
Beneficial impact the regulation is designed to produce.	The beneficial impact of this regulatory action is that it will provide continuity of care with regards to drug therapy for all Medicaid recipients. This action will also result in an increase in the collection of supplemental drug rebate dollars from pharmaceutical manufacturers.

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 are no alternatives that would permit DMAS to collect these rebates. These changes have been approved by the Centers for Medicare and Medicaid Services.

Public participation notice

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.

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, and do not increase or decrease disposable family income.

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.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 30-50-210		Supplemental rebates related to MCO member utilization is not discussed.	Supplemental rebates may be collected for Medicaid member utilization through MCOs.