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## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	DEPT. OF MEDICAL ASSISTANCE SERVICES
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12-VAC-30-10-650
<b>VAC Chapter title(s)</b>	State Plan Under Title XIX of the Social Security Act Medical Assistance Program - General Provisions  Section Title: Drug Utilization Program
<b>Action title</b>	Update to Drug Utilization Review Program
<b>Date this document prepared</b>	August 3, 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.*

DMAS has incorporated changes to the state plan text related to the Drug Utilization Review Program in accordance with the requirements of the Support Act (Public Law No. 115-271). The changes include Support Act provisions related to: claims review limitations; a program to monitor antipsychotic medications by children; fraud and abuse identification; and Medicaid managed care organizations requirements. This regulatory action incorporates the same changes into 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

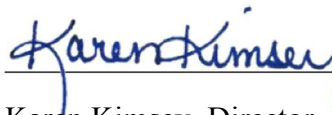
**Statement of Final Agency Action**

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 State 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.

8/3/2020

Date



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 Director of the Department of Medical Assistance Services is amending this regulation to incorporate changes to the state plan text related to the Drug Utilization Review Program in accordance with the requirements of the Support Act (Public Law No. 115-271). These changes ensure that DMAS will remain in compliance with federal regulation to ensure continued federal financial participation. In addition, as a result of the Support Act, DMAS updated its state plan through State Plan Amendment (SPA) #: 19-017 with an effective date of December 31, 2019. This regulatory action is eligible for the fast-track process because none of the changes are expected to be controversial.

## 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.*

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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 the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance and to promulgate regulations according to the Board's requirements.

## 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.*

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DMAS is incorporating changes to the state plan text related to the Drug Utilization Review Program in accordance with the requirements of the Support Act (Public Law No. 115-271). The changes include Support Act provisions related to: claims review limitations; a program to monitor antipsychotic medications by children; fraud and abuse identification; and Medicaid managed care organizations requirements.

## 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.*

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The section of the State Plan that is affected by this amendment is entitled "Program Organization."

## 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.*

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The changes ensure that DMAS remains in compliance with federal regulations to continue to obtain federal financial participation; there are no disadvantages in this regulatory change.

**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**

<p><i>For your agency:</i> 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</p>	<p>There are no DMAS costs associated with these changes.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no costs to other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefit of this regulatory change is that it will ensure continued compliance with federal regulations to ensure continued federal financial participation.</p>

**Impact on Localities**

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs to localities as a result of these changes.
Benefits the regulatory change is designed to produce.	The benefit of this regulatory change is that it will ensure continued compliance with federal regulations to ensure continued federal financial participation.

**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.	Pharmacies and pharmacists.
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.	All pharmacies enrolled with Virginia Medicaid which are approximately 1500
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 costs associated with this regulatory change.
Benefits the regulatory change is designed to produce.	The benefit of this regulatory change is that it will ensure continued compliance with federal regulations to ensure continued federal financial participation.

**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.*

No alternatives would meet the federal mandate that DMAS include these changes in its operating rules for pharmacies and pharmacists.

## 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.*

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No alternatives would meet the federal mandate that DMAS include these changes in its operating rules for pharmacies and pharmacists.

## 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.*

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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.

The Department of Medical Assistance Services 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  
Virginia Department of Medical Assistance Services  
600 East Broad Street  
Richmond, VA 23219  
(804) 371-4300  
[Emily.McClellan@dmas.virginia.gov](mailto:Emily.McClellan@dmas.virginia.gov)

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.*

*If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.*

**Table 1: Changes to Existing VAC Chapter(s)**

<b>Current chapter-section number</b>	<b>New chapter-section number, if applicable</b>	<b>Current requirements in VAC</b>	<b>Change, intent, rationale, and likely impact of new requirements</b>
12 VAC 30-10-650		The section did not include the text that was required by the Support Act.	New text was added to B 11 and new subparagraphs were added to meet the Support Act requirements.