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Fast-Track Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC30-50-520
VAC Chapter title(s)	Drugs or drug categories which are not covered
Action title	Update to Non-Covered Drugs
Date this document prepared	6/10/26

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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.

The Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005 (Pub. L. No. 119-91) eliminated Medicaid Federal Financial Participation (FFP) for drugs "…when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual dysfunction or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration (FDA)." Prior to the enactment of this law, FFP was available for covered outpatient drugs used to treat sexual dysfunction or erectile dysfunction, except for individuals who were sexual offenders.

In accordance with Pub. L. No. 119-91, DMAS has not covered drugs for the treatment of sexual or erectile dysfunction since January 1, 2006, unless such agents are FDA approved to treat a

condition other than sexual or erectile dysfunction. As such, DMAS must amend the regulatory text to align with the State Plan and current DMAS practice.

This regulatory action will also update the regulatory text to match the State Plan and current DMAS practice related to the following:

- Drugs for anorexia, weight loss, and weight gain
- Drugs for cosmetic purposes or hair growth; and
- Non-legend drugs

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.

DMAS= Department of Medical Assistance Services
FFP= Federal Financial Participation
FDA= Food and Drug Administration
SSA= Social Security Administration
SD = Sexual Dysfunction
ED = Erectile Dysfunction

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) that the agency has "adopted final amendments" to the regulation; 3) the name of the agency taking the action; and 4) the title of the regulation. A suggested statement is, "On [insert date] the Board/Department of [insert name] adopted final amendments to the [title of regulation(s)]."

On June 10, 2026, the Department of Medical Assistance Services adopted final amendments to the "Update to Non-Covered Drugs" regulation.

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 the ORM procedures, "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."

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

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 the Department of Medical

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

This regulatory action is being conducted to update the Virginia Administrative Code to reflect changes approved by CMS on June 11, 2025, through a State Plan Amendment.

This rulemaking is expected to be noncontroversial because it is not a new mandate. This practice has been in place since 2006, and this change simply amends the regulations to align with the State Plan and current DMAS practice.

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 (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 the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance 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 is intended to solve.

The rationale for the regulatory amendment is to align the changes with current DMAS practice and the Federal law. The Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005 (Pub. L. No. 119-91) eliminated Medicaid Federal Financial Participation (FFP) for drugs "…when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual dysfunction (SD) or erectile dysfunction (ED), for which the agents have been approved by the Food and Drug Administration (FDA)." Prior to the enactment of this law, FFP was available for covered outpatient drugs used to treat SD or ED, except for individuals who were sexual offenders.

In accordance with Pub. L. No. 119-91, DMAS has not covered drugs for the treatment of sexual or erectile dysfunction since January 1, 2006, unless such agents are FDA approved to treat a condition other than sexual or erectile dysfunction. This regulatory action is essential to protect the health, safety, and welfare of citizens because it ensures that DMAS provides coverage for drugs for conditions deemed medically necessary in compliance with Federal law.

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 regulatory action will update the excluded drug listing, specifically drugs for the treatment of sexual or erectile dysfunction.

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.

There are no anticipated disadvantages to the public or the Commonwealth as a result of this regulatory action. The primary advantage of this change is that it aligns existing DMAS regulations with the approved State Plan and longstanding Federal requirements.

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

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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

Consistent with § 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 the proposed 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 will align the language in the Administrative Code with DMAS' state plan language.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	This regulatory action will align the language in the Administrative Code with DMAS' state plan language.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	None
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;	None

b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	
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.	None
Benefits the regulatory change is designed to produce.	This regulatory action will align the language in the Administrative Code with DMAS' state plan language.

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 can achieve the purpose of this regulatory action.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B 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 action is not expected to affect small businesses.

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.

Consistent with § 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 Syreeta Stewart, DMAS, 600 E. Broad Street, Richmond, VA 23219, 804-839-7282, Syreeta.Stewart@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)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC30-50-520		A. indicates that coverage of anorexiants for other than weight loss requires medical justification. It also indicates	Clarify language to indicate select agents used for anorexia, weight loss, or weight gain will be covered as listed in state's provider manual.

		that FDA-approved drug therapies and agents for weight loss will be covered for recipients who meet disability standards for obesity established by the SSA, and whose condition is certified as life threatening.	
12VAC30-50-520		B.1-2 indicates that agents used for cosmetic purposes or hair growth are not covered, specifically Minoxidil and agents containing hydroquinone.	Clarify language to indicate select agents used for cosmetic purposes or hair growth will only be covered if such agents are determined to be medically necessary and listed in the state's provider manual.
12VAC30-50-520		F. indicates that non-legend drugs, with exceptions listed in 12VAC30-50-100, will not be covered.	Clarify language to indicate that select non-legend drugs will be covered as listed in the state's provider manual.
12VAC30-50-520	G.		Add language to indicate select agents used for the treatment of sexual and erectile dysfunction will only be covered to treat a condition, other than sexual or erectile dysfunction, and listed in the state's provider manual.