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Fast-Track Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC30-50-150
VAC Chapter title(s)	Amount, Duration, and Scope of Medical and Remedial Care Services
Action title	Pharmacists as Providers and Other Licensed Practitioners
Date this document prepared	April 7, 2025

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.

This regulatory action amends existing regulations to address several changes to both pharmacy services and non-physician providers. These changes have already been made in the state plan (see SPA 24-005 and SPA 23-014) and these changes will align the regulations with the state plan text.

With regard to the changes related to non-physician providers, a December 21, 2023 companion letter sent by the Centers for Medicare and Medicaid Services (CMS) and attached to the approval of State Plan Amendment 23-0014, required additional changes to remove references to ophthalmologists, as they are physicians and are covered under the "Physician Services" section of the State Plan, clarifying that optometrists and opticians must be licensed by the state, and specifically listing each type of licensed mental health professional (LMHP) that is permitted to enroll with DMAS under the "other licensed practitioner" (OLP) benefit. These providers have long been covered by DMAS, and there is no change to coverage, but CMS is requesting that DMAS specifically list each type of LMHP.

The changes related to services provided by pharmacists, pharmacy interns, and pharmacy technicians are required by SB 1538 of the 2023 General Assembly, which updates the OLP benefit to cover services under a licensed pharmacist's scope of practice and through collaborative agreements with OLPs.

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
SPA – State Plan Amendment
VAC – Virginia Administrative Code
LMHP-Licensed Mental Health Professional
OLP- Other Licensed Practitioner

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.

On April 7, 2025, DMAS adopted final amendments to the regulatory action entitled, "Pharmacists as Providers and Other Licensed Practitioners."

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 § 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.

The regulations are being amended in accordance with SB 1538 of the 2023 General Assembly and in response to a CMS directive.

The changes in this regulatory action are expected to be non-controversial because they do not represent changes in practice or coverage, and do not involve any costs to Medicaid providers or to the Commonwealth.

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.

The regulations are being amended in accordance with SB 1538 of the 2023 General Assembly and in accordance with a CMS directive.

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.

This regulatory change is needed to allow DMAS to comply with the 2023 General Assembly mandate in SB 1538 and to comply with a CMS requirement. Additionally, the change specifically lists out which licensed practitioners and non-licensed practitioners are covered, which ultimately allows them to be reimbursed for their services and no longer limits their ability to provide care to their patients in need.

This regulatory change is essential to protect the health, safety or welfare of citizens because recognizes healthcare practitioners who are already authorized to provide direct services to Medicaid members, including the potential increase in access to important health care services that was permitted by SB1538 for Medicaid members with additional pharmacy staff able to provide these services.

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 clarify existing language and bring the regulations into alignment with the state plan and DMAS' current practices. Specifically, the changes include:

- Removing the reference to ophthalmologists, as these are physicians and are covered under the "Physician Services" section of the state plan.
- Clarifying that optometrists and opticians must be licensed by the state.
- Specifically listing each type of licensed mental health professional that is permitted to enroll with DMAS under the OLP benefit.
- Requires DMAS to allow for reimbursement to a pharmacist, pharmacy intern, or pharmacist technician in accordance with a GA mandate.

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.

These changes create no disadvantages to the public, the Agency, the Commonwealth or the regulated community. The advantages of these changes to the public and the Commonwealth are that these changes align DMAS regulations with federal and state requirements. Additionally, this action recognizes the potential increase in access to important health care services that was permitted by SB1538 for Medicaid members with the additional pharmacy staff able to provide these services.

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	There are no costs associated with these regulatory changes.
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.	There are no costs to other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	The benefit of this action is to align the VAC with General Assembly and CMS mandates.

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.	There are no costs to localities as a result of these changes.
Benefits the regulatory change is designed to produce.	The benefit of this action is to align the VAC with General Assembly and CMS mandates.

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.	DMAS-enrolled pharmacy providers will be affected by this regulatory change.
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.	None.
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;	None.

c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	
Benefits the regulatory change is designed to produce.	The benefit of this action is to align the VAC with General Assembly and CMS mandates.

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 change existing Virginia regulations in accordance with the pharmacy-related mandates in § 54.1-3303.1, pursuant to SB 1538 of the 2023 General Assembly.

There are also no alternatives to amending the regulatory language to match the CMS requirements related to listing other licensed practitioners.

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 will benefit pharmacies that operate as small businesses as more employees can provide certain pharmacy services, which may decrease patient wait times and potentially increase access to pharmacy services.

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
12VAC30-50-150			Paragraphs B and C: Removed references to "ophthalmologists," clarified that optometrists and opticians must be licensed by the state, and specifically listed each type of OLP that can enroll with DMAS.
12 VAC 30-50-150			Paragraph F: Included references to pharmacy interns and technicians.