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Fast-Track Regulation
Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC30-50-210; 12VAC 30-80-40
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; Fee-for-service providers: pharmacy
Action title	Pharmacy Updates
Date this document prepared	April 4, 2022

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 makes the following pharmacy changes:

- Authorizes prescriptions of contraceptives up to a 12-month supply, in accordance with the 2021 Special Session, Item 313.YYYYY, and Item 288.WWW of the 2025 Appropriation Act.

- Enables DMAS to begin calculating state supplemental pharmacy rebate amounts in accordance with the National Medicaid Pooling Initiative (NMPI) instead of the Virginia Supplemental Rebate Agreement and Addenda. This change will allow Virginia to receive additional rebate amounts and generate savings for the state.

- Authorizes vaccines administered by pharmacies (pharmacists, pharmacy interns, or pharmacy technicians) to be reimbursed at the cost of the vaccine plus an administration fee not to exceed $16, in accordance with the 2021 Appropriations Act, Item 313.UUUUU, and Item 288.SSS of the 2025 Appropriation Act. Vaccines obtained at no cost to the pharmacy shall be reimbursed for the administration fee only.

DMAS submitted two state plan amendments to the Centers for Medicare & Medicaid Services (CMS) that were approved on August 18, 2021, and November 23, 2021, and this regulatory action incorporates those same changes 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.

DMAS = Department of Medical Assistance Services
CHIP = Children's Health Insurance Program
CMS = Centers for Medicare & Medicaid
Services NMPI = National Medicaid Pooling
Initiative PDL = Preferred Drugs Lists
VFC = Vaccines for Children

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 4, 2022, DMAS adopted final amendments to the regulatory action entitled, "Pharmacy Updates."

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 full text of the 2021 Special Session, Item 313.YYYYY and 2025 Appropriation Act, Item 288.WWW, authorizing prescriptions of contraceptives up to a 12-month supply, as well as the 2021 Appropriations Act, Item 313.UUUUU, and the 2025 Appropriation Act, Item 288.SSS, authorizing the reimbursement of pharmacy-administered immunizations for all vaccinations covered under the medical benefit for Medicaid members, is included in the Legal Basis section below.

These regulatory changes are expected to be non-controversial because providing access to contraceptive prescriptions is likely to help facilitate desired family planning outcomes. The cost- savings benefit provided by participation in the NMPI is also non-controversial. It affords DMAS the opportunity to reduce pharmacy budget costs by joining a pooling system that negotiates supplemental rebates from drug manufacturers in exchange for placing their drugs on Medicaid Preferred Drugs Lists (PDLs). In addition, allowing pharmacists, pharmacy interns, and technicians to administer vaccines under a designated reimbursable cost structure represents an increase in access to healthcare services, in an effort to reduce to health disparities.

Two state plan amendments have been approved by CMS and these changes will replicate the state plan text in the Virginia Administrative Code.

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 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.

Item 313.YYYYY of the 2021 Special Session states that DMAS "…shall amend the Medicaid and CHIP State Plans to authorize prescriptions of contraceptives up to a 12-month supply for

eligible beneficiaries in the Medicaid and CHIP programs. The department shall have the authority to promulgate emergency regulations to implement these amendments within 280 days or less from the enactment of this Act."

Item 288.WWW of the 2025 Appropriation Act also states that DMAS "…shall amend the Medicaid and CHIP State Plans to authorize prescriptions of contraceptives up to a 12-month supply for eligible beneficiaries in the Medicaid and CHIP programs. The department shall have the authority to promulgate emergency regulations to implement these amendments within 280 days or less from the enactment of this Act.

Both the 2021 Appropriation Act, Item 313.UUUUU and the 2025 Appropriation Act, Item 288.SSS state that DMAS "…shall amend the State Plan for Medical Assistance to authorize the reimbursement, using a budget neutral methodology, of pharmacy-administered immunizations for all vaccinations covered under the medical benefit for Medicaid members. Reimbursement for fee-for-service members shall be the cost of the vaccine plus an administration fee not to exceed $16. Reimbursement for pharmacy-administered vaccinations for pediatric Medicaid members eligible for free vaccinations through the Vaccines For Children (VFC) program shall include only the administration fee."

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 purpose of this action is to authorize prescriptions of contraceptives up to a 12-month supply, to enable DMAS to begin calculating state supplemental pharmacy rebate amounts in accordance with the NMPI, and to authorize vaccines administered by pharmacies (pharmacists, pharmacy interns, or pharmacy technicians) to be reimbursed at the cost of the vaccine plus an administration fee not to exceed $16. These regulatory changes are essential to protect the health, safety, and welfare of Medicaid members.

The purpose of providing increased access to contraceptives is to foster continuous use of birth control and reduce gaps in contraceptive protection, in accordance with a General Assembly mandate.

The purpose of enabling DMAS to begin calculating state supplemental pharmacy rebate amounts in accordance with the NMPI instead of the Virginia Supplemental Rebate Agreement and Addenda is to allow Virginia to receive additional rebate amounts, which will generate savings for the state.

The purpose of allowing pharmacists, pharmacy interns, and technicians to administer vaccines under a designated reimbursable cost structure represents an increase in access to healthcare services, in an effort to reduce to health disparities.

This regulation change is essential to protect the health, safety, and welfare of citizens because it enhances access to health care and is intended to reduce health disparities across vulnerable populations.

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.

The 2021 Special Session, Item 313.YYYYY and the 2025 Appropriation Act, Item 288.WWW, required DMAS to amend the Medicaid and CHIP State Plans to authorize prescriptions of contraceptives up to a 12-month supply for eligible beneficiaries in the Medicaid and CHIP programs. The department shall have the authority to promulgate emergency regulations to implement these amendments within 280 days or less from the enactment of this Act.

DMAS has initiated the calculation of state supplemental pharmacy rebate amounts in accordance with the NMPI as a cost-saving measure, which will allow Virginia to receive additional rebate amounts.

The 2021 Appropriations Act, Item 313.UUUUU and the 2025 Appropriation Act, Item 288.SSS required DMAS to amend the state plan to authorize the reimbursement, using a budget neutral methodology, of pharmacy-administered immunizations for all vaccinations covered under the medical benefit for Medicaid members. Reimbursement for fee-for-service members shall be the cost of the vaccine plus an administration fee not to exceed $16. Reimbursement for pharmacy-administered vaccinations for pediatric Medicaid members eligible for free vaccinations through the VFC program shall include only the administration fee.

The sections of the State regulations that are affected by this action are 12VAC30-50-210 and 12VAC30-80-40.

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.

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 other 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.	The benefits of these regulatory changes include access to contraceptives and pharmacy- administered vaccines to improve health outcomes for Medicaid Members. The regulatory changes will also meet the requirements of the General Assembly mandates, and ensure consistency across the VAC.

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.	The benefits of these regulatory changes include access to contraceptives and pharmacy- administered vaccines to improve health outcomes for Medicaid Members. The regulatory changes will also meet the requirements of the General Assembly mandates, and ensure consistency across the VAC.

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.	No individuals, businesses, or other entities 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.	No individuals, businesses, or other entities will be affected by this regulatory change.
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 reporting/recordkeeping, development of real estate, fees, or purchases of equipment.
Benefits the regulatory change is designed to produce.	The benefits of these regulatory changes include access to contraceptives and pharmacy- administered vaccines to improve health outcomes for Medicaid Members. The regulatory changes will also meet the requirements of the General Assembly 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 alternative methods will accomplish the objectives of the General Assembly mandates which allow DMAS to authorize prescriptions of contraceptives up to a 12-month supply; begin calculating state supplemental pharmacy rebate amounts in accordance with the NMPI; and authorize vaccines administered by pharmacies (pharmacists, pharmacy interns, or pharmacy technicians) to be reimbursed at the cost of the vaccine plus an administration fee not to exceed $16.

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.

No alternatives can achieve the objective of the General Assembly mandate. 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.

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: Syreeta Stewart, Virginia Department of Medical Assistance Services, 600 East 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.

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC 30-50-210			Text added to align with a General Assembly mandate.
12VAC 30-80-40			Text added to align with a General Assembly mandate.