



Virginia Department of Planning and Budget **Economic Impact Analysis**

12 VAC 30-50 Amount, Duration, and Scope of Medical and Remedial Care and Services Department of Medical Assistance Services

Town Hall Action/Stage: 5469 / 8881

April 17, 2020

Summary of the Proposed Amendments to Regulation

The Board of Medical Assistance Services proposes to remove limiting language that predicates that a supplemental drug rebate agreement can only be between the Commonwealth and manufacturers, and to clarify the regulatory text.

Background

This regulation establishes the authority for the Department of Medical Assistance Services (DMAS) to seek supplemental rebates from pharmaceutical manufacturers for drug purchases for fee-for-service claims and for Medicaid member utilization through managed care organizations (MCO). Supplemental rebates are cash rebates that offset Virginia Medicaid expenditures and that supplement federal rebates. The amount of supplemental rebates is negotiated with drug manufacturers.

With the expansion of managed care, utilization of drugs has shifted significantly away from fee-for-service to managed care over the last two decades. As a result, the amount of supplemental rebates collected from drug purchases for the fee-for-service population shrunk, which in turn caused an erosion in the individual negotiating power of most states.¹ In response, some states have formed multi-state purchasing pools when negotiating supplemental rebates to maximize the amount of rebates they can collect.

In preparation for joining a multi-state purchasing pool, DMAS submitted a state plan amendment that would authorize it, and was subsequently advised by the Centers for Medicare

¹ Supplemental rebates for the managed care drug utilization are retained by MCOs.

and Medicaid Services (CMS) to resubmit the changes when such a plan was impending rather than being a future possibility.² However, during its review, CMS suggested amendments governing the supplemental rebates because some of the language was outdated and not consistent with federal rules. In addition, CMS agreed to amend the language that predicated that an agreement could only be between the Commonwealth and the manufacturers.

Estimated Benefits and Costs

One of the proposed amendments would remove the predicating language. As it stands now, the predicating language is limiting in the sense that it does not accommodate the Commonwealth's membership in a multi-state purchasing pool. Removal of this limitation however would not authorize DMAS to join such a pool. For DMAS to join such a pool, additional approval from CMS and further regulatory action would be needed. Therefore, although this change would remove limiting language, it would have no practical economic impact at this time.

Likewise, the removal of outdated language would also have no practical economic effect other than improving the clarity and accuracy of the regulatory text and satisfying the request from CMS.

Businesses and Other Entities Affected

Virginia Medicaid has supplemental rebate agreements with approximately 35 manufacturers. The amount of supplemental rebates collected in the second half of 2019 was approximately \$12.8 million for 218,176 prescriptions. No adverse economic impact³ on manufacturers is indicated.

Small Businesses⁴ Affected:

This regulatory action does not impact small businesses since the supplemental rebate agreements are with large national pharmaceutical manufacturers.⁵

² Currently, Magellan, DMAS's Pharmacy Benefit Management Services contractor, negotiates Virginia specific supplemental rebate agreements with manufacturers.

³ Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

⁴ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

⁵ Source: DMAS

Localities⁶ Affected⁷

The proposed amendments do not affect any particular locality and do not introduce costs for local governments.

Projected Impact on Employment

The proposed amendments do not affect total employment.

Effects on the Use and Value of Private Property

The proposed amendments do not affect the use and value of private property or the real estate development costs.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

⁶ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

⁷ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.