Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes ☒ Not Needed ☐

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).

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: 4997/8204
April 16, 2018

Summary of the Proposed Amendments to Regulation

The Board of Medical Assistance Services (Board) proposes to authorize the Department of Medical Assistance Services (DMAS) to collect supplemental rebates for drugs dispensed to Medicaid beneficiaries who receive care through managed care organizations.

Result of Analysis

There is insufficient information to accurately compare the magnitude of the benefits versus the costs.

Estimated Economic Impact

Drug rebates have long been collected from participating drug manufacturers to help offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid fee-for-service patients. Under the federal rebate program, a drug manufacturer is required to enter into a national rebate agreement in exchange for Medicaid coverage. The 2010 Affordable Care Act allowed collection of federal rebates for drugs dispensed to Medicaid managed care patients. In this action, the Board proposes to authorize DMAS to collect supplemental rebates in addition to the federal rebates.

Currently, in Commonwealth Coordinated Care Plus program, Medicaid managed health plans are contractually required to cover all "preferred" drugs on Virginia Medicaid's fee-

for-service Preferred Drug List (PDL). The proposed supplemental rebates from managed care drugs will give Virginia Medicaid leverage to control drug costs above and beyond the control exercised by the federally required rebates. DMAS estimates that it would collect about $5 to $6 million in supplemental drug rebates annually.[1] [2] Thus, the main benefit of the proposed regulation is to further offset the state cost of outpatient drugs dispensed to managed care recipients.

The cost will mainly fall on the drug manufacturers as they will be asked to provide additional rebates to the Commonwealth or risk being removed from the managed care PDL. Some of this cost may arguably be offset by the benefit of being on the managed care PDL. Being on the managed care PDL in addition to the fee-for-service PDL may be seen as another opportunity for the drug manufacturers to promote their product, much like having additional shelf space in a store.

Finally, when a change must be made in a managed care recipient's prescription due to implementation of a new PDL, there may be other effects such as the quality and continuance of care, patient compliance with the new regimen, physician and patient satisfaction, and the utilization of other healthcare services, etc. The likely effects of such changes will largely depend on how the resulting managed care PDL will compare to the existing fee-for-service PDL managed care recipients currently have access to. For example, if all manufacturers participate and their drugs are listed in the managed care PDL, then patients would not experience any disruption in their care or loss of access to any specific drugs. If, however, some drugs listed on the fee-for-service PDL are not listed on the managed care PDL then there may be some unintended disruptions or loss of access.

Businesses and Entities Affected

There are 35-40 pharmaceutical manufacturers and approximately 935,000 members enrolled in managed care.

Localities Particularly Affected

The proposed changes do not disproportionately affect any locality more than others.

[1] This estimate is very preliminary. DMAS will not have sufficient data to determine the annual collection of supplemental rebates for drugs dispensed to Medicaid members in managed care until October 2018.
[2] Currently, the federal fee-for-service rebate collections amount to approximately $20 million per quarter and the supplemental rebate collections amount to $700,000 per quarter. The federal managed care rebate collections have been approximately $80 million per quarter.

Projected Impact on Employment

No significant impact on employment is expected.

Effects on the Use and Value of Private Property

The amount of supplemental rebates that may be collected from an affected manufacturer is unlikely to be significant relative to its asset value. Thus, no significant impact on the use and value of private property is expected.

Real Estate Development Costs

No impact on real estate development costs is expected.

Small Businesses:

Definition

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."

Costs and Other Effects

None of the affected pharmaceutical manufacturers is a small business. Thus, the proposed regulation does not impose any costs or other effects on small businesses.

Alternative Method that Minimizes Adverse Impact

There is no adverse impact on small businesses.

Adverse Impacts:

Businesses:

The proposed regulation allows DMAS to collect an estimated $5-6 million in additional rebates from pharmaceutical manufacturers.

Localities:

The proposed regulation does not adversely affect localities.

Other Entities:

The proposed regulation does not adversely affect other entities.

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 Number 17 (2014). 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(C): 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.