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 30-80 Methods and Standards for Establishing Payment Rates; Other Types of Care
Department of Medical Assistance Services
Town Hall Action/Stage: 4456/8106
March 13, 2018

Summary of the Proposed Amendments to Regulation

The proposed action implements a Centers for Medicare and Medicaid Services (CMS) rule requiring states to pay pharmacies based on the drug's ingredient cost plus a professional dispensing fee.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Pursuant to the federal Affordable Care Act, CMS published a final rule in the Federal Register on February 1, 2016[1] that requires states to pay pharmacies based on the drug's ingredient cost, defined as the actual acquisition cost (AAC) plus a "professional dispensing fee." Consequently, the 2016 Acts of the Assembly, Chapter 780, Item 306.OO[2], and the 2017 Acts of Assembly, Chapter 836, Item 306.OO[3], directed the Department of Medical Assistance Services (DMAS) to implement a pricing methodology to modify or replace the current pricing methodology for pharmaceutical products that is cost neutral or creates cost savings. DMAS

[1] https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf
[2] https://budget.lis.virginia.gov/item/2016/1/HB30/Chapter/1/306/
[3] https://budget.lis.virginia.gov/item/2017/1/HB1500/Chapter/1/306/

implemented the new methodology on January 9, 2017 on federal authority. The emergency regulation to that effect became effective June 16, 2017.[4] This action permanently implements the pricing methodology.

Prior to the CMS final rule, Virginia Medicaid utilized an estimated acquisition cost (EAC) methodology to pay pharmacies that was based on "lesser of" logic that reimbursed pharmacies using the federal upper payment limit, Virginia's maximum allowable cost (MAC), Virginia specialty maximum allowable cost, the estimated acquisition cost (EAC) or the provider's usual and customary amount plus a dispensing fee, whichever was less. Virginia's EAC was based on the published Average Wholesale Price (AWP) minus a percentage discount established by the Virginia General Assembly (12 VAC 30-80-40). This methodology did not meet the requirements of the new federal rule and the dispensing fee of $3.75 did not reflect actual dispensing costs and did not meet the CMS definition of a "professional dispensing fee".

In order to establish a reasonable dispensing fee that meets the CMS definition of AAC and a "professional dispensing fee" referenced in their proposed rule, DMAS, in collaboration with a nationally recognized consulting company in developing pricing carried out a cost of dispensing survey in 2014. The consultant determined that the weighted average cost of dispensing prescriptions to Virginia Medicaid members was $10.65. That estimate translated in 2014 to $22.6 million annual increase in dispensing fee reimbursements.[5]

DMAS also chose to utilize the CMS National Average Drug Acquisition Cost (NADAC), which is offered by CMS to meet, in part, their definition of AAC. NADAC is based on a comprehensive national survey carried out on behalf of CMS that provides wholesale purchase prices of all covered drugs by retail community pharmacies in the United States (U.S) and published weekly by CMS. When NADAC is not available, the new methodology provides reimbursement at the lowest of the wholesale acquisition cost or the provider's usual and customary charge. The new methodology was estimated in 2014 to reduce annual reimbursements for drug ingredients by $21.3 million offsetting largely the anticipated increase due to the higher dispensing fee.

[4] http://townhall.virginia.gov/l/ViewStage.cfm?stageid=7358
[5] A $6.90 increase for 3,272,796 claims.

DMAS reports that the new methodology has been cost neutral as expected. In addition, the new methodology has already been in effect. Thus, no significant economic impact is expected upon promulgation of this permanent regulation. The main impact is increasing reimbursements for dispensing costs while reducing reimbursements for ingredient costs. The U.S. Office of the Inspector General has repeatedly demonstrated that AWP, which the previous Virginia methodology was based on, often overstated drug prices and inflated the reimbursements.[6] As explained above the proposed dispensing fee was based on a survey and was reflective of actual dispensing costs. Therefore, although there appears to be no significant difference in total reimbursement to pharmacies, the proposed methodology is beneficial in the sense that it reflects more accurately the actual costs of ingredients and dispensing.

Businesses and Entities Affected

The proposed amendments primarily affect how provider pharmacies are reimbursed for their costs. There are approximately 1,400 pharmacies participating in Virginia Medicaid program.

Localities Particularly Affected

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

Projected Impact on Employment

No impact on employment is expected.

Effects on the Use and Value of Private Property

No 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."

[6] https://oig.hhs.gov/oei/reports/oei-03-11-00060.pdf

Costs and Other Effects

Some of the 1,400 participating pharmacies are small businesses. The proposed amendments do not impose costs on small businesses. The other effects on small pharmacies are as discussed above.

Alternative Method that Minimizes Adverse Impact

No adverse impact on small businesses is expected.

Adverse Impacts:

Businesses:

The proposed regulation does not have an adverse impact on businesses.

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.