Virginia Department of Planning and Budget

Economic Impact Analysis

12 VAC 30-10 State Plan Under Title XIX of the Social Security Act Medical Assistance Program; General Provisions
Department of Medical Assistance Services
Town Hall Action/Stage: 5514 / 8942
April 8, 2021

Summary of the Proposed Amendments to Regulation

As the result of a federal mandate, the Board of Medical Assistance Services (Board) proposes to amend the Drug Utilization Review (DUR) Program provisions in the *State Plan Under Title XIX of the Social Security Act Medical Assistance Program; General Provisions* regulation (regulation) to align with the Medicaid State Plan for Medical Assistance Services (state plan).

Background

Federal

Section § 1902 (a) of the Social Security Act [42 U.S.C. 1396a] establishes the federal requirements for administering State Plans for Medical Assistance including specific administration, eligibility, payment, and reporting requirements. Section 1004 of the federal Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Public Law No. 115-271) amended Section § 1902 (a) effective October 1, 2019, requiring compliance with the drug review and utilization requirements under subsection (oo)(1) in an effort "to reduce opioid related fraud, misuse and abuse."[1]

[1] See https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf

State

To comply with the SUPPORT Act, DMAS has already updated its state plan through Virginia State Plan Amendment (SPA) #: 19-017 effective December 31, 2019.[2] According to DMAS, the proposed amendments to the regulation are identical to the SPA. Thus, the requirements are already in effect.

Part of the current regulation is as follows:

> B. The DUR program is designed to educate physicians and pharmacists to identify and to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs as well as:
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> 1. Potential and actual adverse drug reactions
> 2. Therapeutic appropriateness
> 3. Overutilization and underutilization
> 4. Appropriate use of generic products
> 5. Therapeutic duplication
> 6. Drug disease contraindications
> 7. Drug-drug interactions
> 8. Incorrect drug dosage or duration of drug treatment
> 9. Drug allergy interactions
> 10. Clinical abuse/misuse

The Board proposes to add the following:

> 11. Provisions of Section 1004 of the SUPPORT ACT (below)
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> C. SUPPORT ACT Provisions
>
> 1. Claim Review Limitations
>
> a. Prospective safety edits including early, duplicate fill, and quantity limits for clinical appropriateness for opioids.
>
> b. Maximum daily Morphine Milligram Equivalents (MME) safety edits: A maximum dosing limit on opioids limits the daily morphine milliequivalents (as recommended by clinical guidelines)
>
> c. Concurrent Utilization Alerts: Prospective drug to-drug interaction alerts will require a response from the pharmacy if an opioid and benzodiazepine or opioid and antipsychotics are being

[2] See https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/VA/VA-19-0017.pdf

dispensed within an overlapping period with retrospective reviews performed on an ongoing periodic basis.

d. Comprehensive Retrospective DUR is performed on opioid prescriptions on an ongoing periodic basis.

2. Programs to Monitor Antipsychotic Medications to Children. Antipsychotic agents are reviewed for age appropriateness, duplicate therapy, and adverse effects in children based on the FDA product approval and clinical guidelines.

3. Fraud and Abuse Identification. The Client Medical Management (CMM) program for fee-for-service (FFS) beneficiaries that may require restriction to physician, pharmacy or both limiting the beneficiary's access to services identified as not medically necessary, excessive or both. The beneficiary's designated physician is responsible for supervising, coordinating, and providing initial and primary medical care; initiating written referrals for specialist care and for maintaining the continuity of patient care.

Estimated Benefits and Costs

There are six managed care organizations (MCOs) that have contracted with DMAS to provide managed care services to Medicaid recipients. DMAS and each of the MCOs have their own DUR programs. DMAS' program is for fee-for-service Medicaid recipients. A large part of the DUR programs involve pharmacists receiving immediate alerts when the items listed in 12VAC30-10-650.B (see above) are detected, as well as retrospective reviews.

All of the new requirements that were added to the state plan through SPA were also added to the MCOs' contracts. Thus, these requirements are already in effect. With the exception of Concurrent Utilization Alerts (see 12VAC30-10-650.C.1.c above), DMAS does not believe any of the new requirements caused the MCOs to substantively alter their practices or affected cost. DMAS does not know if the MCOs were producing Concurrent Utilization Alerts for opioid and benzodiazepine or opioid and antipsychotics being dispensed within an overlapping period. If any of the MCOs were not producing these alerts, they would have needed to reprogram their computer system to start producing such alerts to pharmacists. In addition to the time cost of reprogramming,[3] there is potential benefit in producing these alerts in that the likelihood of some adverse drug interactions may be reduced.

[3] If the MCO used an outside firm for programming, it would be a fee cost instead of the time of an MCO employee.

According to DMAS, the agency was already doing everything in the new language prior to it being added to the state plan. Thus, DMAS and fee-for-service Medicaid recipients were not directly affected.

Businesses and Other Entities Affected

The proposed amendments concern the approximate 1,500 pharmacies that are enrolled with Virginia Medicaid, the six MCOs that have contracted with DMAS, and Medicaid recipients. Adding the proposed language to the regulation would not increase costs for any entity.

Small Businesses[4] Affected:

The proposed amendments do not appear to adversely affect small businesses.

Localities[5] Affected[6]

The proposed amendments do not disproportionally affect any particular locality. The proposal does not introduce costs for local governments.

Projected Impact on Employment

The proposal does not affect employment.

Effects on the Use and Value of Private Property

The proposal does not affect the use and value of private property. The proposal does not affect 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

[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] "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.

[6] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

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.