

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

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4790 / 7891
May 17, 2017

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to allow a partial fill of a Schedule II prescription if requested by the patient or the prescriber under specified conditions. Schedule II prescriptions include opiates such as morphine and oxycodone, as well as other drugs.¹

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

The current regulation permits partial filling of Schedule II prescriptions for patients in long-term care facilities and for patients with a medical diagnosis documenting a terminal illness under set circumstances and conditions. The current regulation also allows partial filling of a prescription for a drug listed in Schedule II if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and she makes a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not

¹ U.S. Drug Enforcement Administration's list of Schedule II controlled substances:
https://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_12.htm

or cannot be dispensed within the 72-hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

The Board proposes to allow prescriptions for Schedule II drugs to be filled in partial quantities, even if a full quantity is available, if: 1) the total quantity of all partial fillings doesn't exceed the total prescribed, 2) the prescription is written and filled in accordance with state and federal law, and 3) the remaining portions are filled not later than 30 days from the original date on the prescription. The proposed amendments would be beneficial. For example, say a physician writes a 14-day prescription for post-surgical opioid pain medication, but the patient prefers to try the drug for a few days before filling the full prescription. To avoid having a quantity of drugs which may or may not be needed, under the proposed regulation the patient may request a partial fill with the ability to have the remainder dispensed if necessary. This is potentially beneficial for two reasons. First, the partial fill may have a cost-savings advantage, especially for self-pay patients. Second, the partial fill would create the potential of having fewer unused or unnecessary Schedule II drugs available for abuse or diversion. The proposed regulation does not introduce cost. Thus, the proposed amendments would create a net benefit.

Businesses and Entities Affected

The proposed amendments potentially affect the 1,852 permitted pharmacies in the Commonwealth, their customers, pharmacists, and physicians.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments would not significantly affect employment.

Effects on the Use and Value of Private Property

The proposed amendments do not significantly affect the use and value of private property.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

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

The proposed amendments would not significantly affect costs for small businesses.

Alternative Method that Minimizes Adverse Impact

The proposed amendments would not adversely affect small businesses.

Adverse Impacts:**Businesses:**

The proposed amendments would not adversely affect businesses.

Localities:

The proposed amendments would not adversely affect localities.

Other Entities:

The proposed amendments would 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.

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