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VA 175051 2017

Citation: 18 VAC 110-20-310
Agency: Department of Health Professions/Board of Pharmacy
Version: Proposed Rule
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BOARD OF PHARMACY

Fast-Track Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-310).**

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: August 23, 2017.

Effective Date: September 7, 2017.

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Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system and under a specific mandate of Chapter 82 of the 2016 Acts of Assembly.

The statutory authority for the board to promulgate regulations to regulate the security and integrity of drugs and devices is found in § 54.1-3307 of the Code of Virginia.

Purpose: The purpose of the amended regulation is to offer more flexibility in dispensing Schedule II drugs, so the drug is not dispensed in a quantity beyond what the patient or prescriber initially desires. The prescriber may write for a seven-day supply, or a 14-day supply for a post-surgical patient, but the patient may prefer to try the drug for a few days before filling the full prescription. For example, a patient may be prescribed an opioid for pain after a procedure in the doctor's office. To avoid having a quantity of drugs, which may or may not be needed, he may request a partial fill with the ability to have the remainder dispensed if necessary. The partial fill may provide a cost-savings advantage, especially for self-pay patients, but the primary advantage would be the potential of having fewer unused or unnecessary Schedule II drugs available for abuse or diversion. The goal is to meet a patient's need for medication but offer greater protection for public health and safety.

Rationale for Using Fast-Track Rulemaking Process: The ability for a pharmacist to partially fill a Schedule II prescription at the request of a patient or a prescriber is consumer friendly, less restrictive, and not controversial. Therefore, the fast-track rulemaking process is appropriate.

Substance: Regulations for partial dispensing of a Schedule II controlled substance are amended to allow a partial fill if requested by the patient or the prescriber and if (i) the total quantity of all partial fillings does not exceed the total prescribed, (ii) the prescription is written and filled in accordance with state and federal law, and (iii) the remaining portions are filled not later than 30 days from the original date on the prescription.

Issues: The advantage to the public is an option for partial filling of a Schedule II prescription as requested. There are no disadvantages to the public. There are no advantages or disadvantages to this agency or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

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 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.

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the analysis of the Department of Planning and Budget.

Summary:

The amendments permit a pharmacist to partially fill a Schedule II prescription at the request of a patient or a prescriber and establish requirements so the drug is not dispensed in a quantity beyond what the patient or prescriber initially desires.

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

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

A. The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and he 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 or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

B. Prescriptions for Schedule II drugs written for patients in long-term care facilities may be dispensed in partial quantities, to include individual dosage units. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II drugs in all partial dispensing shall not exceed the total quantity prescribed. Schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

C. Information pertaining to current Schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, identification of the long-term care facility, identification of drug authorized (to include dosage form, strength, and quantity), listing of partial dispensing under each prescription, and the information required in subsection B of this section.

2. Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.

D. A prescription for a Schedule II drug may be filled in partial quantities to include individual dosage units for a patient with a medical diagnosis documenting a terminal illness under the following conditions:

1. The practitioner shall classify the patient as terminally ill, and the pharmacist shall verify and record such notation on the prescription.

2. On each partial filling, the pharmacist shall record the date, quantity dispensed, remaining quantity authorized to be dispensed, and the identity of the dispensing pharmacist.

3. Prior to the subsequent partial filling, the pharmacist shall determine that it is necessary. The total quantity of Schedule II drugs dispensed in all partial fillings shall not exceed the total quantity prescribed.

4. Schedule II prescriptions for terminally ill patients may be partially filled for a period not to exceed 60 days from the issue date unless terminated sooner.

5. Information pertaining to partial filling may be maintained in a computerized system under the conditions set forth in subsection C of this section.

E. A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:

1. The total quantity dispensed in all partial fillings does not exceed the total quantity 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 after the date on which the prescription is written.

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