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Fast-Track Regulation
Agency Background Document

Agency name	Board of Medicine; Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Elimination of pharmacist in mixing, diluting & reconstituting
Date this document prepared	12/15/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The proposed amendment eliminates the pharmacist as a practitioner who can perform a second check of mixing, diluting or reconstituting drugs in a physician office by a specifically trained person and also eliminates the pharmacist as a practitioner who can perform mixing, diluting or reconstituting without a second check. A pharmacist is required by law to follow USP-NF for compounding of drug products and does not fall under the exemption for physicians and persons in their practices.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

MDR = mixing, diluting & reconstituting
USP-NF = United States Pharmacopeia-National Formulary

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On December 4, 2015, the Board of Medicine adopted an amendment to section 400 of 18VAC85-20, Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The exemption for MDR from requirements of compounding is found in:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning: ....

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug

or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed prescribing patterns; (ii) by or for a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.) or a person supervised by such practitioner pursuant to subdivisions 4, 6, or 19 of § 54.1-2901, shall not be considered compounding. ...

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amended regulation is consistency with the law for compounding by pharmacists under provisions of the Drug Control Act. The amendment is essential to protect the health and safety of citizens for whom drugs are being compounded in a physician office and to eliminate confusion about the role of a pharmacist in a physician practice.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

There is no controversy in the adoption of this amendment; it is recommended for consistency with advice by the Office of the Attorney General to the Board of Pharmacy and to the Board of Medicine Committee reviewing regulations for MDR.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The proposed amendment to section 400 eliminates the pharmacist as a practitioner who can perform a second check of mixing, diluting or reconstituting drugs in a physician office by a specifically trained person and also eliminates the pharmacist as a practitioner who can perform mixing, diluting or reconstituting without a second check. A pharmacist is required by law to follow USP-NF for compounding of drug products and does not fall under the exemption for physicians and persons in their practices.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public is greater protection in the compounding of sterile drug products. There are no disadvantages.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest to the regulated community, government officials, and the public.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods that will accomplish the objective.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	There are no costs to the state.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Pharmacists who are employed in physician practices to compound drugs.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the entities affected. The Board of Pharmacy has been advising physicians and pharmacists that any mixing, diluting or reconstituting by pharmacists must be in compliance with USP-NF, so it is doubtful that any practices will be affected. This action brings regulations into conformity with legal advice.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no costs for compliance. MDR by pharmacists constitutes compounding and has been required to comply with USP-NF.
Beneficial impact the regulation is designed to produce.	Consistency with the law and elimination of confusion and questions from physicians and pharmacists.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives; the regulation should be amended for consistency with the Code.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
400	Sets out requirements for immediate-use sterile mixing, diluting, or reconstituting	Eliminates the pharmacist as a practitioner who can perform a second check of MDR by a specifically trained person and as a practitioner who can perform MDR without a second check. Pharmacists must practice under the regulations and laws of the Board of Pharmacy. Therefore, any MDR function performed by a pharmacist would constitute "compounding" and not mixing, diluting or reconstituting. Compounding of a sterile drug product by a pharmacist must be performed under the provisions of § 54.1-3410.2., which includes a

		requirement that: "*pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding*."