Virginia Regulatory Town Hall

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Fast Track Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 85-20
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Exemption for vaccines from second check requirement
Document preparation date	2/27/08

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The proposed action will exempt the mixing, diluting or reconstituting of vaccines that is performed by personnel under the supervision of a doctor from the requirement for a second check by a doctor, pharmacist, or by a physician assistant or registered nurse who has been specifically trained.

Statement of agency final 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 February 21, 2008, the Board of Medicine took action to amend 18 VAC 85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry or Chiropractic through the fast-track regulatory process to implement a change to the requirements for mixing, diluting or reconstituting in a physician practice.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) 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. …

Provisions of the Drug Control Act that necessitate the adoption of regulations by the Board of Medicine are 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. …

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling

or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The goal of this action is to eliminate the requirement for a second check of a mixed or reconstituted vaccine in a physician practice. For the doctor in a busy pediatric practice or a family practice, the requirement for a second check necessitates that the doctor interrupt his/her time seeing patients to check on what an assistant has already prepared before administration or that the doctor employ a specifically-trained RN or PA to give vaccines since a second check would not be required. While there may be a very slight risk of harm from improperly reconstituted vaccines, the benefit of having physicians spend their time seeing patients rather than checking vaccines outweighs any potential risk. Doctors are required to ensure that all personnel under their supervision who are involved in mixing, diluting or reconstituting are appropriately trained and utilize the practices and principles of disinfection techniques and solution compatibility. Therefore, the Board believes the amendment is beneficial to the health and safety of patients in those practices.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendment because the proposal was unanimously supported by board members who believe there would no opposition and full support from the physician community. Additionally, the amendment may be reflective of how most physician practices are currently being conducted with an unlicensed person reconstituting the vaccine and administering without the doctor conducting a second check.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The proposed fast-track action amends 18VAC85-20-400 by exempting the mixing, diluting or reconstituting of a vaccine that is performed by personnel working under the supervision of a doctor of medicine or osteopathic medicine from having a second check by a doctor, a pharmacist, or by a specifically trained physician assistant or registered nurse.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The advantage to the public of this amendment would be the availability of vaccines, both pediatric and adult, in physician offices where it is not feasible or cost-effective to have a doctor, pharmacist or other appropriate licensee perform a second check when a vaccine has been mixed or diluted by a specifically-trained unlicensed assistant. While there is a very slight chance that under-dilution or over-dilution or the mixing or reconstituting of a vaccine with sterile water could put the public at risk, the chances of harm are very slight. The Board believes the overall benefit of allowing an exemption from the second check for this particular mixing or diluting outweighs any potential for harm.

There are no disadvantages to the agency or the Commonwealth of the proposed amendments.

There are no other pertinent matters of interest.

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	The agency will incur some one-time costs (less than $1,000) for mailings and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings or distribute notices by email. There are no ongoing expenditures related to this amendment. As a special fund agency, the Board must generate sufficient revenue to cover its

	expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals affected would be personnel who are trained to mix and administer vaccines and the doctors who employ them.
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 (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.	There is no estimate of how many practices these changes would affect since the Board does not license physicians by specialty. The exemption for vaccines would affect mostly pediatric and family practices where vaccines are routinely administered.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There would be a reduction in costs to the affected entities if those physician practices are following the current requirement for a second check to be performed by the doctor, a pharmacist or a specifically-trained RN or PA.

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.

There is no alternative to the proposed amendments that would accomplish this action. If the requirement for a second check of vaccines that are mixed or reconstituted before administration is routinely being ignored, the change in regulation will make current practice legal. If the regulation is not amended, it could potentially subject a number of doctors to disciplinary action for a violation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes.

Current	Current requirement	Proposed change and rationale

section number		
400	Sets the requirements for immediate-use sterile mixing, diluting or reconstituting	Eliminates the requirement for a second check of any mixing, diluting or reconstituting of a drug performed by an unlicensed person under the supervision of a doctor of medicine or osteopathic medicine. *Approximately half of the pediatric vaccines currently being administered are already pre-mixed, but the other half require mixing or reconstituting with sterile water (which is a controlled substance). Therefore, that constitutes an act that falls within the regulations specified in section 400 – including a requirement for a second check if the mixing or reconstituting is not performed by a doctor, a pharmacist or a specifically trained PA or RN.*