Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 85-20 – Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Department of Health Professions
August 7, 2006

Summary of the Proposed Regulation

The Board of Medicine (board) proposes permanent rules for mixing, diluting and reconstituting sterile solutions to replace emergency rules put into place in December, 2005. These emergency rules were put into place to comply with Chapter 475 (2005 Acts of the Assembly) which exempts doctors of medicine and osteopathic medicine who mix, dilute or reconstitute (MDR) short term use drugs from the Drug Control Act definition of compounding.

Result of Analysis

The benefits likely exceed the costs for this proposed regulatory change.

Estimated Economic Impact

Prior to legislation passed by the General Assembly in 2005, places like doctors' offices, oncology clinics and out-patient surgery clinics mixed drugs for same day use (or for longer term use by, for example, patients undergoing allergen therapy). In response to a pharmacist at an oncology clinic being cited by the Board of Pharmacy for allowing unlicensed individuals to practice MDR, and for working in an office that had not been licensed by the Board of Pharmacy, the General Assembly carved out an exception to compounding rules that would allow these medical facilities to continue their MDR practices. As required by legislation, the board instituted emergency rules to put this exception into Department of Health Profession (DHP) regulations.

Emergency regulations that became effective in December, 2005 allow doctors and medical clinics to continue MDR of drugs with certain restrictions. All drugs have to be prepared in ways that avoid the possibility of direct contact contamination. Administration of

MDR drugs labeled “immediate use“ must begin within eight hours. Emergency drugs used in the practice of anesthesiology and allergens may be start to be administered after this eight hour limit. Doctors of medicine or osteopathic medicine who engage in MDR of drugs must:

- Utilize the practices and principles of disinfection techniques, aseptic manipulations and solution compatibility.
- Ensure that all personnel under their supervision who are involved in MDR are trained in principles of sanitation, aseptic manipulation and solution compatibility.
- Establish procedures for verification of accuracy and sanitation in MDR. These procedures have to include protocols for a second check on MDR of drugs. These second checks may be performed by a doctor, pharmacist, physician’s assistant or a licensed nurse. MDR performed by doctors, or pharmacists need not receive a second check.
- Provide a designated, sanitary work space and equipment appropriate for aseptic manipulation of drugs.
- Document certain information in patient records. This information includes the names of MDR drugs that were administered, the date these drugs were prepared, and the date they were administered.
- Develop a policy and procedures manual with rules for training and to be followed in mixing, diluting or reconstituting of sterile products.

Any drugs that are hazardous to the personnel who would be mixing them, must be mixed in compliance with all federal and state laws (OSHA standards, clean air act standards, etc). Emergency regulations state that doctors retain responsibility for patient care and must monitor and document any adverse drug reactions.

Emergency rules also reiterate that MDR drugs that are not considered “immediate use” are defined as low, medium or high risk compounding by Chapter 797 of the U.S. Pharmacopeia. Doctors who do this type of MDR will follow “immediate use” rules until July 1, 2006. Thereafter, this type of MDR must comply with all applicable standards in Chapter 797.

In response to comments by interested parties, mainly members of the regulated community, the board proposes several changes to MDR rules before they are finalized. Because most doctors’ offices and clinics are open for longer than eight hours, the board proposes to

extend the start of administration of immediate use drugs to with 10 hours of MDR. The board also adds language to clarify that, regardless of any time limit set in these rules, administration cannot exceeded drug manufacturer time limits for use. The board also proposes to clarify that doctors need not document their own training and that references to licensed nurses in the emergency rules are meant to read as registered nurses licensed by the Board of Nursing.

Even though qualified nurses and physician's assistants are allowed to perform second checks for MDR drugs, the emergency rules do not allow these individuals to engage in MDR of drugs without a second check on their own work. The board proposes to add registered nurses and physician's assistants to this list of individuals who can engage in MDR without a second check.

The board also proposes to ease the paperwork burden for this regulation by eliminating the need for preparation dates of drugs to be documented in patient files and changing the requirement for a "manual" to document policies and procedures to a requirement for "written policies and procedures". The proposed rules require that procedures for verification be established and *implemented* rather than just established, as required by the emergency rules.

In response to comments asking that physicians be allowed to implement and teach aseptic techniques specific to their setting, specific techniques that define aseptic manipulation will be eliminated from these proposed MDR rules.

Since emergency rules were put into place, members of the regulated community have incurred costs associated with training personnel and documenting both correct MDR of drugs (second checks) and use of MDR drugs by patients that they likely were not incurring when they were practicing MDR outside of the then existing regulatory structure. The proposed rules will decrease, but not eliminate, these costs. The proposed rules do offer a benefit for public health in that there are now codified rules that will tend to protect patients from improperly mixed drugs. The benefits that will likely be realized in increased safeguards on patient safety will likely outweigh the costs that remain after promulgation of these proposed rules.

Businesses and Entities Affected

The proposed rules, and the emergency rules they replace, will affect any doctors who engage in mixing, diluting or reconstituting drugs for use during regular office hours or, in

certain instances, for longer term patient use. The Commonwealth currently licenses approximately 27,190 doctors of medicine and 1,145 doctors of osteopathic medicine.

Localities Particularly Affected

The proposed rules will affect all localities in the Commonwealth.

Projected Impact on Employment

To the extent that the proposed rules cause doctors to begin in-office mixing diluting and reconstituting drugs, employment opportunities may be created for qualified individuals to engage in this activity. It seems, though, that most doctors' offices that engage in MDR practices were already following currently allowed practice before emergency rules were put in place. If this latter scenario more closely resembles practice before emergency rules, the proposed rules will likely have little impact on employment in the Commonwealth.

Effects on the Use and Value of Private Property

The Department of Health Professions reports that regulants will incur minimal training and documentation costs to comply with the proposed rules. To the extent that costs for regulants increase, but revenues do not experience a corresponding increase due to this regulatory change, the proposed rules will likely lead to a (likely very small) decrease in profits and the value of affected regulants' businesses.

Small Businesses: Costs and Other Effects

The Department of Health Professions reports these proposed rules will likely affect approximately 5,000 small businesses in the Commonwealth. These businesses will incur training and documentation costs. Changes made to these rules between the emergency and proposed stage of this regulatory action likely minimize these costs.

Small Businesses: Alternative Method that Minimizes Adverse Impact

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Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.