Virginia Regulatory Town Hall

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-20-10 et seq.
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Rules for mixing, diluting and reconstituting
Document preparation date	6/22/06

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

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

The Board proposes to replace "emergency" regulations which have been in effect since December 21, 2005. Chapter 475 of the 2005 Acts of the Assembly required the Board of Medicine to comply with amendments to the Drug Control Act (§ 54.1-3400 et seq.), exempting doctors of medicine or osteopathic medicine who mix, dilute or reconstitute drugs from the definition of compounding. The second enactment clause of the bill stated:

> *2. That notwithstanding the provisions of Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1, the Board of Medicine shall, within 280 days of the enactment of this act, promulgate regulations establishing standards for the mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient by a practitioner of medicine or osteopathy or a person supervised by such person, and the transportation of these drugs. The Board of Medicine shall also promulgate regulations establishing standards for facilities in which mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient by a*

practitioner of medicine or osteopathy or a person supervised by such person occurs, including a regular inspection program.

The key provisions of the new regulation include the definition and requirements for "immediate-use" sterile mixing, diluting or reconstituting, requirements for low, medium or high risk mixing, diluting or reconstituting and the responsibilities of the supervising doctor.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe 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, 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. …

Changes to 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 purpose of the regulatory action is compliance with a statutory mandate for regulations establishing standards for mixing, diluting or reconstituting of sterile drug products by doctors or personnel under their supervision to be administered to patients with minimal requirements that protect the safety, integrity and efficacy of drugs that will be administered to patients in doctors' practices. In addition, the law requires establishment of standards for facilities in which the mixing, diluting or reconstituting of sterile drug products occurs and for the transportation of such drugs.

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.)

This regulatory action adds Part IX for the Mixing, Diluting or Reconstituting (MDR) of Drugs for Administration. For the purpose of applicability, immediate-use MDR is defined as no direct contamination and 10 hours of less between preparation and administration. Emergency drugs used in anesthesia and allergens are allowed to exceed the 10-hour limit. Standards for safe procedures in immediate-use MDR, training of personnel involved, checks for accuracy, work space and equipment and documentation are set in section 400. Mixing, diluting or reconstituting that is hazardous to personnel must be consistent with federal OSHA standards. Mixing, diluting or reconstituting that does not fall under the definition of immediate-use must be conducted in accordance with requirements of USP Chapter 797 for compounding of sterile drug products. Finally, doctors who mix, dilute or reconstitute are responsible for patient care and for monitoring and document adverse reaction. They must also disclose that they mix, dilute or reconstitute drugs in their practices in a manner prescribed by the board and are subject to unannounced inspection.

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.

1) The primary advantage to the public is some measure of increased safety for the mixing, diluting or reconstituting of drug products that will be administered to a patient. Many patients who receive such products have very vulnerable immune systems, so the introduction of even miniscule amounts of contaminates can have risks. Patients who are receiving chemotherapy, for example, need to be assured that the mixing occurs under aseptic manipulations and that the dosages have been properly mixed and checked for maximum accuracy and efficacy. There are no disadvantages to the public.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other matters of interest.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	a) 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; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will on-going expenditures relating to inspections of physician practices in which mixing, diluting and reconstituting occurs. The enactment clause on Chapter 475 requires that regulation of MDR include a "regular inspection program." While procedures have not been developed for such a program, it is anticipated that doctors will be asked to inform the Board at the time of the next renewal as to

	whether they or person under their supervision mix, dilute or reconstitute drugs in their practices. Based on that information, the Board will likely conduct a random audit of those practices for compliance with Board regulations. It is likely that these inspections will be included in the responsibilities of a person trained as a pharmacy inspector. The increased workload for the inspectors could eventually lead to the need for an increased number of inspectors.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The entities that are likely to be affected by these regulations would be doctors of medicine or osteopathic medicine who mix, dilute or reconstitute sterile drug products or who supervise personnel in their practice who mix, dilute or reconstitute.
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 are 27,191 doctors of medicine who have active licenses and 1,145 doctors of osteopathic medicine. Not counting the estimated number who are not currently practicing and those working in large health care organizations, it is estimated that there may be 5,000 small businesses affected.
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.	The costs for compliance for the vast majority of small businesses should be minimal since documentation and training requirements are minimal and are consistent with current medical practices. The doctor will be required to use and train personnel in techniques that protect the patient who will receive the mixed drug product, but no special equipment or spaces are required. For those doctors who engage in high risk compounding, their practices are already required by federal law to comply with OSHA rules, so these regulations do not impose additional costs. Compounding that does not qualify as immediate use is likely performed in large medical centers where JCAHO accreditation already requires compliance with USP 797.

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 were no viable options to the adoption of regulations; it was mandated by Chapter 475 of the 2005 Acts of the Assembly. Given the scope of the regulated activity and potential impact of requirements on mixing, diluting and reconstituting drug products by doctors or persons under their supervision, the Board decided to constitute an ad hoc committee and task it with

developing recommendations for the emergency regulations and, following public comment on the NOIRA, drafting proposed regulations. Chaired by John Armstrong, MD, a specialist in infectious disease, the committee was comprised of doctors with expertise in specialties where mixing, diluting and reconstituting drug products commonly occurs and doctors from practices in urban and rural Virginia. Member of the committee included James T. May, MD, hematologist/oncologist; Richard Ingram, MD, hematologist/oncologist; James Bowles, MD, rural family practice; Burt Sundin, MD, plastic surgery; Hugh Bryan, MD, orthopedic surgeon; and Thomas Leecost, DPM, podiatrist and President of the Board. In addition, the committee included two pharmacists who have expertise in compounding - David Newton, Professor of Pharmacy at Shenandoah University and the Chair of the 2000-2005 Sterile Compounding Committee of the Council of Experts for the United States Pharmacopeia, and Lea Ann Hansen, hematology/oncology at MCV School of Pharmacy. The committee held five public meetings in which all parties were encouraged to participate, and members worked individually on language for the group's consideration. Throughout the course of discussion and development of regulatory language, members of the committee communicated with colleagues in their specialties and in other specialties.

In the process of negotiated rule-making, there was a wide range of opinion, hours of discussion, and numerous drafts and redrafts. The regulation recommended to the Board was a consensus document that did not satisfy all the interested parties in its entirety but was adopted to achieve a balance of public safety and impact on practice.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

The Notice of Intended Regulatory Action was published in the Register on January 23, 2006 and sent to the Public Participation Guidelines list with comment requested until February 22, 2006. The following comments are summarized:

Hugh Bryan, M.D. – Documentation and handling requirements of immediate-use mixing should be minimal; regulations should increase patient safety and outcomes, not restrict the ability of physicians to practice medicine.

Joseph Leming, M.D. – The Board should delay implementation of these onerous and meritless regulations as they do not increase patient safety as defined by mortality and/or morbidity.

Board's response: *The Board has proposed significant reductions in the amount of documentation and oversight of mixing, diluting and reconstituting required. Implementation of the law is not an option since the Board is mandated to promulgate regulations, including standards for facilities that mix, dilute and reconstitute drugs.*

The Asthma and Allergy Society of Virginia, representing over 85 allergists in Virginia – Supports the continuation of an immediate-use classification for allergens, including the

provision allowing initiation to exceed 8 hours after preparation. Expresses concern about the requirement for a second check in section 400; are not opposed to procedures for verification of the accuracy of the product but believes that the proper training of personnel and adherence to procedures is the key to ensuring accuracy.

Board's response – *In the adoption of proposed regulations, the Board has eliminated documentation of training and the requirement for a second check if the MDR was performed by a licensed practitioner.*

Medical Society of Virginia – MSV concurs with Board's recommendations for mixing, diluting and reconstituting drugs with greater risks and with the requirement for physician responsibility for patient care and documentation of adverse reactions. MSV requested clarification of the applicability of the regulations to physicians in settings other than office practice and suggested that the Board make them apply only to those practice settings in which the physician has clear control over the facility and personnel. The regulations are too prescriptive in nature and the amount of documentation, recordkeeping and oversight required exceeds the concomitant return in patient care and safety. MSV suggested specific changes to sections of regulation.

Board's response – *The Ad Hoc Committee reviewed all the suggested amendments to emergency regulation; the Board's acceptance or modification of the recommendations is discussed in the detail of changes.*

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. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number	Proposed change and rationale
n/a	400	**Requirements for immediate-use sterile mixing, diluting or reconstituting.** Subsection A. For the purposes of this chapter, the mixing, diluting, or reconstituting of sterile manufactured drug products, when there is no direct

		contact contamination and administration begins within 10 hours of the completion time of preparation shall be considered immediate-use. If manufacturers' instructions or any other accepted standard specifies or indicates an appropriate time between preparation and administration of less than 10 hours, the mixing, diluting or reconstituting shall be in accordance with the lesser time. No direct contact contamination means that there is no contamination from touch, gloves, bare skin or secretions from the mouth or nose. Emergency drugs used in the practice of anesthesiology and administration of allergens may exceed 10 hours after completion of the preparation, provided administration does not exceed the specified expiration date of a multiple use vial and there is compliance with all other requirements of this section. **Changes from emergency regulation:** **At the request of the Medical Society, the time-limit for "immediate-use" was increase from 8 to 10 hours, as more consistent with a typical day in a physician practice.** **The Board also added a requirement that administration cannot exceed the specified expiration date of a multiple use vial, even for those drugs that are allowed to exceed the 10 hour limit for immediate use.** *Multiple use vials should be labeled with an expiration date to alert the practitioner and the patient of the date after which the date may not be safe for administration. The addition of such a requirement is important for patient safety to avoid possible contaminations or infections.* *The committee first reviewed the standards for compounding drug products found in Chapter 797 of the U. S. Pharmacopeia, which is recognized as the official compendia of drug standards. The intent of Chapter 797 is to "prevent harm and fatality to patients that could result from microbial contamination (nonsterility)…" Currently, there are three levels of compounding under USP – Low, Medium and High Risk. Compounding must be performed in an ISO Class 5 laminar airflow workbench (hood) which is located in an ISO Class 8 buffer room with an ante area.* *New definitions and standards have been proposed for USP Chapter 797 that would create an exemption from the ISO Class 5 requirement for "immediate-use" compounded products, defined as three or fewer sterile products when there is no direct contact contamination, and administration begins within one hour and is completed within 12 hours of preparation. The immediate-use exemption became the starting point for regulations governing mixing, diluting and reconstituting by doctors, but it became apparent that the limitation of three or fewer products and the beginning of administration within one hour would be too burdensome on a number of doctors' practice and the patients they serve. Therefore, the committee concluded that immediate-use could entail the preparation of any number of products with administration to begin within 10 hours, the equivalent of a day of office hours. Exceptions were made for: 1) products for which the manufacturer or another accepted standard specifies an appropriate time*

		of less than 10 hours; 2) emergency drugs that are used in anesthesiology, since it is common practice to mix up those drugs at the beginning of the day and have them available on the cart for emergency administration at any time during procedures requiring anesthesia, which often extends beyond 10 hours; and 3) administration of allergens to exceed the ten hours after preparation, since many of them are prepared and sent home with the patient to administer over a periods of days or weeks. The product must be mixed, diluted or reconstituted with no direct contact contamination in accordance with standards set in subsection B. B. Doctors of medicine or osteopathic medicine who engage in immediate-use mixing, diluting or reconstituting shall: 1. Utilize the practices and principles of disinfection techniques, asceptic manipulations and solution compatibility in immediate-use mixing, diluting or reconstituting; and **Change from emergency regulation:** **Since the definition and all the specific requirements for asceptic manipulation were deleted from subdivision 2 of subsection B, subdivision 1 was added to generally state the responsibility of the doctor to use proper practices and adhere to certain principles. The onus rests on the doctor to know the proper techniques and ensure that they are followed by personnel under his/her supervision.** 2. Ensure that all personnel under their supervision who are involved in immediate-use mixing, diluting or reconstituting are appropriately and properly trained in and utilize the practices and principles of sanitization techniques, aseptic manipulations and solution compatibility. **1st change from emergency regulations:** **At the request of the Medical Society, the Board eliminated the requirement that evidence of training by a doctor of medicine or osteopathic medicine be documented and maintained in personnel files.** **2nd change from emergency regulations:** **The specific techniques that define aseptic manipulation were included in the emergency regulation because the Ad Hoc Committee believed some physicians and staff are failing to adhere to proper practices which could compromise the safety of the drug being mixed and administered. Believing that physicians should have the discretion to implement and teach aseptic technique in various clinical settings, the Medical Society recommended deletion. The Ad Hoc Committee and the Board agreed with the comment and deleted that portion of the regulation that sets out the specific elements of aseptic manipulations.** 3. Establish *and implement* procedures for verification of the accuracy of the product that has been mixed, diluted, or reconstituted to include a second check performed by a doctor of medicine or osteopathic medicine or a pharmacist or by a physician assistant or a *registered* nurse who has been specifically trained pursuant to subdivision B 2 of this subsection in

		immediate-use mixing, diluting or reconstituting *Since mixing, diluting and reconstituting can be performed by unlicensed persons for whom compounding sterile drug products is not typically within their scope of training and education, it is necessary to have a second check of the procedure and solution performed by a person who has compounding within their scope of practice or by a licensee who has been specifically trained in immediate-use mixing, diluting or reconstituting.* **Change from emergency regulation:** **The Board added a requirement to "implement" procedures for verification of the accuracy of the product; it is assumed that established procedures would be implemented but the Committee recommended specificity in the rule. The term "licensed" nurse was changed to "registered" to clarify the level of training and knowledge necessary for a licensee to perform the check for accuracy.** **The Medical Society had recommended deletion of a requirement for a second check, but the Ad Hoc Committee did not accept the recommendation since there are no requirements for unlicensed persons who may be mixing, diluting or reconstituting drugs and no documentation of their training.** Mixing, diluting or reconstituting performed by a doctor of medicine or osteopathic medicine, a pharmacist or by a specifically trained physician assistant or registered nurse does not require a second check. **Change from emergency regulation:** **The emergency regulation did not allow a physician assistant or a registered nurse to mix, dilute or reconstitute without a second check, but since those licensees are allowed to perform the second check for an unlicensed person, it was logical to include them in the listing of practitioners who do not require a second check.** 4. Provide a designated, sanitary work space and equipment appropriate for aseptic manipulations. *While the Board stopped short of requiring a laminar hood for immediate-use mixing, diluting or reconstituting, it was agreed that space and equipment set aside for aseptic manipulation was essential to ensure sterility and safety.* **Board response to MSV comment: MSV had recommended the deletion of "equipment" from this requirement, so it would not be necessary to have equipment appropriate for aseptic manipulations. While not specifically requiring clean gloves and sterilizing equipment, the Board declined to eliminate equipment completely.** 5. Document or ensure that personnel under his supervision documents in the patient record or other readily-retrievable record that identifies the patient and the following: the names of drugs mixed, diluted or reconstituted, the date of preparation, and the date of administration as evidence that the mixing, diluting or reconstituting was immediate-use.

		When there is an inspection of a physician office or investigation of a complaint, a physician must be able to document that the mixing, diluting or reconstituting being performed qualified for the definition of "immediate-use." The elements required to be placed in the patient record are consistent with standard practice for most physicians. **Change from emergency regulation:** **The Medical Society requested deletion of all specific elements of the documentation, such as the date of preparation and the names of drugs being mixed. They also recommended that the requirement from the doctor to either document himself or ensure that personnel under his supervision document be deleted. The Board considered the comment and determined that the emergency rule could be amended by deleting the date of preparation as evidence that the mixing, diluting or reconstituting was immediate use. Documentation in the patient or other record that identifies the patient, the drugs administered and the date of administration does not constitute an additional burden on a practitioner because that information should always be included in any complete medical record.** 6. Develop and maintain written policies and procedures to be followed in mixing, diluting or reconstituting of sterile products and for the training of personnel. *Policies and procedures are necessary for consistency in a practice and for a physician to be able to provide evidence of training personnel and demonstrate that established practices are compliant with regulations.* **Change from emergency regulation:** **The Board followed the change recommended by the Medical Society and eliminated the need for a policy and procedure "manual".** C. Any mixing, diluting or reconstituting of drug products that are hazardous to personnel shall be performed consistent with requirements of all applicable federal and state laws and regulations for safety and air quality, to include but not be limited to those of the Occupational Safety and Health Administration (OSHA). For the purposes of this chapter, Appendix A of the National Institute for Occupational Safety and Health publication, *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* will serve as the reference list of hazardous drug products. *Although certain drugs, such as chemotherapy, may qualify for immediate-use mixing, diluting or reconstituting, their toxicity to personnel requires an additional level of protection and sterility. Those hazardous drug products are currently listed in Appendix A of an OSHA publication and mixing, diluting or reconstituting of those products requires compliance with applicable federal and state laws for safety and air quality.*
n/a	410	**Requirements for low, medium- or high-risk sterile mixing, diluting or reconstituting.**

		A. Any mixing, diluting or reconstituting of sterile products that does not meet the criteria for immediate-use as set forth in 18VAC85-20-400 A shall be defined as low-, medium-, or high-risk compounding under the definitions of Chapter 797 of the U. S. Pharmacopeia (USP). *If the mixing, diluting or reconstituting being performed does not meet the Board's liberal definition of immediate-use, the compounding then falls under the requirements of Chapter 797 as the standard for sterility and safety.* B. Until July 1, 2007, all low-, medium-, or high-risk mixing, diluting or reconstituting of sterile products shall comply with the standards for immediate-use mixing, diluting or reconstituting as specified in 18VAC85-20-400. Beginning July 1, 2007, doctors of medicine or osteopathic medicine who engage in low-, medium-, or high-risk mixing, diluting or reconstituting of sterile products shall comply with all applicable requirements of USP Chapter 797. Subsequent changes to the USP Chapter 797 shall apply within one year of the official announcement by USP. C. A current copy, in any published format, of USP Chapter 797 shall be maintained at the location where low-, medium- or high-risk mixing, diluting or reconstituting of sterile products is performed. *With the changes proposed to USP Chapter 797, all pharmacies and other entities that engage in sterile compounding will have until July 1, 2007 for compliance with requirements for buffer zones and clean rooms for compounding. Therefore, the Board granted the same timeframe for compliance, but until such time, anyone who engages in low-, medium-, or high-risk mixing, diluting or reconstituting of sterile products must comply with Board requirements for immediate-use.*
n/a	420	**Responsibilities of doctors who mix, dilute or reconstitute drugs in their practices.** A. Doctors of medicine or osteopathic medicine who delegate the mixing, diluting or reconstituting of sterile drug products for administration retain responsibility for patient care and shall monitor and document any adverse responses to the drugs. *The ultimate responsibility for mixing, diluting or reconstituting of sterile drug products remains with the doctor who has delegated such procedures to persons under his supervision. The rule reiterates that responsibility and the obligation to monitor and document any adverse responses.* B. Doctors who engage in the mixing, diluting or reconstituting of sterile drug products in their practices shall disclose this information to the board in a manner prescribed by the board, and are subject to unannounced inspections by the board or its agents. *Disclosure of mixing, diluting or reconstituting of sterile drug products in their practices will likely take the form of a check box on the biennial renewal form. There is no additional application or form to submit to comply with this requirement.*