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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Permits for outsourcing pharmacies
Date this document prepared	10/6/15

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

In compliance with the second enactment clause of Chapter 300 of the 2015 Acts of the Assembly, the Board of Pharmacy is promulgating regulations to implement the requirement of law that facilities engaged in the compounding of sterile drugs and registered with the U. S. Secretary of Health and Human Services as outsourcing facilities must hold a permit to compound or ship compounded drugs into Virginia. Regulations set fees for approval of applications and renewal of permits and registration. Requirements for pharmacies that are or

are not applicable to outsourcing facilities are specified, and requirements for pharmacist supervision, recordkeeping, and renewal are also established. Finally, regulations specify that if a compounding pharmacy shares physical space with an outsourcing facility, the more stringent standards of Good Manufacturing Practices are applicable.

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.

FDA = Food and Drug Administration
PIC = Pharmacist-in-charge
USP = United States Pharmacopeia

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

This is an emergency regulation because the second enactment of Chapter 300 of the 2015 Acts of the Assembly requires that the Board of Pharmacy promulgate regulations to be effective in 280 days or less from enactment, which was March 17, 2015. Therefore, the Board has authority to promulgate an emergency regulation under § 2.2-4011 of the *Code of Virginia.*

Legal basis

Other than the emergency authority described above, 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) the promulgating entity, i.e., agency, board, or person.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

The specific authority to issue permits and regulate outsourcing facilities is found in:

§ 54.1-3401. Definitions

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. Every outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations except §54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.

The authority to promulgate emergency regulations is found in the Administrative Process Act in:

§ 2.2-4011. Emergency regulations; publication; exceptions.

…B. Agencies may also adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment and the regulation is not exempt under the provisions of subdivision A 4 of § 2.2-4006. In such cases, the agency shall state in writing the nature of the emergency and of the necessity for such action and may adopt the regulations. Pursuant to § 2.2-4012, such regulations shall become effective upon approval by the Governor and filing with the Registrar of Regulations.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board of Pharmacy sought legislative authority in 2015 to facilitate the implementation of the Drug Quality and Security Act by creating a new licensing category and oversight for outsourcing facilities and nonresident outsourcing facilities.

As of July 1, 2015, state law recognizes "outsourcing facilities," but regulations are necessary to provide for permits and oversight. There are approximately 50 outsourcing facilities currently registered with the FDA and likely more will register in the next year. Without a provision for the Board of Pharmacy to license these facilities, these entities will likely not be able to ship into the Commonwealth. This has the potential to negatively impact access to critically needed compounded drugs. Unlike outsourcing facilities that may legally compound sterile drugs for office administration, pharmacies under federal law may only compound human drugs pursuant to patient-specific prescriptions. Emergency regulations are promulgated to allow permitting of in-state facilities and registration of non-resident outsourcing facilities.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Section 54.1-3307 of the Code of Virginia directs the Board of Pharmacy to regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. It further states the Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

In response to the meningitis outbreak resulting from contaminated compounded drugs from the New England Compounding Center in 2012 which sickened 751 people and killed 64 people, including five Virginians, Congress passed the Drug Quality and Security Act in the Fall of 2013. It creates a new licensing category under Section 503B of the Federal Food, Drug, and Cosmetic Act called outsourcing facilities. These entities are large-scale sterile compounding facilities that provide compounded drugs predominantly to hospitals, physician offices, or medical clinics for administration to patients. Due to the risk associated with compounding sterile drugs on a large-scale, these facilities are required under federal law to compound in compliance with Current Good Manufacturing Practices, similar to a pharmaceutical manufacturer. Regulations promulgated by the Board will ensure that outsourcing facilities

located in the state or shipping drugs into Virginia have oversight that will protect public health and safety.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
20	n/a	Sets the fees for pharmacists and facilities licensed under this chapter	Subsection C sets the initial application fees: For an outsourcing facility permit, the application fee is $270, which is identical to an application fee for a pharmacy, non-restricted manufacturer, and wholesale distributor. For registration of a non-resident outsourcing facility, the application fee is $270, which is identical to a non-resident pharmacy and non-resident wholesale distributor. Subsection D sets the annual renewal fees: Renewal deadlines and fees for outsourcing facilities are identical to pharmacies, non-restricted manufacturers and wholesale distributors. Subsection E sets the late fees, which are identical to pharmacies, non-restricted manufacturers and wholesale distributors. *Outsourcing facilities operate similarly to manufacturers, wholesale distributors and pharmacies; therefore, the fee is similar to those facilities.*
n/a	215	Sets the requirements for an outsourcing facility to obtain a permit and standards for practice	Subsection A states the requirement in law for any facility engaged in sterile compounding without a prescription for a specific patient to have a permit or, in the case of non-resident facilities, to be registered with the Board. Subsection B requires that an outsourcing facility comply with all requirements for a pharmacy with the exception of those that are not applicable to a facility that does

			not deal directly with the public. *Outsourcing facilities typically compound drugs without a patient-specific prescription to supply large health systems. While they may also compound patient-specific drugs, the operation is different from that of a traditional pharmacy, and therefore certain requirements for a pharmacy, relating to dispensing, prescriptions awaiting delivery, prescriptions and chart orders, automated prescription records and preparation of prescriptions, should not apply.* Subsection C establishes some additional requirements that may not be applicable to the general practice of pharmacy but are necessary for safe practice in an outsourcing facility. 1) All outsourcing facilities have to have a PIC who routinely practices at that location, and a pharmacist must be present at all times the facility is open. *All pharmacies are required to have a PIC who "shall control all aspects of the practice of pharmacy,"* but rules for outsourcing facilities specially require that the PIC routinely practices in the facility and that a pharmacist must be present at all times the facility is operating. *2)* Recordkeeping requirements specify that records must be maintained for five years and available upon request. The composition of a compounding record is specified to ensure that the Board would be able to trace all the ingredients of a compounded drug in case there is a recall or some issue identified that might put the public at risk. Quality control records must be maintained, including stability and sterility testing that is used to determine the date beyond which the drug should not be used. *3)* Requirements for renewal specific to outsourcing facilities are included in Subsection C. They include documentation that a) the facility is registered under the Federal Food, Drug and Cosmetic Act; b) the facility has a current inspection report; and c) it complies with Good Manufacturing Practices. Any facility that fails to

			register with the Act or fails to submit a current inspection report cannot renew a permit or registration in Virginia.
321	n/a	Sets rules for compounding controlled substances	Subsection A is amended to clarify that pharmacies that do not share physical space with outsourcing facilities must perform compounding in accordance with USP, which is the current rule. Subsection B is added to specify that pharmacies that do share physical space with outsourcing facilities must perform compounding in accordance with Good Manufacturing Practices, which has a higher standard for performing sterile compounding.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no viable alternatives to meet the essential purpose of the action. The second enactment of Chapter 300 requires the Board to promulgate regulations within 280 days of enactment.

Not creating a new licensing category for outsourcing facilities creates inconsistency between federal and state compounding laws, does not allow the Board of Pharmacy to fulfill its responsibility in law to regulate compounding, potentially negatively impacts patient access to critically needed compounded drugs, and prevents entities from doing business as an outsourcing facility in Virginia.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

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 and family stability.