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Proposed Regulation
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	3/25/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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

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.

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.

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 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.
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 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.

Regulations set fees for approval of applications and renewal of permits and registration, similar to fees for other facilities regulated by the Board. 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.

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 more accountability, safety and consistency in the sterile compounding of drugs being supplied to hospitals and other facilities for patient administration. There are no disadvantages;
2) There are no advantages or disadvantages to the agency; this will be a new responsibility for inspectors who must be specifically trained to inspect outsourcing facility; and
3) Promulgation of regulations for the issuance of permits to outsourcing facilities is a statutory mandate: "*A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.*"
Fees for outsourcing permits should make Virginia a highly competitive place to do business; in New York, the registration fee is $825; in California, the fee for a pharmacy that does sterile

compounding is $780; in Tennessee, the fee for an outsourcing facility that does sterile compounding is $775. In Virginia, the fee is $270.

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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage 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.

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**	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 no additional costs 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. On-going expenditures relating to facility inspections or investigations should be offset by fees collected from applicants and permit holders.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Large-scale sterile compounding facilities that provide compounded drugs predominantly to hospitals, physician offices, or medical clinics for administration to patients are required to obtain a permit from the Board of Pharmacy.
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.	The FDA has currently registered 59 such facilities. The Virginia Board currently has 16 applications pending registration under the emergency rules.
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**	The cost for an outsourcing facility permit will be $270 initially, and $270 annually to renew the permit.

regulations.	
Beneficial impact the regulation is designed to produce.	Permits for outsourcing facilities and routine inspections of those facilities will provide greater assurance of the safety and efficacy of compounded drugs.

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 to the proposal considered. As of July 1, 2015, state law recognizes "outsourcing facilities," but regulations are necessary to provide for permits and oversight. 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.

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 is no alternative regulatory method; the action is mandated by legislation passed in the 2015 General Assembly.

Public comment

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

There was a comment period on the NOIRA to replace emergency regulations from 12/28/15 to 1/27/16. No comment was received.

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.

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.

The proposed regulations are identical to the emergency regulations that became effective 12/7/15 with the exception of an edit in section 215 to correctly identify subsection of section 190 that do not apply to outsourcing facilities.

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 <u>not</u> 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 <u>do</u> share physical space with outsourcing facilities must perform compounding in accordance with Good Manufacturing Practices, which has a higher standard for performing sterile compounding.