Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Regulatory reform changes
Date this document prepared	4/2/13

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Amendments are adopted to: 1) facilitate electronic renewal of licenses; 2) accommodate verification of practical experience for pharmacy interns coming from some other states; 3) eliminate the requirement for pharmacy technicians to submit documentation of continuing education to renew registration; 4) allow for more than one pharmacist to be involved in verifying the accuracy of a prescription and clarify documentation for each involvement; 5) modify requirement for labeling in unit dose dispensing systems to protect patient privacy; 6) allow for current technology that uses compliance packaging instead of unit dose dispensing system in hospitals or long-term care facilities; and 7) eliminate the requirement for an alarm system for teaching institutions that only stock schedule VI drugs.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On March 12, 2013, the Board of Pharmacy adopted fast-track amendments to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

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.

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18 VAC 110-30-10 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 statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including the dispensing of controlled substances is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.
The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. 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 which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.
8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 purpose of amended regulation is to eliminate requirements that are not necessary to protect the integrity and safety of prescription medication or to assure the competency of applicants and those renewing their technician registration. As new technology is developing and pharmacy systems change and become more automated, the Board has amended its regulations to facilitate pharmacy practice that maintains safeguards and reduces the possibility of human error in dispensing of prescription drugs.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The Board has opted to use the fast-track process for two reasons: 1) the action is consistent with the Governor's project to reform regulations that are unnecessarily burdensome; and 2) it does not anticipate any objection to the changes.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

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allow for current technology that uses compliance packaging instead of unit dose dispensing system in hospitals or long-term care facilities; and 7) eliminates the requirement for an alarm system for teaching institutions that only stock schedule VI drugs.

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 of the regulatory action is less burdensome and costly regulation for applicants, registrants and pharmacies that utilize newer technology and dispensing systems. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) The action is the result of a review conducted by staff of the Board of Pharmacy and the Department pursuant to the Governor's Regulatory Reform Project.

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.

The proposed regulation does not affect any locality.

Regulatory flexibility analysis

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.

Since the intent is to promulgate less burdensome and costly regulations, there are no alternative methods for accomplishing the objective of reducing the regulatory burden.

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	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 or entities for necessary functions of regulation. There would be little or no additional expense for promulgation of the amended rule. Consideration of the proposed rule has been during a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that would be affected would be pharmacies, pharmacists and pharmacy technicians. A few applicants from other states would be positively affected.
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 currently 1772 pharmacies that are licensed to do business in the Commonwealth. Since pharmacies are not licensed by category, it is unknown how many are hospital, retail, compounding or other type of pharmacy. It is estimated that less than one half of pharmacies are small businesses. There are 11,941 pharmacists and 12,227 pharmacy technicians.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential	There are no costs associated with the changes to regulations.

purposes that are a consequence of the proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	Amendments to section 425 will allow for compliance packaging in addition to unit dose dispensing; pharmacies using such technology will avoid the $250 fee and delay in implementation currently necessary to apply for a pilot project or use of innovative technology. An amendment to section 710 will eliminate the requirement for an alarm system in teaching institutions that only stock schedule VI 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.

Following the close of comment on the periodic review, staff of the Board reviewed the regulation in light of current practices and interpretation of regulations. Staff recommendations were presented to the full Board on March 12, 2013. Only those changes that would reduce the regulatory burden were considered for adoption in this fast-track action.

Periodic review/small business impact review result

If this fast-track regulation is <u>not the result</u> of a periodic review/small business of the regulation, please delete this entire section.

If this fast-track regulation <u>is</u> the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

1) The Notice of Periodic Review was published in the Register of Regulations, posted on Townhall and sent to the public participation mailing list for the Board of Pharmacy with the opportunity for comment from November 5th to December 5th. A summary of comment is:

Commenter	Comment	Agency response
Kurt Bell, RPh	Commented on regulatory actions from the accrediting body and federal programs and requested that the Board consider ever-evolving demands on pharmacists and pharmacies prior to instituting more regulations or enforcement of regulations.	Board appreciated the comment and has made efforts to reduce the regulatory burden in response to new technology and requests from pharmacists provided amended requirements continue to safeguard the safety and integrity of prescription medications.
Michelle Lincoln Omnicare	Requested two changes: 1) Amendment to section 425 on robotic pharmacy systems to allow for use of such systems to utilize compliance packaging of drugs in addition to unit dose dispensing; and 2) Amendment to section 280 on transmission of a prescription order by facsimile machine to exclude schedule VI drugs from requirement for a cop of an original prescription from a long-term care facility.	1) The Board adopted amendments to section 425 to accomplish the intent of the request. 2) The Board will consider the amendment requested at the time the regulation in section 280 is fully evaluated.

The regulation meets the criteria in Executive Order 14 as it is necessary for public health and the safety of prescription medications; it is clearly written and easily understandable. There have been no complaints or concerns from the public about complexity and no conflict with state or federal law or regulation. In 2006, Chapter 20 was thoroughly reviewed and Chapter 50, Regulations Governing Wholesale Distributors, Manufacturers and Warehousers was carved out to reduce the complexity and focus the chapter on the regulation of pharmacists and pharmacies. Chapter 20 and has been amended thirty-two times (32) in the last ten years to address changes in technology and practice and to respond to legislative mandates. There are currently three other actions on Chapter 20 that have been flagged on Townhall as reducing the regulatory burden, and two additional actions adopted in response to a legislative mandate or response to petition for rulemaking.

Family impact

Please assess the impact of the proposed 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.

Detail of changes

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

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
20	Establishes fee amounts and schedules for renewals	To accommodate electronic renewal notices and encourage one-time payments, amendments clarify that the renewal fees may be paid at any time up to the expiration date. Renewal notices are now being sent electronically; and if a licensee has not paid by a certain date, a paper copy is sent by regular mail. By changing the language from "due (*date)"* to "due no later than (*date*), it clarifies that the fee may be paid any time prior to the due date. Subsection I is deleted because it only applied to renewals for the 2009-2010 renewal cycle.
40	Establishes regulations for practical experience required for initial licensure	Subsection F is amended to provide: F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state ~~does not use internships to gain practical experience in pharmacy but~~ relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification. *Intern hours in a few states (Georgia, for example) are certified by the pharmacy school rather than the Board, even though the Board does issue an intern registration to gain 500 additional hours above 1,000 gained while in school. The school simply certifies all 1,500 hours, so the regulation needs to be amended to accommodate this situation.*
105	Sets out the requirements for renewal and reinstatement of pharmacist licenses and pharmacy technician registration	Subsection B is amended to allow a pharmacy technician to renew by "attestation of having obtained" required continuing education (CE). Currently, the regulation requires "proof" of required CE. *The Board has not required pharmacy technicians to submit proof of CE since 2009, so the regulation is inconsistent with Board policy. Additionally, the Board does not require proof for any other licensing category; it only requires attestation.*
270	Establishes the requirements for dispensing of prescriptions and certification of completed prescriptions	Subsection C is amended to After the prescription has been prepared and prior to the delivery of the order, ~~the~~ a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a

		certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515. *At its June 12, 2012 meeting, the Board discussed a possible conflict between Regulations 18VAC 110-20-270 and 18VAC 110-20-276. Regulation 18VAC110-20-270 C suggests that one pharmacist shall verify the accuracy of the prescription product in all respects and assume responsibility for the entire transaction. However, Regulation 18VAC110-20-276 requires the identification of individual pharmacists involved in central or remote dispensing and thus, suggests that multiple pharmacists may assume responsibility for individual dispensing functions associated with dispensing one prescription product. Furthermore, the Board discussed current dispensing practices and the required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product. To address the perceived conflict until the regulation in 270 could be amended and to assist in determining which pharmacist to hold responsible for a dispensing error, the Board adopted Guidance document 110-22. The proposed amendments in subsection C are recommended to resolve the regulatory conflict and are consistent with the Board's current guidance.*
420	Sets out the requirements for unit dose dispensing systems.	Subsection A is amended to provide that the patient's individual drug drawer or tray shall be labeled "in a manner to identify the patient and his location without violating health privacy laws." The current requirement for the drawer or tray to be labeled with the patient's name may violate HIPPA.
425	Sets out requirements for robotic pharmacy systems	Subsection A will provide: "Consistent with 18VAC110-20-420, a ~~A~~ pharmacy providing services to a hospital or a long-term care facility ~~using a unit dose dispensing system may operate~~ and operating a robotic pharmacy system ~~dispensing~~ that dispenses drugs in bar-coded unit dose~~, bar-coded drugs~~ or compliance packaging, ~~and~~ is exempted from 18VAC110-20-270 C, provided the

		accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter." The use of compliance packaging is added throughout the regulation. *Current regulations restrict technology which uses compliance packaging instead of unit dose packaging in hospitals or long-term care facilities. The Board recently approved a pilot program to use compliance packaging because regulations did not allow for use of the technology. Amendments to section 425 will allow for compliance packaging in addition to unit dose dispensing; pharmacies using such technology will avoid the $250 fee and delay in implementation currently necessary to apply for a pilot project or use of innovative technology.*
710	Sets out the requirements for storage and security for controlled substances registrants	Subsection E is amended to allow an exception to the requirement for an alarm system for teaching institutions possessing only schedule VI drugs. *The requirement for an alarm system appears to be overly burdensome for teaching institutes, e.g., colleges of pharmacy stocking drugs for student laboratories. An exception to the requirement is in place for other entities, and there do not appear to be concerns about diversion at teaching institutions if they are stocking only schedule VI drugs.*