Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes ☐ Not Needed ☒

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).

Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4538/8119
April 26, 2018

Summary of the Proposed Amendments to Regulation

As the result of a periodic review[1], the Board of Pharmacy (Board) proposes to mainly update and reformat the regulation to improve clarity and readability. The proposed regulation also contains a number of changes to address issues identified in practice or to streamline enforcement.

Result of Analysis

The benefits likely exceed the costs.

Estimated Economic Impact

The majority of the changes in this action are intended to improve clarity and readability of the regulation without introducing any new requirements or altering existing ones. However, there are proposals that represent a change in practice. One such change is the proposed update of the practices that constitute unprofessional conduct. Based on situations encountered in disciplinary cases and/or included in other chapters enacted by other health regulatory boards, the Board proposes to update what constitutes unprofessional conduct. For example, obtaining money or property of a patient by fraud or misrepresentation, providing false information to the compliance inspector, performing acts to deceive, defraud, or harm the public are now listed in

[1] http://townhall.virginia.gov/l/ViewPReview.cfm?PRid=1466

this section. This change does not directly affect any particular person or entity at this time, but may be the basis of a disciplinary action for someone in the future.

In another change, the Board proposes to specify that if the pharmacy is not operational within 90 days from issuance of a new permit, the permit is rescinded unless an extension is granted. Normally, controlled substances should not be left in a facility that is not operational. This change was prompted by a questionable pharmacy operation that came to the Board's attention, but the Board could not take action due to lack of authority to rescind such a permit. Under the proposed rule, the Board will allow 90 days from the date the permit is issued for last minute preparations to occur. This change is not expected to have any direct impact on any regulated entity at this time because the questionable pharmacy operation has already been ceased, but will likely strengthen the Boards enforcement authority if and when needed.

Similarly, one of the medical equipment suppliers has challenged the Board's authority to request hours of its operation. Medical equipment suppliers are sometimes open for limited hours complicating enforcement. Without such information, the Board could not effectively schedule an unannounced inspection of the facility. Thus, the Board proposes to require that a medical equipment supplier must designate the hours of operation when it is open to the public and to require notification to the Board and to the public if those hours change. These requirements are similar to those for pharmacies. With the requested information, the Board will know the hours of operation, when the facility is open, and when an inspection can occur.

The Board is also concerned with the adequacy of the current requirements to become a pharmacist-in-charge. There is no minimum experience requirement to become a pharmacist-in-charge, yet the position requires broad knowledge of pharmacy operations and significant responsibilities for the inventory and security of the pharmacy. Thus, the Board proposes to require a minimum of two years of experience before becoming a pharmacist-in-charge. This change will narrow the pool of eligible pharmacists to become a pharmacist-in-charge, but will likely improve public safety and protect the pharmacists who might be assigned the job of pharmacist-in-charge before he/she was ready to assume such a responsibility.

The Board proposes to require a temperature record for cold storage units and for maintenance of such record for two years. The facilities are already required to have proper refrigeration equipment to protect the integrity and safety of certain drugs such as vaccines.

According to the Department of Health Professions (DHP), inexpensive tools are available to measure and record temperatures in a cold storage. This change will make sure that information to check compliance will be available for review by inspectors. Regulants may also benefit from proper refrigeration by reducing waste of valuable drugs due to exposing drugs to improper temperatures.

The Board proposes to add language that the policy and procedure manual must include provisions for granting and terminating user access in settings where automated devices dispense and administer drugs. According to the Board, it is vital that only appropriately qualified users have access to automated devices that dispense drugs to prevent diversion for personal use or for sale.

The Board proposes to require that five of the required 15 hours of continuing education for annual renewal be obtained in courses or programs that are live or interactive. The Board also proposes to allow two new activities that may be used to fulfill required live or interactive continuing education, including one hour for attendance at a board meeting or hearing and one hour for serving as a preceptor for someone gaining practical experience. The Board believes pharmacists benefit from some interaction in an educational environment; so a portion of continuing hours is proposed to be live or interactive. DHP notes that it would not be necessary for a pharmacist to attend a course in person; participation in an interactive, real-time course would suffice. To the extent live or interactive continuing education is more effective than other settings, this change should be beneficial.

The Board proposes to give a pharmacist who is presented with a forged prescription the option of returning it to the customer or keeping it for law enforcement. Current regulation prohibits the return of a forged prescription, but DHP notes that pharmacists sometimes feel threatened by refusing to return it. The regulation is being amended to give the pharmacist the option depending on the situation. This change will likely help pharmacists to safely get themselves out of a dangerous situation in the case of a criminal attempt to obtain drugs from them by forged prescriptions.

In response to a petition for rulemaking[2], the Board proposes to allow sharing of prescriptions between a provider pharmacy for a long-term care facility and a back-up pharmacy for such a facility to dispense drugs up to a seven–day supply. Currently, the prescription must be transferred to the back-up facility to dispense any drugs. This change will facilitate coverage when the provider pharmacy experiences a temporary shortage in a medication that is needed at the facility.

Finally, the Board proposes to allow that a stat-drug box may include a substitution of liquid for solid dosage unit for each drug schedule. This change will provide more flexibility to the pharmacies that utilize stat-boxes.

Businesses and Entities Affected

There are 34,789 persons or entities that have been issued a license, registration, or permit by the Board. These entities include, but are not limited to, pharmacists, technicians, interns, pharmacies, manufacturers, wholesalers, warehouses, medical equipment suppliers, etc.

Localities Particularly Affected

The proposed regulation does not affect any particular locality more than others.

Projected Impact on Employment

No significant impact on employment is expected.

Effects on the Use and Value of Private Property

No significant impact on the use and value of private property is expected.

Real Estate Development Costs

No significant impact on real estate development costs is expected.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "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."

[2] http://townhall.virginia.gov/L/ViewPetition.cfm?petitionId=233

Costs and Other Effects

There is no estimate of the number of small businesses. However, the majority of pharmacies are part of large national chains. The costs and other effects on any small business would be the same as discussed above.

Alternative Method that Minimizes Adverse Impact

The proposed changes are not likely to create a significant adverse impact on small businesses.

Adverse Impacts:

Businesses:

The proposed changes are not likely to create a significant adverse impact on businesses.

Localities:

The proposed regulation will not adversely affect localities.

Other Entities:

The proposed regulation will not adversely affect other entities.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a

proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.