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: 5480/9236
June 2, 2021

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to amend 18 VAC 110-20 *Regulations Governing the Practice of Pharmacy* (regulation) in order to incorporate certain practices that are currently only authorized as part of pilot programs in select hospitals. Specifically, the Board seeks to: (i) amend section 425 *Robotic Pharmacy Systems* to add the conditions under which medication carousels may be utilized and (ii) create a new section regarding the use of Radio Frequency Identification (RFID).

Background

In order to facilitate the adoption of new technologies in the practice of pharmacy, the Board can authorize select hospital systems to implement new technologies under pilot programs. The Department of Health Professions (DHP) reports that 26 approved pilot programs are currently active, of which 9 use medication carousels, 3 use RFID technology, and the rest address other issues unrelated to this action. DHP also reports that the earliest medication carousel pilot was authorized in 2012, and the earliest RFID pilot was authorized in 2014. Since then, no incidents of error or harm have been reported to the Board, as is required of pilot programs. Thus, the Board proposes to amend the regulation so that these technologies can be adopted by hospital systems without having to first secure authorization for a pilot program.

Medication carousels

Medication carousels are containers consisting of several long horizontal shelves secured behind glass. Several bins of medication sit on each shelf, and an operator can rotate the shelves

until the desired bin and medication are presented. The carousel could be operated by a pharmacist or pharmacy technician, and access to the medications in a carousel can be restricted to the specific authorized staff. In a hospital setting, medications may be removed from the pharmacy carousel on a physician's order for a specific patient, or they may be placed in an automatic drug dispensing system, which is essentially a smaller medication carousel located in an emergency room or an in-patient floor.

Medication carousels are often used in conjunction with a robotic pharmacy system, which automatically dispenses barcoded unit-doses based on information entered into the dispensing software. According to DHP, along with barcode labeling and scanning, the use of medication carousels has reduced medication errors and made inventory management more accurate and efficient. Thus, the Board seeks to add language regarding medication carousels to section 425 *Robotic Pharmacy Systems* rather than create a new section.

The proposed amendments, which largely specify the oversight responsibilities of the pharmacist(s), are conditioned on the extent to which automation software is already in use. For example, a pharmacist would not be required to verify the accuracy of a patient-specific drug removed from a medication carousel: (i) if the order was entered into the dispensing software by a pharmacist and transmitted electronically to the medication carousel and (ii) if the dispensed medication is scanned by both the pharmacy technician retrieving the medication and the nurse or other staff who is authorized to administer the medication. The requirements for medications to be retrieved from the carousel and placed in an automatic drug dispenser are analogous; a pharmacist would not need to check every dose of every medication transferred from the carousel to the dispenser by the pharmacy tech: (i) if the pharmacist entered the order in the dispensing system and (ii) if the barcode on the medication was scanned by the pharmacy tech and again by the person administering the drug.

Finally, a pharmacist would be required to verify the accuracy of all drugs that are manually removed by a pharmacy technician without the use of barcode scanning technology. A pharmacist would also be required to perform a daily random check of five percent of drugs that were prepared that day utilizing the medication carousel technology and maintain a record with the date, a description of any discrepancies, and their initials. Such records would need to be

maintained for a minimum of two years and be available for inspection or audit within 48 hours of a request by the Board.

RFID technology

RFID technology has been used in inventory management for crash carts and kits used by emergency services since about 2011.[1] RFID tags (which are similar to barcodes but can be encoded with much more information) are affixed to every medication placed in an emergency kit or on a crash cart tray. Entire kits or trays are placed in a scanner, which "reads" all the RFID tags and can indicate which medications need replacement. Prior to the adoption of this technology, pharmacy technicians would have to check each item in each kit or tray, which took much longer and resulted in higher error rates.

The Board proposes to create a new section 505 *Use of radio-frequency identification* containing the responsibilities of pharmacists and pharmacy technicians using RFID technology. Specifically a pharmacist would be required to update, develop and maintain the RFID database, issue tags to specific drugs, and develop lists for each kit. Pharmacy technicians would be allowed to place RFID tags on drugs, retrieve tagged drugs from the hospital's inventory to place onto kits, and utilize the scanning device that verifies that the kit contains the drugs it is supposed to as per the list programmed by the pharmacist. A pharmacist would be required to verify that all drugs have been accurately tagged prior to storage in the hospital's inventory and perform a daily random check of five percent of all kits that were prepared that day using the RFID technology. The pharmacist would need to maintain a record of the daily checks, including the date of verification, a description of any discrepancies and their initials and maintain these records for one year. Pharmacies using RFID technology would also be exempt from certain verification requirements contained in other sections of the regulation, since they would now be redundant.[2]

[1] The University of Maryland Medical Center, one of the first to implement the use of RFID technology in emergency kits, reported lower re-stocking times and reduced error rates. See https://www.baltimoresun.com/health/bs-hs-rfid-for-crash-carts-20120727-story.html and https://kitcheck.com/blog/university-maryland-presentation-ashp-fewer-errors-efficiency-kit-check/.

[2] Specifically, the proposed language indicates that, "Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355."

Estimated Benefits and Costs

Adding language regarding the use of these new technologies to the regulation would directly benefit the hospital systems currently engaged in the pilot programs since they would no longer have to pay the renewal fee of $260 per renewal period (generally two years) or pay for any unannounced inspections. Hospitals wanting to implement these technologies would also benefit by not having to apply for a pilot program or pay the initial application fee of $325. In general, having the requirements in the regulation would also benefit hospitals weighing whether to adopt these new technologies by making the cost of future regulatory compliance more transparent. In addition, hospitals that have implemented the pilot programs as well as those choosing to adopt these technologies in the future would benefit from the cost-savings offered by the technologies directly: more efficient inventory control, less staff time spent verifying medications being dispensed or re-stocking kits. Staff and patients would similarly benefit from lower error rates in medication dispensing or the re-stocking of emergency medical kits. The cost of technology adoption largely falls on the hospitals choosing to do so, although some portion of such costs would likely be passed on to payers. Developers and providers of the technology would also benefit to the extent that the proposed amendments encourage more hospitals to adopt these technologies.

Businesses and Other Entities Affected

The proposed amendments primarily affect hospitals and hospital systems, which are generally not-for-profit. DHP reports that these technologies are more likely to be adopted by large hospital systems as compared to smaller independent hospitals, since they are more easily able to absorb the fixed costs of adopting a new technology and more likely to find it cost-effective. Smaller hospitals will likely adopt the use of the technology as technology-related costs decrease; clear regulation from the Board regarding how the technology may be used may also encourage adoption. As mentioned previously, businesses providing these new technologies would also be affected to the extent that the proposed amendments lead to a greater demand for their products and services. Consumers or payers would be affected to the extent that costs of adopting the new technologies are passed on to them

Small Businesses[3] Affected

The proposed amendments are unlikely to adversely affect any small businesses. Any small businesses in Virginia that provide these technologies to hospitals would benefit from the proposed amendments if it increases the demand for their services; the number of such firms is unknown.

Localities[4] Affected[5]

The proposed amendments do not introduce new costs for local governments and are unlikely to affect any locality in particular.

Projected Impact on Employment

The proposed amendments are unlikely to affect the employment of pharmacists or pharmacy technicians in hospitals. DHP reports that the use of this technology was purported to free time for pharmacists to perform more clinical-related functions.

Effects on the Use and Value of Private Property

To the extent that the proposed amendments increase demand for the new technologies, the value of the providers of the technology may increase. Real estate development costs are not affected.

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 14 (as amended, July 16, 2018). 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(D): 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.

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[3] 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."

[4] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[5] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

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.