Office of Regulatory Management

Economic Review Form

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555
Date this document prepared	July 20th, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Proposed

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct & Indirect Costs & Benefits (Monetized)	A brief overview of the regulatory changes are included. A full overview of the proposed regulations can be found in the Agency Background Document (ABD) on TownHall. This action, started from a petition for rulemaking, rectifies inconsistencies for requirements for storage of stat/emergency drugs in automated distribution devices (ADDs) versus less-secured tackle-style boxes and will eliminate a requirement that a pharmacist submits a prescription before stat drugs in an ADD can be accessed in the event of an emergency, eliminating any potential delay in getting medications to a patient in need for those nursing homes who choose to use an automated dispensing device. This regulatory change does not require the owning or utilization of an ADD, thus the Board is mandating no costs to the regulated community. Nonetheless, a financial analysis is included with the cost of ADD implementation assuming a facility that wants to use one does not already possess one. There is no "one size fits all" ADD, and price can depend on factors such as integration into the system's electronic medical record. There is a wide range of costs associated with using an ADD, including up-front costs and annual costs. Most of the costs are spread out over a 5-year window, in addition to contracts that most dispensing companies require for the use of their systems. However, depending on what ADD a facility purchases will depend on how useful it will be to them. Facilities like hospitals often use state of the art ADDs to best ensure drug security and patient safety, while smaller clinics may not need to utilize that level of device. Facility need will factor greatly into the decision to purchase and operate one of these devices. Considering the potential utilization of these devices, it is reasonable to consider a wide range of devices that would fit the needs of the specific nursing home facilities when considering costs. A low-tech ADD that keeps electronic record of drugs and access logs starts as low as $4,000, with models costing as much as $7,000. A more advanced ADD can cost anywhere from $30,000 to $100,000, depending on the technological capabilities one chooses. These are ranges, and most of the devices will fall somewhere between them. Benefits of this change include greater patient safety and security as well as drug safety and security, which can be difficult to calculate. Once again, this regulation simply allows equal use of ADDs and traditional tackle-style boxes in storing and access stat/emergency drugs in emergencies and does not require the use or adoption of an ADD.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $7,000 - $100,000	(b) Incalculable
(3) Net Monetized Benefit	Unknown. No requirement for costs in regulation	
(4) Other Costs & Benefits (Non-Monetized)		
(5) Information Sources	Narcotic Cabinet Buyer's Guide — CareDirect (caredirectllc.com)	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	The status quo does not allow the same quick access of an ADD that the new regulation proposes. Thus, most kits are less secure tackle-style boxes. Nursing homes have inquired about being able to use ADDs but they are unable because the regulations as currently written would not allow them to access the drugs quickly in the event of an emergency. There is no cost associated with the status quo.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	$0	
(5) Information Sources		

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no alternative approach to consider since this is an inconsistency in the Board's regulations that can only be addressed through Board action.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources		

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on local partners.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(4) Assistance		
(5) Information Sources		

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on families.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(4) Information Sources		

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on small businesses.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(4) Alternatives		
(5) Information Sources		

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved	Initial Count	Additions	Subtractions	Net Change
18VAC110-20	993	0	0	0

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Length	New Length	Net Change in Length