Medication Purchasing Tool Working Group

Procurement, Purchasing, Security, and Disposal of Medications for Virginia Emergency Medical Services Agencies

Introduction

The purpose of this document is to provide Virginia EMS agencies with information on options for the procurement, purchasing, security, and disposal of medications to assist in ensuring compliance with federal and state regulatory requirements. Although this document offers specific vendors, not all are known to the authors, and as such, it is recommended agencies perform their own due diligence in selecting products and executing purchasing agreements.

Acknowledgments

Listed below are the subject matter experts that contributed to the development of this document.

- Brian J. Frankel, Assistant Chief, Stafford County Fire and Rescue (Chair, EMS Medication Purchasing Tool Working Group)

- Joshua Crawford, System Director, Clinical Pharmacy Services, Bon Secours Mercy Health

- Cynthia Williams, Vice President and Chief Pharmacy Officer, Riverside Health System

- Gill Abernathy, Pharmacy Manager, Purchasing & Contracts, Inova Health System

- Andrew Slater, Deputy Executive Director, Northern Virginia Emergency Response System

This document was compiled with support from the public safety project management office at the Northern Virginia Emergency Response System (NVERS).

Drug Enforcement Administration (DEA) Licensing Requirements

Refer to the DEA/CSR Licensure Toolkit for additional information.

DEA License Note Tips

- Select a naming and address convention that will be used consistently and exactly for all licenses, group purchasing organization (GPO) rostering, and wholesaler account applications.

- If wholesaler requires a global location number (GLN), request that your wholesaler assign a GLN. For more information, please visit: https://gs1us.org.

Virginia Board of Pharmacy Inspection Tips

1) Submission of an electronic application, with a credit card, is the most effective method.

   a. If choosing to mail a check, ensure the check and the application are mailed together.

2) Print the inspection form from the Board of Pharmacy's website (https://www.dhp.virginia.gov/Boards/Pharmacy/ApplicantResources/) and review in preparation for the on-site visit.

    a. This will save much time in passing the inspection the first time and not having to reschedule.

3) Have a security system representative present for the inspection so they can demonstrate the system's features and answer questions, to include:

    a. What are the redundant communication methods available if the primary system is offline?

    b. Who will receive the notification of the alarm?

        i. Ensure this is someone authorized to access the medication room.

4) Test and confirm that the system covers every possible corner of the medication room.

    a. Security is the primary focus of pre-opening inspection.

5) Maintain duplicative, paper copies of all necessary documents for inspection purposes.

6) Do not stock medications in the room prior to passing inspection.

7) Upon passing the inspection, the license will appear on the Board of Pharmacy website's License Lookup within one week.

Procurement Process

Medication Pricing Arrangements Principles

- Increased volume correlates to lower pricing.

- Contract pricing is lower than pricing without a contract.

- There are pricing terms on the product itself, as well as with the wholesaler who provides the service.

- Product pricing is called contract price (if you have a contract). If not, you pay the wholesale acquisition cost (e.g., retail price).

- Wholesaler terms are usually called "cost of goods" or "cost plus/cost minus."

    o This is the price paid for by the wholesaler to 1) obtain and keep the pharmaceuticals in stock, 2) manage shortages by setting allocations to fairly allot available inventory, 3) maintain regulatory compliance, 4) provide Drug Supply Chain Security Act (DSCSA) individual product pedigree tracking data, 5) "load" contract pricing, 6) maintain invoicing and payment systems, 6) deliver pharmaceuticals, 7) accept returns, and 8) make a reports system available.

Medication Procurement Options

Wholesalers

The most cost-effective option for medication procurement is the use of wholesalers. Working with a wholesaler will require a contract and an account. To purchase, your agency must be licensed by the Board of Pharmacy. Pharmaceuticals may be purchased via "pharma" accounts (e.g., large volume pharmaceuticals with GPO pricing available) or "med-surg" accounts (e.g., lower volume pharmaceuticals and supplies with GPO pricing available).

The largest, best-known national pharmaceutical wholesalers include:

- Cencora (formerly Amerisource Bergen)
  - https://www.amerisourcebergen.com/provider-solutions
- McKesson
  - https://www.mckesson.com/Contact-Us/Form/Contact-McKesson-Medical-Surgical/
- Cardinal
  - https://www.cardinalhealth.com/en/product-solutions.html

A few Med-Surg suppliers include:

- Henry Schein
  - https://www.henryschein.com/us-en/medical/c/pharmacy
- Curascript
  - https://curascriptsd.com/Newsroom/online-ordering-experience
- Besse Medical (now owned by Cencora)
  - https://www.besse.com/distribution-services

Retail Pharmacies

EMS agencies may also seek to purchase from a distributor or (in small amounts) from a retail pharmacy that obtains pharmaceuticals from wholesalers. To note, pharmacies are limited by the DEA to less than 5% of controlled substances distributed, compared to what is dispensed via a prescription. This is an option for agencies that only require small quantities of medications and do not want to pursue contracts or other purchasing agreements. However, this is likely to be more costly than purchasing from a wholesaler.

Direct Procurements

This is the process of establishing accounts with pharmaceutical manufacturers to purchase items directly from them. Some, but not all, manufacturers offer direct purchasing. However, there are several disadvantages to this approach, to include:

- The establishment of multiple accounts/agreements.
- Longer delivery times.
- Additional shipping fees.
- Identification of multiple options to account for drug shortages.
- Numerous invoices.
- Requirement to provide paper or electronic DEA 222 forms to multiple entities.

Cooperative Purchasing Agreements

Cooperative purchasing is an arrangement between multiple entities to combine their purchasing requirements into a single contract, thereby increasing the volume to leverage economies of scale. The GPO will negotiate contract pricing with pharmaceutical manufacturers on behalf of the GPO members. The larger aggregated purchasing volume ensures better contract pricing. Membership in some GPOs is free, while others may have a membership fee. The costs of GPO membership are usually offset by pharmaceutical and supply cost savings. Generally, you can only be a member of one GPO. The wholesaler you purchase pharmaceuticals from will "load" the pricing of the GPO you belong to in their purchasing portal. Contract pricing may not always load correctly, so verification is recommended.

GPOs available to Virginia EMS agencies include:

- **MMCAP Infuse,**
  https://infuse-mn.gov/

    o MMCAP is a national cooperative GPO for government agencies and nonprofits that provide healthcare services. MMCAP is operated by the State of Minnesota, Office of State Procurement, and is self-funded. It has over 38,000 members across all 50 states. Use of MMCAP is free for members and purchasing from contracts is voluntary. The contracts awarded through this GPO are annually and competitively solicited, meet local government procurement requirements, and leverage the purchasing volume of 38,000 members to negotiate discounted pricing and optimal terms.

    o The Pharma wholesaler pharmaceutical purchasing contract is held by Cardinal Health

    o There are seven (7) medical supply contracts available to MMCAP members:

        ▪ Concordance H.S.

        ▪ Henry Schein

        ▪ McKesson Med-Surg

        ▪ Medical Solutions

        ▪ Medline

        ▪ Premier Medical

        ▪ Lochness

    o Pharmaceutical disposal services, for return credit in some instances, are supported by MMCAP contract with Inmar RX.

        ▪ In most cases, Inmar RX will provide return shipping labels/materials to EMS agencies. For customers with high return volume, InmarRX will supply courier service to facilitate return.

        ▪ Return credit for eligible medication disposals through InmarRX will post to your Cardinal Health (pharmaceutical wholesaler) account once fully processed- usually months later.

MMCAP Representative – Eastern Region	<u>MMCAP Infuse</u> • Phone: 651-201-2420 • Email: mmcap.infuse@state.mn.us <u>Jeff Schimbeno,</u> Senior Healthcare Consultant, MMCAP Infuse • Phone: 732-757-5470 • Email: jeff.schimbeno@state.mn.us
MMCAP State POC – Commonwealth of Virginia	<u>Tiffany C. Walker,</u> Deputy Director, Sourcing and Contracting, Department of General Services, Division of Purchases and Supply • Phone: 804-786-0078 • Email: tiffany.walker@dgs.virginia.gov
Northern Virginia Emergency Response System (Utilizes MMCAP contracts – can answer introductory questions)	Email: info@nvers.org

- **Vizient, Virginia Hospital and Healthcare Association (VHHA) Solutions,**
  VHHA Solutions

  o Vizient is a GPO that many health systems use.

  o Fee-for-service use of Vizient GPO contracts through VHHA Solutions.

  o In Virginia, the following EMS Councils have enrolled in this GPO:

    ▪ Central Shenandoah EMS Council

    ▪ Lord Fairfax EMS Council

    ▪ Old Dominion EMS Alliance

    ▪ Peninsulas EMS Council

    ▪ Tidewater EMS Council

    ▪ Western Virginia EMS Council

  o Virginia EMS agencies may be able to purchase through this GPO if they already have an account with the below listed vendors. The use of the Vizient contract may provide cost savings and/or additional rebates.

    ▪ Cardinal Health

    ▪ Henry Schein

    ▪ McKesson Med-Surg

    ▪ Medline

- Owens & Minor

Vizient GPO Contracts - VHHA Solutions	Bryan Hudson, Director of Business Development • Phone: 804-965-1280 • Email: bhudson@vhha.com
	Matthew Marry, Chief Executive Officer • Phone: (804) 965-1383 • Email: mmarry@vhha.com

- **National Procurement Partners Government (NPPGov),**
  https://.nppgov.com

  o NPPGov is a national cooperative procurement organization, offering publicly solicited contracts to government entities nationwide. Their contracts are created through a public solicitation and award process by a Lead Public Agency.

  o The organization serves a variety of government and nonprofit organizations.

    - Public Safety GPO and Law Enforcement GPO are programs of NPPGov with contracts that focus on fire/rescue and law enforcement members' needs. All members have access to a broad range of publicly solicited contracts along with individual discount programs and negotiated contracts for below threshold purchases.

  o NPPGov uses a Lead Public Agency to publicly solicit and award contracts through a request for proposal (RFP) process. Members are eligible to access these contracts by signing an intergovernmental agreement with the Lead Public Agency, thereby eliminating the need to complete their own RFP process. NPPGov staff and legal counsel facilitate this process and provide necessary documentation and support.

    o NPPGov recently contracted with LifeAssist for EMS medications, supplies, and equipment. https://nppgov.com/contract/life-assist/

NPPGov Contact	Brian Clough, Account Manager • Customer Care: 800-824-6016 • Mobile: 206-494-4569 • Email: brian.clough@mynpp.com

Purchasing Guidance

Purchasing requirements at the local level will be dictated by state regulations, as well as internal procurement practices. Agencies should refer to both the Board of Pharmacy processes and internal procedures for additional information.

Pharmaceutical Purchasing Pointers

- The unique identifier for a particular pharmaceutical product is the NDC #.
- Medication errors can occur when:
  - A different concentration of the product is accidentally purchased (e.g. Ketamine 10mg/ml vs. 100mg/ml).
  - A container volume much larger than the dose to be administered to the patient is purchased (e.g. fentanyl 250mcg/5ml vs. 100mcg/2ml or Magnesium 5 grams/10ml vs. 1gram/2ml).
  - Substitute product administration mechanisms work differently than the regular product (e.g. varying types of epinephrine auto-injectors).
  - Look alike, sound-alike products are purchased, e.g. Humulin R U-100 insulin vs. Humulin N U-100ml).
  - Something previously purchased only in vials is purchased in amps (or vice-versa) without communication to users.
- Wholesalers "stock-out" items on occasion (e.g., purchasing a volume higher than average, experienced a supplier delay in order filling, experienced a shipping delay, an order was not placed, etc.). Do not assume that all products are in stock every day.
  - Order a week or so in advance of need.
- Plan accordingly! Wholesalers observe certain holidays.
- Products are usually returnable to a wholesaler for full credit if unopened and within 30 days of purchase, but for a lesser credit amount after that.
- Unusually low-priced drugs might be low-priced for a reason (e.g., <6 months expiration)

Medical Supplies

Medical supplies include schedule VI equipment, such as needles, syringes, IV tubing, and more.

Medication Distribution Equipment

Medication distribution equipment, discussed in additional detail later in this document, includes lockable storage containers (e.g., roller lockers, safes, etc.), pelican-type containers, drug boxes (e.g., tackle boxes), numbered seals, and controlled substances kits (bag type).

Medical Supply Vendors

Schedule VI equipment and some storage solutions are available through many EMS medical supply vendors already used on a day-to-day basis by agencies- check what is already available to your agency. Two reputable vendors with large product catalogs include:

- Bound Tree Medical[1]
- Life Assist[2]

Medication Tracking Software

The chain of custody and tracking for schedule II-V pharmaceuticals is critical. Software exists with the ability to track lot numbers, expiration dates, financial/purchase order numbers, disposal validation, etc. and has automated notification processes. Suggested software vendors include:

- Operative IQ
- PSTrax
- Check-It Vector Solutions
- Schedule 2
- LogRx
- FirstDue

Shortage Prevention and Management

There is rarely a shortage of expensive, high profit pharmaceuticals. However, inexpensive, low-profit ones are frequently in short supply. Moreover, sterile injectables are likely to be in shortage more often than easier-to-manufacture oral tablets.

Recommendations for preventing or managing pharmaceutical shortages include:

- Do not assume that because an item is currently available, it will be available the following day. It is best to maintain several weeks to months stock on hand.
    - If there are no alternatives, maintain more of the pharmaceutical.
    - If there are alternatives, not as much supply needs to be maintained.
    - This also covers agencies for simple wholesaler stockouts, but not national shortages.
- When shortages occur, they impact the most obvious alternative drugs or dosage forms.
- When shortages are significant and at the national level, professional associations and GPOs often recommend alternatives; but they may not be published in a timely fashion.

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[1] Fairfax County's Contract Vehicle has a rider that is open to all agencies.
[2] A contract vehicle is available through NPPGov.

- When pharmaceuticals go on shortage, wholesalers' remaining supply is allocated in the interest of fairness.
    - Allocations are usually based on the last ninety (90) days' worth of purchasing history. It can be beneficial to have history on two (2) different generics, but constantly switching products or wholesalers is not wise, as your agency will not be a preferred customer.
    - Ensure an "active backorder" is maintained in your wholesaler system for drugs on shortage. This essentially serves as a place in line to receive medications once they come off shortage. Note the word active – Old backorders sometimes are purged from the wholesaler's system so need to check a few times per week that the back order is still in place.

- The manufacturer's sales representative cannot produce a pharmaceutical that does not exist, but they can sometimes be of help – ensure their contact information is maintained.

- Use the American Society of Health-System Pharmacists (ASHP) or a GPO as source of drug shortage information (see Appendix A for additional information). The Food and Drug Administration's (FDA) shortages information is usually delayed by one (1) month.

- Plan ahead! Shortages typically worsen in early January, as manufacturers are closed the last one (1) to two (2) weeks of the year, wholesaler buyers take vacation, couriers are overwhelmed with holiday deliveries, respiratory illnesses rise, and manufacturers often exceed the number of controlled substances they are allowed by the DEA to produce for the year.

- Most recalls and resulting shortages are caused by drug quality issues. It is often worth paying higher prices to buy from a manufacturer of higher quality. One, non-subscription, indicator of quality is the FDA Inspection Result Database, which ranks based on the following categories:
    - Official Action Indicated = Bad
    - Voluntary Action Indicated = Common
    - No Action Indicated = Excellent

- During pharmaceutical shortages, especially for prefilled syringes (e.g. Abboject), the manufacturers may request and receive FDA approval for extended expiration dating, therefore do not dispose of pharmaceuticals nearing their expiration, if a shortage is likely to occur.

- Registered Outsourcing Facilities, or 503B, are FDA and state-licensed bulk compounding facilities. They are held to higher standards than pharmacies, but not as high as drug manufacturers. They are legally allowed to produce pharmaceuticals that are on the FDA Drugs Shortages List. It is recommended that EMS agencies establish an account with one (1) or more 503B.
    - Refer to the Virginia Board of Pharmacy License Lookup for Non-Resident Outsourcers for those licensed to ship to Virginia.
    - 503Bs typically procedure pharmaceutical with one (1) to twelve (12) month expiration dates. Manufacturers procure pharmaceuticals with two (2) to four (4)

year expiration dates. 503Bs operate largely on manufacture-to-committed demand, with up to four (4) weeks for shipment.

Diversion Prevention

To avoid the diversion of pharmaceuticals, the following guidance is offered:

- A supervisor must review controlled substance (or other pharmaceutical) purchasing reports for any appearance of purchases (or usage) without reasonable explanation.

  - To note, this also applies for pharmaceuticals loaned to other agencies.

- It is possible to set up ordering where one (1) person queues up the order and a second submits it.

- Do not provide individuals with buying rights who have outside influences to divert, as it is often friends, significant others, or family members who pressure someone to divert.

- Do not provide individuals under high financial pressure with buying rights.

- Do not store personal backpacks or purses in the medication room.

- Require a two (2) person process for check-in and entry into electronic or paper logs for controlled substances.

- Require approval to open any new accounts and maintain a log of the accounts.

  - Do not share passwords for purchasing site. Each user will need their own unique access.

  - Controlled substance storage areas have cameras with a relatively long footage retention time.

  - Biometric access to controlled substances is more secure than code locks or passwords. If codes or passwords are used, they should be changed on a pre-determined frequency.

    - Refer to the Board of Pharmacy guidance and DEA regulations for additional guidance on multi-layer security.

  - Access to medications should be removed from departing employees on the day of departure.

  - Pharmaceuticals should only be ordered for delivery on the days authorized staff are present to receive the delivery.

  - Packing slips should be cross-checked upon delivery, to ensure all items are accounted for, as well as signed, dated, and filed.

Additional Guidance

- EMS agencies should establish criteria to guide purchasing. For example, what are the most critical components – cost, manufacturer quality, avoiding short-dated product, avoiding waste, minimizing risk of drug error by purchasing vial size close to dose size and consistent product, etc.

- Consider United States (or comparable country)-based manufacturers over other manufacturers.

- Review the FDA Orange Book for information on generics or easily interchangeable pharmaceuticals.

- Avoid pharmaceutical delivery to sites that may have no personnel present at time of delivery.

- Validate the Virginia licensing of each supplier on the Board of Pharmacy website's or ask the supplier.

- If pharmaceuticals are obtained at non-profit pricing, "own use" provisions apply, and can only be shared/sold to other non-profits or not to for-profit entities.

- Agencies are allowed to share/sell less than 5% of their purchased controlled substances (CII-V) to another legal entity without obtaining a Board of Pharmacy distributer license and operating in separate physical space.

Medication Security

Disposal Companies

Pharmaceutical disposal companies, also known as "reverse distributors," are entities that will collect expired or unused medications. In some instances, the companies obtain credit from pharmaceutical manufacturers, especially for unopened packages, to offset the cost for the service.

Expired or unusable C-II controlled substances are transferred via DEA 222 form, so that legal possession transfers to the reverse distributor. Service models include: 1) self-service ship-back (less expensive) and 2) on-site service representative visit. Most GPOs have contracts with one (1) or more of these reverse distributors, but they can also be engaged directly. It is recommended that EMS agencies utilize a known company, as bad actors have sought to take advantage of the model.

Reputable companies include:

- Inmar RX Solutions, Inc.[3]

- Pharma Logistics

- Inventory and Returns (IMC Pharma)

Equipment Solutions

Non-automated (Medication Room) Drug Storage

Non-automated drug storage solutions are lockable, penetration resistant, cabinets secured to building construction features, to ensure the security of medications within EMS agencies. Healthcare companies, as well as non-healthcare companies, such as the following, offer these solutions:

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[3] A contract vehicle with Immar RX has been established through MMCAP GPO members and includes a return credit option.

Healthcare Company	Non-healthcare Company
Uline	Lowes
Harloff	The Home Depot
HealthCare Logistics	Amazon
Waterloo	Web Restaurant Store

Alternative solutions include the custom fabricated cabinets (e.g., metal fabricators and locksmiths), as well as narcotics safes, such as:

- CompX eLock
- Medixsafe
- Scripps Safe
- V-line Industries Security Cases
- Resus Tailor Drug Bag
- Safe and Vault

Automated Dispensing Cabinets with Software

Automated dispensing solutions, such as cabinets with associated software, provide secured, limited access to pharmaceuticals with an electronic record of all cabinet access. These solutions require the use of a server (physical or as a paid service from a third-party vendor), as well as routine maintenance (e.g. software upgrades, additions and deletions of user accounting with staff turnover, downtime plans, etc.). If additional controlled substance manager software is purchased, it should interface with the DEA and Controlled Substances Ordering System (CSOS) to ensure for an integrated electronic record of controlled substances receipt and dispensing.

List below are the most purchased cabinets and acquisition options. The automated dispensing cabinets system (e.g., hardware and software) ranges, but is estimated at $50,000, not including auxiliary cabinets, the server, additional software, or annual maintenance contracts.

Equipment options commonly found in an **EMS** application include:

Vendnovation	- Becky Allen Email: becky@vendnovation.com - 3rd party: Life-Assist
UCapIt	- Patti Day Email: pday@idsvending.com - 3rd party: Boundtree
IVM	- Chris Ahlfeld Email: chris_a@ivminc.com - Sell direct, 3rd party: Unknown

Equipment options commonly found in a **hospital** setting include:

- Omnicell
- BD
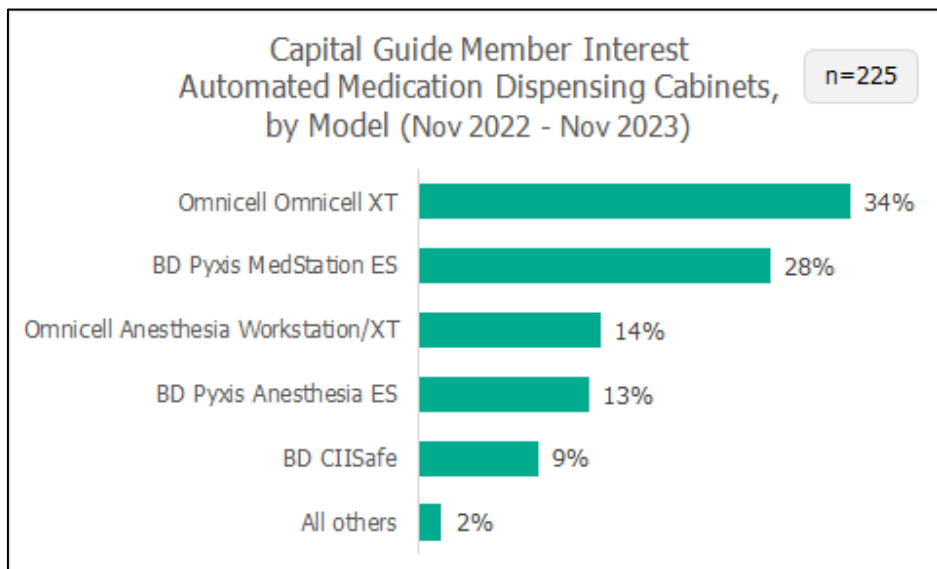- ARxIUM Innovative Pharmacy Solutions
- BD Pyxis Medflex

Table 1. Automated Medication Dispensing Cabinet Models[4] [5]

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[4] ECRI.com, *Procurement Trends: Automated Medication Dispensing*, December (2023)
[5] "All others," as listed in the table include ARxIUM, Cerner, and TouchPoint Medical.

Table 2 demonstrates that the estimated cost to purchase an automated dispensing cabinet is roughly $50,000 – with sixty (60) month leasing options at a comparable price. Table 3 offers that nearly three-quarters of consumers purchase equipment, over leasing or rental options.
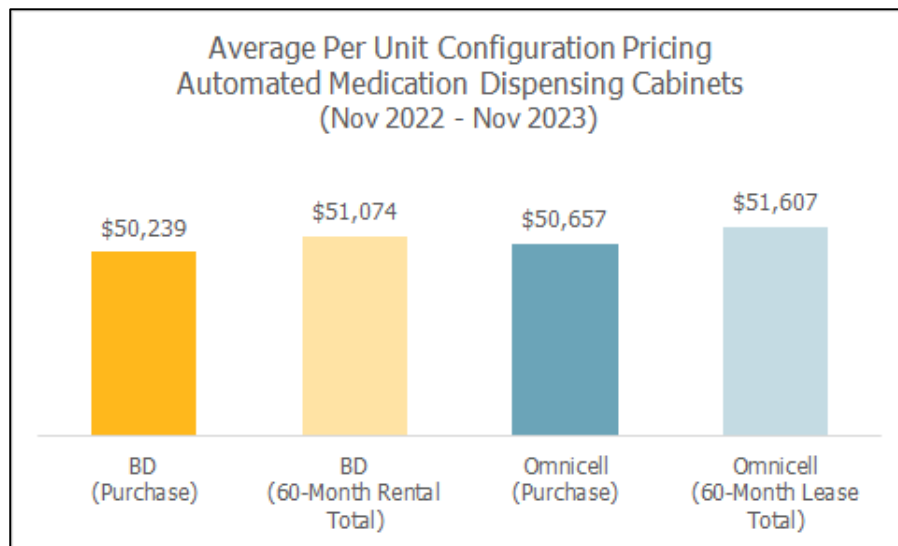

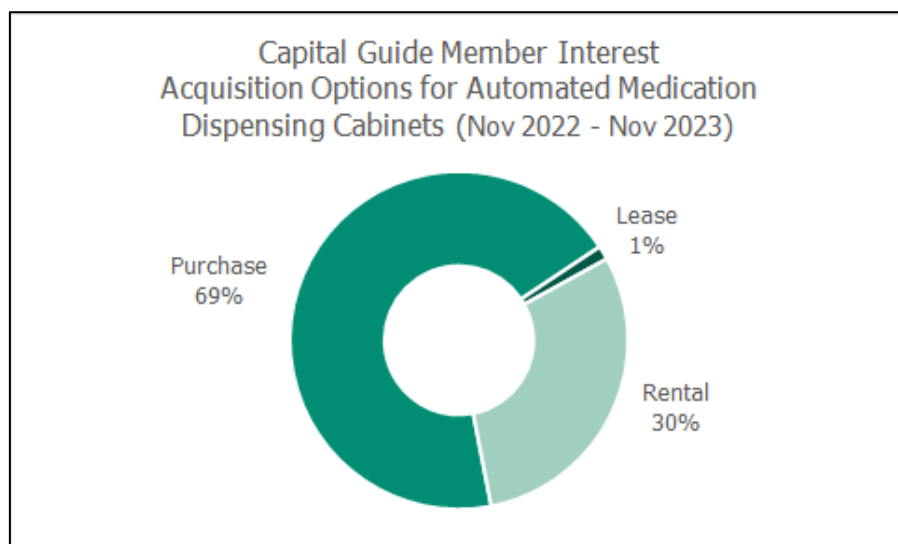**Table 2. Average Per Unit Cost for Automated Medication Dispensing Cabinets[6]**

Table 3. Acquisition Outcomes for Automated Medication Dispensing Cabinets[7]

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[6] ECRI.com, *Procurement Trends: Automated Medication Dispensing*, December (2023)
[7] ECRI.com, *Procurement Trends: Automated Medication Dispensing*, December (2023)

Appendix A: Resources

MMCAP Infuse Documents and Information

Virginia Board of Pharmacy Guidance

1) Virginia Board of Pharmacy Guidance Document,
   110-41: Emergency Medical Services Drug Kits

2) Virginia Board of Pharmacy Guidance Document,
   110-5: Theft or Loss of Drugs

3) Virginia Board of Pharmacy Regulations,
   Controlled Substance Registration

4) Virginia Board of Pharmacy,
   Controlled Substance Registration Inspection Form

Federal Regulations

1) 21 USC §823; Federal Law Pertaining to EMS Pharmaceuticals

2) 21 CFR 1300, 1301, 1304, 1306 and 1307; Federal Regulations Related to EMS
   Pharmaceuticals

Drug Enforcement Administration Information

1) 2020 Proposed DEA Final Rule pertaining to EMS drugs,
   Federal Register, Vol. 85, No. 193, October 5, 2020, pages 62634-62651

2) DEA Contact Information

3) DEA Pharmacist's Manual

   a. Practical info such as how to complete a DEA 222
      drug order form, how to report loss or theft, etc.

4) DEA License Application

5) DEA CSOS Application

Food and Drug Administration Information

1) FDA Orange Book (validating a generic)

Pharmaceutical Shortages Information

1) Drug Shortages Information

2) ASHP – Current Drug Shortages

3) Vizient Inc.

   a. Search on "drugname" Shortage Mitigation

Appendix B: Revision History

This document was finalized on May 10, 2024. Subsequent updates or revisions to this document are anticipated. The revision history, to include date and a brief description of changes will be captured in this appendix.

Date of Revision	Description of Change	Revision Author
5/10/2024	Initial publication.	Purchasing Tool Working Group
5/21/2024	Fixed broken link for the Board of Pharmacy inspection forms.	Purchasing Tool Working Group
7/23/2024	Corrected broken hyperlinks and added additional medication bag to storage solutions.	Purchasing Tool Working Group