

## Minnesota Board of Pharmacy

Approved by the Board on June 7, 2017

### Guidance Concerning the Use of Medication Bar Code Scanning During Stocking of Automated Drug Distribution Systems in Hospitals

Minnesota Rule 6800.2600, subp. 3G requires a licensed pharmacist to **certify all packaging, labeling, and stocking** associated with the use of an automated drug distribution system (ADDS). Unless the certification process utilizes a fail-safe bar coding, certification must be performed by a pharmacist. Additionally, pharmacy technicians are required to be under the direct supervision of a pharmacist per Minn. R. 6800.3850, subp. 5. A pharmacist must perform the final certification of the prescription drug order per Minn. R. 6800.3100. And, Minn. R. 6800.3200 for prepackaging and labeling includes requirements for documentation of prepackaging within a control record, and documentation of the unique identifier of the packager and of the supervising pharmacist.

Pursuant to Minnesota Statute § 214.108, the Board is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding on any court or other adjudicatory body. This document has been approved by the Minnesota Board of Pharmacy and offers guidance to hospital pharmacies seeking the required approval for the use of bar code scanning by a pharmacy technician for validation of the accuracy of medications distributed from the pharmacy for stocking associated with the use of ADDS (e.g., loading and restocking). Some of the areas addressed below contain recommendations that do not have the force of law. **Other areas concern issues that are addressed in statutes or rules. For those areas, the requirements in the law control.** The Board strongly recommends that hospital pharmacies using bar code scanning by a pharmacy technician for validation of the accuracy of medications for stocking of ADDS develop policies and procedures (P&Ps) with all of these issues in mind, even those that are not addressed in statutes and rules. While each policy review or variance request is considered on its own merits, the Board seeks to handle these reviews and requests so that the individuals and businesses that are regulated by the Board are treated in a fair manner.

**Definitions:** See page 7 for a complete list of definitions.

#### **Background:**

1. The use of bar code scanning is increasingly prevalent and available in hospitals for inventory management, dose preparation and packaging, and distribution of medications from the pharmacy. The use of bar code scanning may include, but is not limited to:
  - a. Receiving of medication inventory from suppliers.
  - b. Placement of medications into pharmacy inventory locations (e.g., pharmacy-based ADDS, medication carousel, narcotic cabinet/vault, and other pharmacy inventory locations).
  - c. Prepackaging of unit-dose (UD) medications (automated or manual).
  - d. Relabeling of UD medications.

- e. Compounding (scanning of source ingredients).
- f. Distribution of medications from the hospital pharmacy for stocking of decentralized ADDS (e.g. loading and restocking).
- g. Removal of medications from ADDS.

## 2. Types of UD Bar Codes

- a. Manufacturer's bar code-a national drug code (NDC) based bar code printed on the UD label during packaging by a manufacturer.
- b. Pharmacy generated bar code-a product specific bar code generated within the pharmacy and printed on the UD medication label during automated packaging, or manually applied to the UD medication label.
 

Uses:

  - i. Automated UD prepackaging of bulk medications that are not commercially available in unit of use packaging with machine readable bar codes. The product information and bar code are printed on the medication packaging. Examples: oral solid UD or oral liquid UD medications.
  - ii. Manually applied pharmacy generated bar codes. Examples:
    - 1. Compounded medications (e.g. sterile preparations)
      - a. Patient specific individual doses are labeled with a bar code that references an order number.
      - b. Anticipatory compounding of pharmacy prepared sterile doses may be labeled with a bar code that references a lot number and the amount of medication.
    - 2. Relabeling of manufactured drug products. Examples:
      - a. Multi-use medication products, where the manufacturer's bar code may only be located on the outer box or package. Examples:
        - i. Inhalers
        - ii. Topical creams/ointments
        - iii. Ophthalmic solutions/suspensions/ointments
        - iv. Otic solutions/suspensions
      - b. Relabeling of UD medications that are not bar coded, or that contain bar codes that are not machine readable. Examples:
        - i. Vials
        - ii. Ampules
        - iii. Syringes
        - iv. Respiratory inhalation solutions
      - c. Manual packaging of medications to allow for bar code scanning. Examples:
        - i. Low volume UD packaging of oral solids or liquids
        - ii. Patient specific doses
        - iii. Non-formulary medications
        - iv. Patient's own medications

## **Recommendations:**

### 1. Pharmacy Prepared UD Medications Certified by a Pharmacist

- a. Procedures for the preparation of UD medications by a pharmacy technician, under 2.b. above, must include final certification by a pharmacist prior to placement within pharmacy inventory locations.
- b. Procedures should not only include verification of the accuracy of the labeling and medication contained within the packaging, but also a scan of the UD package bar code with the same device used to scan the medication at the point of BCMA, when available, to verify the bar code. Documentation of the completion of this step should be recorded within the prepackaging, relabeling or anticipatory compounding log, when appropriate.

### 2. ADDS Configurations

- a. Profiled ADDS (LIP controls ordering, healthcare professional administers):
  - i. LIP enters patient-specific medication orders by CPOE or provides written orders, that are reviewed and verified by a pharmacist in the pharmacy computer system prior to removal of the medication from the ADDS.
  - ii. The LIP delegates removal of the medication from the ADDS and administration of the medication to the patient to another qualified healthcare provider (e.g. nurse).
  - iii. The medication is administered by BCMA. Exception: medication overrides, limited to urgent situations that require immediate medication access.
  - iv. Locations: inpatient patient care areas.
- b. Non-Profiled ADDS (LIP controls ordering, healthcare professional administers):

Recommended configuration:

  - i. LIP enters patient-specific medication orders by CPOE or provides written orders, that are reviewed and verified by a pharmacist in the pharmacy computer system prior to removal of the medication from the ADDS.
  - ii. The LIP delegates removal of the medication from the ADDS and administration of the medication to the patient to another qualified healthcare provider (e.g. nurse, radiology technician, etc.) under their direction and supervision. Medication administration may or may not be administered by BCMA (BCMA is preferred). Exception: medication overrides, limited to urgent situations that require immediate medication access.
  - iii. The LIP is physically present within the patient care environment.
  - iv. Locations: ED, Radiology, operative areas, and preferably ambulatory and OP clinics.

Alternative configurations (for use in very limited OP settings):

- i. Patient-specific medication standing order/protocol may or may not be entered into CPOE, or may be a written order. The medication order may or may not be reviewed by a pharmacist in the pharmacy

computer system prior to removal of the medication from the ADDS (review of the order by a pharmacist prior to removal is recommended).

- ii. In some settings where allowed by the hospital, a very limited number of medications may be obtained after 'auto verification' of a standing order/protocol developed for the specific needs of the individual patient care area, allowing for retrospective review by a pharmacist (this should be limited to areas where access to the medication is emergent).
  - iii. For both settings, the LIP delegates removal of the medication from the ADDS and administration of the medication to the patient to another qualified healthcare provider (e.g. nurse, etc.) under their direction and supervision. Medication administration may or may not be administered by BCMA (BCMA is preferred). Exception: medication overrides, limited to urgent situations that require immediate medication access.
  - iv. The LIP is physically present within the patient care environment.
  - v. Locations: Limited OP clinics or procedural areas, as defined by the hospital.
- c. Non-profiled ADDS (LIP controls ordering, administers the medication):
- i. Medication order/protocol generally is not generated or entered by CPOE, and not reviewed and verified by a pharmacist prior to removal of the medication from the ADDS.
  - ii. LIP controls ordering, removal of the medication from the ADDS, and administration of the medication (or may delegate removal and administration to another qualified healthcare provider under their direct supervision).
  - iii. May allow for scanning of the bar code upon removal of the medication with printing of a syringe/container label and/or audible read back of the medication name (e.g., Codonics®).
  - iv. Additional technologies that may be available:
    - 1. Bar code-assisted syringe labeling systems.
    - 2. Point-of-care bar code-assisted anesthesia documentation systems.
  - v. Locations: Anesthesia (e.g., MD, CRNA), procedural areas (cardiac catheterization lab), specialty departments.

### **3. Hospital pharmacies with existing variances:**

- a. Depending upon the bar code technologies in place, hospital pharmacies with a current variance for the use of pharmacy technicians for visual validation of the accuracy of medications to be distributed to ADDS may no longer need a variance.
- b. Hospital pharmacies should review their processes and determine whether they meet the bar code scanning requirements below.
- c. Hospital pharmacies that are able to meet the requirements should incorporate bar code scanning into their ADDS P&Ps, and resubmit them to the Board for review and approval.

4. **Requirements to meet Minn. Rule 6800.2600, subp. 3G:** for bar code scanning of the medication product bar code (e.g. manufacturer's UD barcode or a pharmacist certified pharmacy prepared UD barcode) by a hospital pharmacy technician for validation of the accuracy of medications distributed from the pharmacy for stocking associated with the use of ADDS (e.g., loading and restocking): (Note: see ADDS configurations under item 2 above)
  - a. **Profiled ADDS (LIP controls ordering, nurse administers) locations:** Requires scanning of the medication product bar code **during the following two steps** prior to medication administration:
    - i. Bar code scanning required on picking **or** with loading or restocking of an individual ADDS drawer, bin or pocket; **plus,**
    - ii. Bar code scanning on medication administration (BCMA).
  - b. **Non-Profiled ADDS (LIP controls ordering, HC professional administers) locations:** Requires scanning of the medication product bar code **during two of the following steps**, prior to medication administration:
    - i. Bar code scanning required on picking; **and/or,**
    - ii. Bar code scanning with loading or restocking of an individual ADDS drawer, bin or pocket; **and/or,**
    - iii. Bar code scanning on medication administration (BCMA).
  - c. **Non-Profiled ADDS (LIP controls ordering and administers) locations:** Requires scanning of the medication product bar code **during two of the following steps**, prior to medication administration:
    - i. Bar code scanning required on picking; **and/or,**
    - ii. Bar code scanning required with loading or restocking of an individual ADDS drawer, bin or pocket; **and/or,**
    - iii. Bar code scanning required on **removal** from the ADDS, preferably with generation of a label (e.g. codonics label); **and/or,**
    - iv. Bar code scanning of the medication bar code required on **administration**, preferably with visual or audible confirmation of the medication.
5. **Hospital pharmacies unable to meet Minn. Rule 6800.2600, subp. 3G:** Hospital pharmacies that are unable to meet the bar code scanning requirements listed above, and that have a current variance to utilize pharmacy technicians for visual validation of the accuracy of medications for stocking of ADDS, will need to have their variance reviewed by the Board.

**Additional Safety Considerations:**

(Note: the following are recommended within the references listed at the end of this document, but are not required. Hospital pharmacies should evaluate best practices and incorporate recommendations appropriate for their settings into policies and procedures.)

1. Incorporate the use of bar code scanning within the pharmacy for inventory quality control of manufactured UD medications. For example:
  - a. The manufacturer's UD package bar code or inner NDC should be scanned and verified as incoming shipments are received, prior to placement within pharmacy inventory locations.
  - b. Rationale:

- i. A wholesaler may ship a generic medication made by a different manufacturer, where the bar code is not contained in the database for use within the pharmacy or bar code medication administration (BCMA) system.
  - ii. A manufacturers may change their bar code content, requiring scanning to make sure the medication contains a readily readable bar code for BCMA or stocking of ADDS.
2. Set up all ADDS as profiled, including where possible outpatient areas (e.g., ED, same day surgery, OP clinics).
3. Store only a limited number of medications in non-profiled ADDS.
4. Although medications administered in non-profiled areas may be administered without entry of an electronic medication order, the hospital should consider having all departments where medications are administered use the same BCMA and eMAR for recording medications administered during procedures. Although an automated check for the 6-Rs is not possible without electronic order entry, there are still valuable safety checks available by using the BCMA system in these areas, for example screening for allergies, appropriate dosing and administration guidelines, and medication interactions.
5. Minimally, within quality improvement policies and procedures, hospitals should include pharmacy involvement in the review and evaluation of bar code scanning rates for medication administration, to identify issues and areas for improvement.

### **Policy and Procedure Recommendations**

6. Recommended procedure for the use of bar code scanning by a pharmacy technician for validation of the accuracy of medications for distribution from the pharmacy to ADDS:
  - a. A pharmacy technician will pick the desired quantity of each medication indicated within the ADDS fill report, as follows:
    - i. Select one medication at a time from the medication carousel or pharmacy inventory location.
    - ii. Select the desired quantity of the medication, and place within a bag or bin.
    - iii. Visually inspect each individual medication package for accuracy of the medication name and dose, and to ensure each dose is within expiry.
    - iv. Scan the bar code of one UD medication package label (manufacturer's or pharmacist certified barcode), individually or within a strip, to ensure the accuracy of the medication selected.
  - b. A second pharmacy technician should validate the accuracy of each medication dose picked, according to hospital policy or procedure. Validation requires the second pharmacy technician to visually inspect each dose within the bag/bin to verify the following:
    - i. Medication name
    - ii. Medication dose
    - iii. Medication quantity
    - iv. Medication expiry
  - c. Document the unique identifier of each pharmacy technician completing the picking and bar code scanning validation, and the visual validation of medications for stocking of the ADDS within a manual or electronic log.
7. Use of bar code scanning during loading or restocking of medications into an ADDS by a pharmacy technician:

- a. A pharmacy technician shall scan the bar code of one UD medication package label, individually or within a strip, to ensure the accuracy of the medication being loaded or restocked to the ADDS pocket.
  - b. Upon opening of the ADDS pocket, the pharmacy technician shall visually validate the accuracy of the medication and pocket, enter the correct quantity for restocking, and updated the expiration date as required.
8. As required within Minn. R. 6800.2600, subp. 3F, implement policies requiring an independent double check when removing organizationally defined high-alert medications from non-profiled, non-LIP controlled ADDS.

### **Definitions**

1. Automated Drug Distribution Systems (ADDS): a computer controlled decentralized medication storage device used to distribute UD medications and track medication use. ADDS are located in hospital patient care units, surgical suites, emergency rooms, outpatient clinics, and other setting. Also referred to as an automated drug cabinet (ADC), automated dispensing device (ADD), automated dispensing machine (ADM), automated medication distribution system (AMDS).
2. Bar code (BC): a printed symbol made up of black and white spaces arranged in a specific pattern representing a series of characters that is machine readable, and provides a method for communication of data to an automated system. Since 2004, the FDA has required that certain human drug and biological product labels contain a bar code consisting of, at a minimum, the National Drug Code (NDC) number. Types of bar codes:
  - a. Linear bar code: a one dimensional (1-D) bar code made up of black and white spaces used to encode a national drug code (NDC) or hospital specific code. Currently, most commonly used on manufactured medications.
  - b. Two-dimensional (2-D) data matrix bar code: a small symbol usually seen as a square with dots rather than bars and with a large character capacity, typically used to encode an NDC, lot number and expiration date.
  - c. GS1 Databar bar code (formerly Composite Reduced Space Symbology (RSS) bar code): a very small linear bar code containing only the NDC; or a stacked combination of linear and 2D bar codes containing the NDC, lot number, expiration date, and more.
3. Bar code medication administration (BCMA): a process utilizing a bedside point-of-care system for scanning a machine-readable bar code on a medication label prior to medication administration. The BCMA software allows healthcare practitioners to ensure the ~~six~~ rights (~~6~~-Rs) before a medication is administered to a patient, and facilitate the documentation of medication administration in the electronic medication administration (eMAR) system.
4. Bar code technology: the use of scanning equipment to decipher identification on a medication label for the National Drug Code (NDC), and/or lot number, and expiration date, on all UD, unit-of-use, and injectable drug packaging, or identification on an internally applied medication label.
5. Bar code-assisted syringe labeling systems: allows a provider to scan a manufacturer's bar code on each drug vial and print a syringe label containing the drug name, strength, quantity, diluent and diluent volume, expiration date and provider's initials. The system also provides an audio and visual read back of the drug name and concentration.
6. Computerized prescriber order entry (CPOE): a system used by prescribers to enter patient care orders electronically, typically for hospitalized patients.

7. Six Rights (6-Rs): a term used to describe the right medication, for the right patient, at the right time, in the right dose, via the right route, with the right documentation, during patient medication administration.
8. Licensed independent practitioner (LIP): an individual, as permitted by law and regulation, and also by the organization, to provide care and services without direction or supervision within the scope of the individual's license and consistent with the privileges granted by the organization. Within a hospital setting, an LIP is an individual able to prescribe and administer medications.
9. Medication Carousel: an automated drug storage system located in the central pharmacy that controls access to medications through a user name and password. Bar code verification is required during receiving, stocking, picking and return of medications to ensure the right drug is picked and restocked to the correct location.
10. National Drug Code (NDC): an identification code assigned to a specific company, product, and package size by the U.S. Food and Drug Administration (FDA).
11. Override: a medication withdrawal function that allows a nurse, or other caregiver, limited access to certain medications before order review and approval by a pharmacist, especially in cases of patient emergencies. The override list should be developed and approved by a multi-disciplinary committee of physicians, pharmacists and nurses, to include those medications for which there is a clinically urgent need that outweighs the potential risk of medication error.
12. Practitioner: As defined in MN Stat. §151.01, subd. 23. "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.
13. Point-of-care bar code-assisted anesthesia documentation systems: allows the syringe label bar code to be scanned immediately before administration to automatically populate the anesthesia record with the medication and/or dose administered, however bar code scanning is not linked to a profiled medication order.

### References

1. American Society of Health-System Pharmacists. ASHP statement on barcode verification during inventory, preparation, and dispensing of medications. Am J Health-Syst Pharm. 2011; 68:442–445. Available at: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements-bar-code-verification-inventory-preparation-dispensing-medications.ashx?la=en>. Accessed May 31, 2017.
2. American Society of Health-System Pharmacists. ASHP guidelines on the safe use of automated dispensing devices. Am J Health-Syst Pharm. 2010; 67:483-490. Available at: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines-safe-use-of-automated-dispensing-devices.ashx>. Accessed May 31, 2017.



3. Institute for Safe Medication Practices (ISMP). Guidance on the interdisciplinary safe use of automated dispensing cabinets (2008). Available at: <http://www.ismp.org/Tools/guidelines/ADC/default.asp>. Accessed May 31, 2017.