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QUALITY DIRECTIVE FOR UNIT-DOSE PACKAGING AND BARCODE LABELING

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy and procedures for establishing a Pharmacy Barcode Quality Plan by implementing unit dose packaging and barcode labeling best practices.

2. BACKGROUND

a. Bar Code Medication Administration (BCMA) depends on appropriate barcode labeling of all medications. Circumvention of BCMA scanning at the point-of-care is reduced when all medications dispensed from Pharmacy have appropriate readable barcode labels.

b. The intent of this Directive is to improve scannability of barcoded medications at the point-of-care. The Health Systems Committee advised the National BCMA Program Office be tasked with developing a quality Barcode Program for unit dose packaging and barcode labeling.

c. Barcode metrics ensure that at least 95 percent of unit dose medications dispensed from Pharmacy have machine-readable barcodes at the point-of-care.

d. The National BCMA Program Office website provides access to additional supporting documents:

(1) Causes and Effects for Scanning Circumvention document at <http://vaww1.va.gov/bcmapmo/docs/CausesofBCMACircumventionRelatedtoLabelingIssues.doc>; and

(2) Labeling Problem Solving Matrix at <http://vaww.va.gov/bcmapmo>.

NOTE: Although best practices are being shared within VHA, they are not all inclusive; facilities are encouraged to develop additional best practices.

3. POLICY: It is VHA Policy that each facility must have a written barcode quality plan in place within each inpatient pharmacy and that all medications have machine-readable barcoded labels.

4. ACTION

a. **Facility Director.** Each VHA Facility Director, or designee, is responsible for ensuring effective:

(1) **Barcode Labeling.** This includes:

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(a) Adequate and capable resources to package or re-package products not available in barcoded unit dose, including oral liquids and solids.

(b) Barcoding and labeling on unit dose packaging of ward stock items in all areas including:

1. Intravenous (IV) solutions,
2. Controlled substances;
3. Items in unit-based dispensing cabinets; and
4. Items transferred into patient care areas.

(c) An automated packaging solution to apply barcodes to unit dose medications.

(d) Barcode labels securely fastened to the immediate container of the drug.

(e) Bulk or multi-dose containers (insulin, topicals, and inhalers) having the barcode label affixed directly to the product.

(f) Packaging resources, which includes affixing small barcode labels to ampules and vials, or the capability to affix barcodes to plastic over-wrap or tamper-evident plastic bags.

(g) Placing labels on small items such as ampules, vials, and ointment tubes that scan at the point-of-care (avoiding curvature of the barcode) that will not cover lot number and expiration date information.

(2) **Packaging.** This includes:

(a) Medication packaging in accordance with the United States Pharmacopoeia (USP), American Society of Health-Systems Pharmacists (ASHP) Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs, and all applicable laws and regulations;

(b) Formalizing safety processes for packaging medications and replenishment of automated dispensing cabinets; automated packaging equipment internal to pharmacy; and a computer or non-computer generated unique packaging number utilized for packaging medications;

(c) Quality control measures to prevent incorrect medication packaging and re-packaging;

(d) Maintaining packaging and labeling logs inclusive of a unique sequential numbering system in accordance with applicable practice standards and laws; and

(e) Labels being printed with barcodes for pharmacy-prepared, patient specific medications.

(3) **Quality Control.** This includes ensuring that:

(a) Procurement best practices are followed for purchase of manufactured individually barcoded or unit dose medication for institutional patient care where available; and

(b) The device used for scanning into the synonym field is compatible with barcode readers used in the patient care areas.

(4) **Inventory Control and/or Procurement.** This includes ensuring that:

(a) The manufacturer's barcoded National Drug Code (NDC) numbers are scanned into the synonym field of the Drug File [50];

(b) The Intended Use field is set to "QUICK CODE" before being put into active inventory so that non-recognizable barcodes do not reach the patient's bedside; and

(c) Unit dose medications are purchased with scannable barcodes.

b. **Pharmacy Chief.** The Pharmacy Chief, or designee, is responsible for:

(1) Ensuring that medications dispensed have readable barcodes;

(2) Establishing a baseline using data collected from the first quarter and measuring progress over time (see Att. B);

(3) Reporting results and success rate percentages to the BCMA Coordinator;

(4) Ensuring follow up on any areas of concern from results reporting;

(5) Ensuring the data collection reporting, tracking, and trending is achieved within the prescribed time frame; and

(6) Engaging the assistance of others as needed in problem solving.

c. **BCMA Coordinator.** BCMA Coordinator, or designee, is responsible for:

(1) Establishing a baseline using data collected from the first quarter and measuring progress over time; and

(2) Using direct observation to assess the scannability of different medications for a total of twenty observations every quarter and reporting the results quarterly to the BCMA Multidisciplinary Committee (see Att. B).

5. REFERENCES: VHA Manual MP-2, Part VII.

6. FOLLOW-UP RESPONSIBILITY: The Office of Information, National BCMA Program Office (196J), is responsible for the contents of this Directive. Questions may be addressed to 785-350-4569.

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7. RESCISSIONS: None. This VHA Directive expires February 28, 2011.

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ATTACHMENT A

QUALITY CONTROL PROCEDURES

1. PROCEDURE. Each Veterans Health Administration (VHA) Facility Director and Pharmacy Chief is tasked to ensure:

- a. Easily accessible equipment is available within inpatient pharmacy, including the narcotic vault and the Intravenous (IV) room, a scanner (compatible with or the same as the ones used in patient care area) attached to a computer (mobile or fixed device) that provides appropriate access to the Bar Code Medication Administration (BCMA) software;
- b. Metrics are completed based on the pre-defined parameters as outlined within each specific monitor (see Att. B);
- c. Department of Veterans Affairs (VA) Form 10-0429, Unit Dose Packaging and Labeling Track and Trend Results, is completed on a quarterly basis (see Att. C);
- d. Individuals responsible for completing monitors report results to the BCMA Coordinators;
- e. BCMA Coordinators facilitate discussion of issues and findings in the BCMA Multidisciplinary Committee meetings; and
- f. Problematic barcodes are forwarded to the National BCMA Program Office for verification testing and follow-up.

2. RESOURCES FOR PERFORMING THE MONITORS. Pharmacy staff, Nursing staff, and BCMA Coordinators complete the monitors.

3. FREQUENCY OF SAMPLING AND/OR REPORTING

- a. Aggregate data is collected per defined parameters within each measure and reported quarterly by the BCMA Coordinator, or designee, to the BCMA Multidisciplinary Committee.
- b. Results with less than a 90 percent success rate per quarter require a Root Cause Analysis (RCA) to examine current workflow processes and determine corrective actions.

4. REPORTING MECHANISMS

- a. Data results and success rate percentages are reviewed during BCMA Multidisciplinary Committee Meetings.
- b. Unresolved issues resulting from collected data are reviewed by the members of the Pharmacy and Therapeutics (P&T) Committee or its equivalent.
- c. RCA follows normal distribution to the National Center for Patient Safety (NCPS).

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d. Non-scannable barcodes are forwarded to the National BCMA Program Office. The Program Office tests barcodes through the Bar Code Verification Laboratory. Results are forwarded by the Program Office to GS1 (formerly the Uniform Code Council), the Food and Drug Administration (FDA) for corrective action, and to the submitting facility; and

e. The measures' aggregated success rate percentages are forwarded quarterly through the BCMA Coordinator to the National BCMA Program Office (see Att. C).

ATTACHMENT B

QUALITY CONTROL MONITORS

1. PHARMACY CONTROLLED SUBSTANCE MONITOR

a. Pharmacy Procedure

(1) Test each manufacturer's controlled substance unit dose package on a quarterly basis by scanning a representative of each lot number or internal batch number for each line item; and

(2) Report results quarterly to the Bar Code Medication Administration (BCMA) Coordinator.

b. Exclusion. Items scanned upon arrival into the Pharmacy or during pre-packing.

c. Equation

Numerator: Number of successful controlled substance package scans.

Denominator: Total number of controlled substance packages scanned.

Result: Multiplied by 100 determines the success rate percent.

d. Method

(1) Method of preference is the Enter/Edit Option which displays corresponding synonyms:

(a) At the Pharmacy Data Management option, select Synonym, enter/edit option.

(b) Scan the barcode into the synonym field.

(c) If the item is already in the system, the drug name and strength will appear; and

(d) Make sure the package and drug name on the screen are the same.

(2) If only the barcode number appears at the Synonym enter/edit prompt, the item is not in the drug file.

(a) Go back to the drug name prompt and select the name of the drug from the drug file selection by typing in the name of the drug and selecting the correct item;

(b) Press enter until the synonym prompt appears;

(c) Scan the barcode;

(d) At the quick code selection, enter 1 for quick code; and

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(e) A sample of each lot number must be scanned to check for National Drug Code (NDC) number changes and lot number variation.

(3) When the barcode is scanned at the drug name prompt and two drug names appear, the incorrect product must be deleted from that synonym.

(a) There can be only one synonym for a product. It cannot be shared;

(b) Select the incorrect drug item; and

(c) Enter *shift 2* (@) and delete the incorrect entry.

(4) If the Enter/ Edit Option is not available, the following steps should be followed:

(a) Scan barcode utilizing an available Veterans Health Information Systems and Technology Architecture (VistA) Drug Inquiry Lookup menu option of choice;

(b) The drug name, Internal Entry Number (IEN) and synonym will display if successful;

(c) Verify displayed product matches product scanned;

(d) Problem solve to correct any discrepancies; and

(e) Consult Pharmacy Automated Data Processing Coordinator (ADPAC) as needed.

2. MANUFACTURER'S BARCODE MONITOR

a. Pharmacy Procedure

(1) Test each manufacturer's unit dose, injectable and liquid unit of use packages by scanning a representative (six unique items per day, at least thirty per week) of each manufacturer's NDC number for each line item.

(2) Scan per the following recommendation:

(a) Scan barcode utilizing an available VistA Drug Inquiry Lookup menu option of choice;

(b) The drug name, IEN and synonym will display if successful;

(c) Verify displayed product matches product scanned;

(d) Correct any discrepancies; and

(e) Report results quarterly to the BCMA Coordinator.

b. **Equation**

Numerator: Number of successful manufacturer unit of use package scans.

Denominator: Total number of manufacturer unit of use packages scanned.

Result: Multiplied by 100 determines the success rate percent.

3. **INTRAVENOUS (IV) LABELING MONITOR**

a. **Pharmacy Procedure**

(1) Daily verification per the following recommendations:

(a) Test one label from the beginning, middle, and end of each IV manufacturing run;

(b) Each time a ribbon is replaced on the IV printer (if not thermal); and

(c) Whenever a new spool of labels is placed in the printer to make sure the alignment is correct.

(2) Report results quarterly to the BCMA Coordinator.

b. **Equation**

Numerator: Number of successful IV labels scans.

Denominator: Total number of IV labels scanned.

Result: Multiply by 100 to determine the success rate percent.

c. **Options.** To perform the monitor, use one of the following two options:

(1) **Option 1**

(a) At the Barcode Identification (ID) Return and Destroy IV (PSJI return by barcode ID) prompt, choose: Recycle IV;

(b) Scan the label and the bag number (medication and solution will display if successful);

(c) Verify displayed product matches the information on the label scanned;

(d) Exit (^) menu option to avoid destruction, cancellation, or recycling of the IV label; and

(e) Problem solve to correct any discrepancies.

(2) **Option 2**

(a) At the Medication Administration Menu Pharmacy, select option 8: Label print;

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- (b) Scan the label (bag number only will appear if successful);
- (c) Verify displayed product matches the information on the label scanned; and
- (d) Problem solve to correct any discrepancies.

4. AUTOMATED UNIT DOSE PACKAGING MONITOR

a. **Pharmacy Procedure**

(1) Daily verification of re-packaged units per the following recommendations:

(a) Verify scannability at the beginning, in the middle, and at the end of each medication repackaging run or pick list;

(b) Whenever an adjustment is made to the print heads;

(c) Each time the ribbon is changed.

(2) Report results quarterly to the BCMA Coordinator.

b. **Exclusion.** Items scanned upon arrival into the Pharmacy or during pre-packing.

c. **Equation**

Numerator: Number of successful re-packaged unit of use scans.

Denominator: Total number of repackaged unit of use scanned.

Result: Multiplied by 100 determines the success rate percent.

d. **Repackaged Unit of Use Items** (Automated Unit Dose Packaging Systems such as ATC®, Safety Pak®, OS PAC®, Euclid®, etc.)

(1) Establish repackaging log (drug, strength, lot number, expiration date, date of repack, name of technician, Pharmacist):

(a) After machine completes a repackaging run, select one item from the beginning, middle, and end of the strip;

(b) At the BCMA Drug Lookup (VistA label option 8), scan the barcode on the package;

(c) The name of the scanned drug will appear in the drug name field;

(d) Check the drug name on the package to be sure it matches the drug name on the field prompt;

(e) Check that the drug in the package is correct;

(f) If the item does not scan, clean the print head and run 5 additional items. Repeat above procedures; and

(g) If scan is still not successful, the printer needs to be repaired. *NOTE: Do Not Use!*

(2) Consult Pharmacy ADPAC as needed.

5. PHARMACY RELABELED MONITOR

a. Pharmacy Procedure

(1) Test relabeled unit of use medications by scanning six items per day, or thirty items per week.

(2) Verify each batch for scannability:

(a) At the beginning, in the middle, and at the end of each run,

(b) Whenever an adjustment is made to the print heads, and

(c) Each time the ribbon is changed.

(3) Report results quarterly to the BCMA Coordinator.

b. Exclusion. Items re-labeled upon arrival into the Pharmacy.

c. Equation

Numerator: Number of successful re-labeled scans.

Denominator: Total number of re-labeled scanned.

Result: Multiplied by 100 determines the success rate percent.

d. Relabeled Use Items (Zebra printer, special run barcode labels, etc.).

(1) At the BCMA Drug Lookup (VistA label option 8), scan the barcode on the package.

(2) The drug name, IEN, and synonym displays if successful.

(3) Check the drug name on the package to be sure it matches the drug name on the field prompt.

(4) If the item does not scan, clean the print head and run six additional items. Repeat preceding procedures.

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(5) If scan is still not successful, the printer needs to be repaired. *NOTE: Do Not Use!*

(6) Consult Pharmacy ADPAC as needed.

6. END-USER QUALITY MONITORS

a. **End-user Procedure**

(1) Assess scannability of medications at the point-of-care for a total of twenty observations the first month of every quarter to ensure greater than 95 percent scannability; and

(2) Track data using appropriate End User Check Sheets (see Att. C).

b. **Equation**

Numerator: Number of successful units of use scans.

Denominator: Total number of units of use scanned.

Result: Multiplied by 100 determines the success rate percent.

ATTACHMENT C

**VA FORM 10-0429, UNIT DOSE PACKAGING AND LABELING
TRACK AND TREND RESULTS**

The following form is used to submit data results to the National Bar Code Medication Administration (BCMA) Program Office. The BCMA Coordinator for each facility or health care system must submit their collected data for the Quality Directive for Unit-dose packaging and Bar Code labeling using the VA Form 10-0429, Unit Dose Packaging and Labeling Track and Trend Results by the last day of each reporting quarter. This form can also be found on the VA Forms web site at: <http://vaww.va.gov/vaforms>.



VA Form
10-0429-fill.pdf



The BCMA Coordinator for each Facility or Health Care System must submit their collected data for the Quality Directive for Unit-Dose Packaging and Bar Code Labeling using the following form. The data must be submitted by the last day of each reporting quarter. The BCMA Coordinator will select their VISN, facility, and reporting quarter from the drop down list. Data must be entered for each Pharmacy and End User Monitor within the table. Upon completion of the form, the BCMA Coordinator will click the Submit Form button to transmit their data to the national database. Once data has been transmitted, it may not be edited or resubmitted.

VISN

Facility

Reporting Period

PHARMACY APPENDICES

PHARMACY	SUCCESSFUL SCANS <i>(numerator)</i>	# ITEMS SCANNED <i>(denominator)</i>	SUCCESS RATE <i>(percentage)</i>	COMMENTS FOR CORRECTIVE ACTION
Pharmacy Controlled Substance Quality Monitor				
Pharmacy Manufacturers Barcode Label Quality Monitor				
Pharmacy IV Label Quality Control Monitor				
Pharmacy Automated Unit Dose Packaging Systems Quality Control Monitor				
Pharmacy Relabeled Drugs Quality Monitor				

END USER APPENDICES

END USER	SUCCESSFUL SCANS <i>(numerator)</i>	# ITEMS SCANNED <i>(denominator)</i>	SUCCESS RATE <i>(percentage)</i>	COMMENTS FOR CORRECTIVE ACTION
Controlled Substance Validation Check Sheet (End User)				
Manufacturers Barcode Label Validation Check Sheet (End User)				
IV Label Quality Control Check Sheet (End User)				
Automated Unit Dose Packaging Systems Validation Check Sheet (End User)				
Relabeled Drugs Validation Check Sheet (End User)				