RESOURCE AND PATIENT MANAGEMENT SYSTEM

Bar Code Medication Administration

IHS and VA Collaborative
Standard Operating Procedure

July 2014

Office of Information Technology
Division of Information Technology
Albuquerque, New Mexico

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1.0 General Information

1.1 Purpose of Standard Operating Procedures for BCMA

This Standard Operating Procedures (SOP) incorporates the procedure for notifying the manufacturer or supplier, appropriate governing authorities, and appropriate contracting authorities of problematic drug product bar codes. This also includes instructions for the evaluation of problematic patient wristband bar codes.

1.2 Definitions

None

1.3 Policy

The following procedures will be used by Indian Health Service (IHS) Office of Information Technology (OIT) Help Desk to follow up with the Bar Code Medication Administration (BCMA) Coordinator, Facility Point of Contact (POC), and product vendor if necessary, concerning scanning failures.

1.4 Procedures

1.4.1 Medications

A. The BCMA Coordinator or Point of Contact will gather information related to the causes of scanning failure. This information will be submitted to the IHS Help Desk.

B. If the problem is not related to a problematic bar code, IHS OIT Help Desk will follow up with the facility to request what corrective actions have been taken by the site to address the problems. The results of the intervention will be followed up for three consecutive months.

C. If the problem is related to a problematic bar code, the site will be requested to complete the form in Appendix A: and send a sample to the Bar Code Resource Office (BCRO) Verification lab at the following address:

Steve Corma
VHA BCRO
1073 The Hideout
Lake Ariel, PA 18436

D. When sending the bar code for verification, the following information is required:

1) The point-of-contact at the facility who will receive a report of verification findings.

2) The facility name and mailing address of the point-of-contact, and the best method (e-mail, telephone, ground mail) of communicating the findings to the point-of-contact.

E. If sending pharmaceutical manufacturer/repackaged bar codes, facilities must ensure the following:

1) Bar code label is intact.

2) Package contents have been removed (i.e. remove capsules, tablets, liquids, etc.).

3) Drug name is identified and the Manufacturer/packager is indicated on item or identified and attached to item.

F. If sending a facility-generated bar code, facilities must ensure the following:

1) Bar code label is intact.

2) Package contents have been removed (i.e. remove capsules, tablets, liquids, etc.).

3) Laboratory bar code labels will not be evaluated.

4) Bar Code labels on blood and blood products will not be evaluated.

5) The BCRO should be notified of persistent issues with problematic bar codes not resolved at the local level.

6) Patient identifiers have been blocked out.

7) Provide printer information to include:

a. Manufacturer

b. Name and/or model number

c. Printing method (i.e. ink-jet, direct thermal, thermal transfer, etc.)

d. Ribbon (if used) manufacturer, name, and type (i.e. resin, wax, etc.)

8) Provide print medium information to include:

a. Manufacturer

b. Type or Reorder Number

c. Source

G. The BCRO will perform bar code verification in accordance with ISO/IEC 15416. These industry standard methodologies and specifications have been developed for measuring and assessing the quality of the printed bar code for process control and quality assurance. The results of the verification will be provided back to the Indian Health Care Facility that submitted the bar codes.

H. American National Standards Institute (ANSI)/International Standards Organization (ISO) verification test results lower than grade C trigger communications to suppliers, manufacturers, and re-packagers for corrective action, and notify bar code governing bodies, and notify contracting authorities when minimum quality standards are not met.

I. The Indian Health Care Facility will initiate the Manufacturer Verification Communiqué that communicates the test results to suppliers, manufacturers, and/or re-packagers when the tester identifies an ANSI/ISO grade less than C (see Appendix C:).

J. The distribution will be made in the following manner:

1) Manufacturer Letter: Original hard copy letter will be sent certified mail to the supplier or manufacturer (see Appendix C:).

2) Electronic communications to the National Supply Service Center:

E-Mail Title:

"Bar Code Verification Results Communicated to Vendor Name"

E-Mail Body:

"The Indian Health Care Facility would like to keep you informed of problematic bar codes received for verification testing by the Veterans Health Administration Bar Code Resource Office. The attached letter was sent certified mail on month/day/year. To maintain the integrity of our patient safety systems, we have requested our supplier partners conform to bar code quality printing guidelines by providing products that meet ANSI / ISO verification grade minimum C target A. If you have any questions please contact Name & phone number.

Electronic Attachments:

A copy of the hard copy letter provided to the supplier, manufacturer, and/or re-packager will be attached to these electronic communications.

K. Indian Health Care Facility will report bar code quality scanning problems on marketed drug products to the FDA Med Watch. The Drug Quality Reporting System encourages health care professionals to voluntarily report, through the Med Watch Program, observed or suspected defects or quality problems to provide additional safeguards ensuring bar code quality.

L. When a response is received from a manufacturer/ packager indicating that they are 'changing' their process, Indian Health Care Facility will inquire as to what lot number or expiration date the manufacturer/ packager anticipate these changes will occur. If the facility sends us a product with an expiration date prior to the date given by the manufacturer, notice will be sent to the facility explaining the manufacturer/ packager indicates that they are 'changing' their process and will continue to monitor.

M. The Indian Health Care Facility will be notified of any actions by the manufacturer or re-packager concerning resolution of the problem.

1.4.2 Wristbands

A. The BCMA Coordinator or Point of Contact will gather information related to the causes of the wristband scanning failure. This information will be submitted to the IHS Help Desk.

B. IHS Help Desk will follow up with the facility to request what corrective actions have been taken by the site to address the problems. This information will be logged and recorded by the IHS Help Desk.

C. For instances where equipment failures are suspected:

1) A sample demo patient wristband will be obtained and sent to the BCRO verification lab following the steps identified above. Actual patient wristband should not be submitted.

   a. Wristbands received will be tested for ANSI/ISO verification print quality parameters.

   b. Suggestions will be made in writing regarding how to improve the quality of the printing.

2) Other equipment, process, or cultural issues will be addressed per the recommendations in the BCRO's "Improving Wristband Scan Success and Scan Compliance" document.

3) Additional assistance will be provided based on the individual needs of the facility.

1.5 Responsibility

A. **Medication Testing**: The BCMA Coordinator will be responsible for conducting the monthly medication review.

B. **Wristband Testing**: The BCMA Coordinator will be responsible for conducting the monthly wristband review.

C. **Verification Testing**: If the BCMA Coordinator determines that a scanning failure is due to a bar code, the site will send the wristband or medication packaging to the BCRO Verification lab.

1.6 References

None

1.7 Rescission Date

None

1.8 Change Control

The IHS OIT BCMA Team will provide any control changes to this SOP as it becomes necessary. A review of this SOP will be conducted annually.

1.9 Distribution

IHS OIT BCMA Team

1.10 Appendices

- Appendix A: Clinical Bar Code Closed Loop Verification Reporting Tool
- Appendix B: Bar Code Labeling Matrix
- Appendix C: Letter to Manufacturer

1.11 Annual Review

Date	IHS OIT BCMA Employee	Action or Modification

Appendix A: Clinical Bar Code Closed Loop Verification Reporting Tool

The Clinical Bar Code Closed Loop Verification will evaluate and verify problematic bar code products received from VA Facilities. Problematic bar codes will be reported to the manufacturer, National Acquisition Center (NAC), Food & Drug Administration (FDA), Pharmacy Benefits Management (PBM), and GS1 as applicable. For facility-generated bar codes, the Bar Code Resource Office (BCRO) will make recommendations for improvement to the Bar Code Medication Administration (BCMA) or Bar Code Expansion (BCE) Coordinators.

Mail Problematic Bar Codes to:

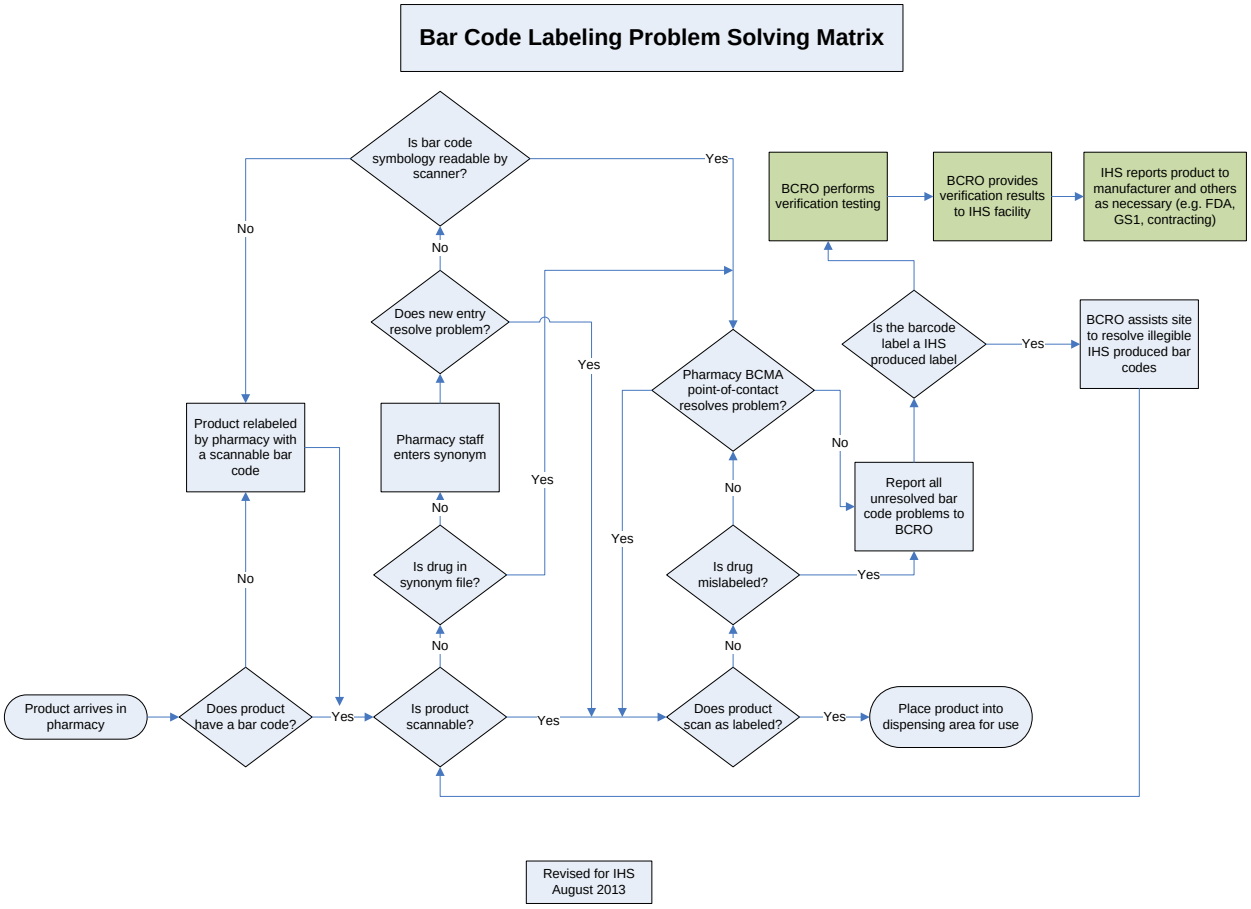
Steve Corma
VHA BCRO
1073 The Hideout
Lake Ariel, PA 18436

Site Information		
Reporting Site	**Person Reporting**	**Email Address**

BCMA	**Problematic Medication Bar Code Information**			
	Medication Name		Strength	
	Drug Manufacturer		Drug Lot Number	
			Expiration Date	
	Problematic Relabeled or IV Label Bar Code Information			
	Printer Manufacturer		Printer Model	
	Print Method (Circle One)	Thermal	Direct Thermal	Ink Jet
	Label Stock Supplier		Label Stock Number	
	Problematic Wristband Bar Code Information			
	Wristband Media Supplier		Media Stock Number	
	Printer Manufacturer		Printer Model	
	Print Method (Circle One)	Thermal	Direct Thermal	Ink Jet
	Scanner Brand		Scanner Model	

BCE	**Problematic Laboratory Bar Code Information**			
	Label Stock Manufacturer		Label Stock Number	
	Printer Manufacturer		Printer Model	
	Scanner Brand (If separate)		Scanner Model	
	Analyzer Brand		Analyzer Model	

Appendix B: Bar Code Labeling Matrix



Appendix C: Letter to Manufacturer

Indian Health Service
Office of Information Technology
[*Insert Address*]

Date

[*Manufacturer Name*]
[*Address*]
[*City*]

Dear Sir/Madam:

1. The Indian Health Service (IHS) Office of Information Technology (OIT) Help Desk has made a strategic commitment and is an industry leader in improving patient safety through the use of bar codes. Our organization currently administers over 600,000 medication doses each month. To maintain the integrity of our patient safety systems, we request our supplier partners conform to bar code quality printing guidelines by providing products that meet American National Standards Institute (ANSI)/International Standards Organization (ISO) verification grade minimum C target A.
2. The product [*product name*] with an NDC number of [*NDC number*] lot number of [*lot number*] and expiration date of [*expiration date*] was provided to the Veterans Health Administration Bar Code Verification Test Lab from an Indian Health Care Facility. Bar code verification testing with a WEBSCAN TruCheck model verifier (Calibrated Conformance Standard Test Card for European Article Numbering/Universal Product Code Symbol Calibration # UPC2-7175 presented the following results:

Verification Criteria	Results
Symbology	
Overall ANSI Grade	
X-Dimension	
Edge Determination	
Minimum Reflectance	
Minimum Edge Contrast	
Decode	
Contrast	
Modulation	
Decodability	
Defects	
Quiet Zone	

3. The product tested is enclosed with this letter.
4. Bar code minimum standards utilized within the Veterans Health Administration must meet ANSI/ISO standards of Grade C target A. The product tested had an overall ANSI grade of [*ANSI grade*]. We request that you make appropriate adjustments based on the detailed information provided to meet or exceed our targeted minimum standards.

5. If you have any questions, do not hesitate to contact [*insert contact name, number and email address for IHS POC*].

Sincerely,

[*Insert name of appropriate signer*]
[*Title*],

Indian Health Service

Glossary

Average Daily Inpatient Census

The total number of patients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).

electronic Medication Administration Record

Technology that automatically documents the administration of medication into certified Electronic Health Record technology using electronic tracking sensors (for example, radio frequency identification) or electronically readable tagging such as bar coding).

Acronym List

BCE	Bar Code Expansion
BCMA	Bar Code Medication Administration
BCRO	Bar Code Resource Office
IHS	Indian Health Service
OIT	Office of Information Technology
POC	Point of Contact
SOP	Standard Operating Procedure
VA	Department of Veterans Affairs
VHA	Veterans Health Administration