

# Impact of the FDA Barcode Ruling on BCMA at a Large Academic Medical Center

## Abstract

In 2004, the Food and Drug Administration (FDA) introduced a new ruling that required certain human drug and biological drug product labels to have barcodes. The mandate became effective April 26, 2004 and allowed manufacturers 2 years to comply<sup>1</sup>. The intent of the FDA ruling is to aid hospitals in reducing medication errors through use of barcode medication administration (BCMA) technology. Many institutions that already employ BCMA, unit-dose barcode (UDBC) all medications intended to be used at the bedside themselves by means of repackaging and re-labeling. This study will describe the impact of the FDA ruling at a large academic medical center implementing BCMA and the feasibility of maximizing use of manufacturer UDBC products for BCMA. This will be accomplished by:

1. Assessing changes and trends in pharmaceutical manufacturer barcodes over a 2 year time period. Attention will be focused on barcode content, consistency of barcode content, manufacturers switching from unit dose (UD) to bulk packaging, and ease of barcode readability with 5 different barcode scanning devices.
2. Identifying specific workflow changes for pharmacy as a result of utilizing manufacturer UDBC products for BCMA implementation. Purchasing habits, acceptance of inventory, and the need for re-packaging or re-labeling will be addressed.
3. Describing the economic impact to pharmacy as a result of utilizing manufacturer barcodes for BCMA implementation by assessing trends and changes in purchasing, repackaging and relabeling, and determine the associated additional labor costs.
4. Identifying causes for nurse override of barcodes at the point of administration and determining any correlation to the use of manufacturer UDBC products.

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<sup>1</sup> Department of Health and Human Services Food and Drug Administration. Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule. Federal Register. Vol 69, No.38; 2-26-04.