



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: AGENDA ITEM XVI - - Request from Loma Linda Heart and Surgical Hospital Pharmacy

FOR DISCUSSION AND POSSIBLE ACTION: Request for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq.

Attachment 1

Background:

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are Barcoded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read. The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

At the June 2014 Board Meeting, Loma Linda appeared before the board seeking an exemption to allow them to secure a centralized packaging license for their University Medical Center, but limitations in their software prohibit full compliance with the barcode requirements specified in Section 4128.4. The items listed in section 4128.4 appear on the label but not in the barcode. Instead Loma Linda requested that the board interpret the meaning of those provisions more broadly to allow additional time following licensure for the hospitals to fully comply with the requirements in statute.

Section 4028.4 requires:

4128.4. Barcode Required; Information Retrievable Upon Reading Barcode

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

The board approved the waiver for the Loma Linda University Medical Center. During the board meeting representatives from Loma Linda indicated that a waiver would also be needed for their Heart and Surgical Hospital Center. In response the board advised that a separate waive request would be required. **Attachment 1** contains the waiver request.

Attachment 1



LOMA LINDA UNIVERSITY
MEDICAL CENTER

July 17, 2014

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Street, Suite N-219
Sacramento, CA 95834

RE: Temporary Exemption BPC 4128.4

Virginia,

I am writing this letter as a follow up to the State Board's Meeting of June 26, 2014, to request an temporary exemption for BPC 4128.4 for The Loma Linda Heart and Surgical Hospital Pharmacy. This would allow The Heart and Surgical Hospital Pharmacy to receive a Centralized Hospital Packaging Pharmacy License (CPL). At the time of the June 26, 2014 Board of Pharmacy meeting, when Loma Linda University Medical Center was granted a temporary exemption for BPC 4128.4, the Board had not yet received the payment for The Heart and Surgical Pharmacy's Sterile Compounding License, thus, the hearing for its request for a Centralized Pharmacy Packaging License temporary exemption could not continue. The packaging procedures for The Heart and Surgical Hospital are the same as the procedures of the Medical Center.

BPC 4128.4 Barcode Required; Information Retrievable Upon Reading Barcode

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory Number.
- (f) The name of the centralized hospital packaging pharmacy.

Currently, in the barcode, we have the National Drug Code Directory number coded in the label. We can retrieve items a, b, c, d, and f, however, this data is not yet inserted into the existing barcode. However, we are working diligently with EPIC, our software provider, to have the required information embedded as soon as possible. Once the timeframe for the "fix" is known, this information will be communicated immediately to the Board.

At this time, we are requesting a five year temporary exemption for BPC 4128.4 for the Loma Linda Heart and Surgical Hospital.

Thank you again for your assistance in this licensure process.


Daniel Kardasinski, Pharm.D.
Director of Adult Pharmacy Services
Loma Linda Heart and Surgical Hospital

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