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State of California—Health and Human Services Agency  
California Department of Public Health



EDMUND G. BROWN JR.  
Governor

December 20, 2012

AFL 12-48

**TO:** General Acute Care Hospitals

**SUBJECT:** Centralized Hospital Packaging Pharmacy

**AUTHORITY:** Business and Professions Code (BPC) 4029, 4128, 4128.2, 4128.3, 4128.4, 4128.5, 4128.6, 4128.7  
California Code of Regulations (CCR), Title 22 Section 70261- 70269  
Health and Safety Code Sections 109875 et al.

This All Facilities Letter is being issued to notify hospitals of recently enacted legislation (AB 377, Statutes of 2012, Chapter 687) which amended the Business and Professions Code (BPC) to allow a hospital pharmacy, which meets specified criteria, to operate a centralized hospital packaging pharmacy. Effective January 1, 2013, a hospital that chooses to operate a centralized hospital packaging pharmacy is required to obtain a specialty license from the Board of Pharmacy (BOP); this license is subject to annual renewal.

With a specialty license from the BOP, a centralized hospital packaging pharmacy is able to prepare unit dose packages for single administration from bulk drug containers; prepare compounded unit dose drugs for parenteral therapy; and prepare compounded unit dose drugs for administration to inpatients provided the unit dose medication is labeled and barcoded in accordance with BPC 4128.4. In addition, the centralized hospital packaging pharmacy is able to repackage drugs for delivery to another hospital under common ownership which is located within a 75-mile radius, and to prepare and store a limited quantity of unit-dose medications in advance of receiving a patient-specific prescription.

While the BOP is responsible for compliance, enforcement, and licensure of pharmacies, including those operating within a general acute care hospital, the Licensing and Certification (L&C) Program of CDPH has enforcement authority over the hospitals themselves, including required pharmaceutical services. Operation of a centralized hospital packaging pharmacy **does not** supersede the requirements in the pharmaceutical service regulations of Title 22 CCR Sections 70261- 70269. In an effort to keep the department apprised of the activities being performed within the hospital,

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please notify your local District Office (DO) if you obtain the centralized hospital packaging pharmacy license from the BOP. For your convenience the list of all District Office addresses and contact information can be found using the following link:

<http://www.cdph.ca.gov/certlic/facilities/Pages/LCDistrictOffices.aspx>

For additional information regarding centralized hospital packaging pharmacy provisions, please contact the BOP at (916) 574-7900.

The compounding or repackaging/re-labeling of drugs may be subject to Sherman Food, Drug, and Cosmetic Law, as well as other relevant state and federal statutes and regulations pertaining to the production of finished pharmaceuticals. Facilities are encouraged to contact CDPH's the Food and Drug branch at (916) 650-6500 to ensure compliance.

The information in this AFL is a brief summary of AB 377. Facilities are responsible for following all applicable laws. CDPH's failure to expressly notify facilities of legislative changes does not relieve facilities of their responsibility for following all laws and for being aware of all legislative changes. Facilities should refer to the full text of BPC Sections 4029, BPC Sections 4128 through 4128.7 and HSC 109970 to ensure compliance.

Sincerely,

**Original signed by Debby Rogers**

Debby Rogers, RN, MS, FAEN  
Deputy Director  
Center for Health Care Quality