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DIVISION 2. HEALING ARTS [500 - 4999.129] (*Division 2 enacted by Stats. 1937, Ch. 399.)*

CHAPTER 9. Pharmacy [4000 - 4427.8] (*Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)*

ARTICLE 7.6. Centralized Hospital Packaging Pharmacies [4128 - 4128.7] (*Article 7.6 added by Stats. 2012, Ch. 687, Sec. 2.)*

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

- (1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
- (2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.
- (3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

(Amended by Stats. 2015, Ch. 241, Sec. 1. (AB 486) Effective September 2, 2015.)

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) This section shall become operative on January 1, 2025.

(Repealed (in Sec. 8) and added by Stats. 2023, Ch. 723, Sec. 9. (SB 816) Effective January 1, 2024. Operative January 1, 2025, by its own provisions.)

4128.3. A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

(Added by Stats. 2012, Ch. 687, Sec. 2. (AB 377) Effective January 1, 2013.)

4128.4. (a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient's bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

(Amended by Stats. 2015, Ch. 241, Sec. 2. (AB 486) Effective September 2, 2015.)

4128.5. (a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

- (1) The date that the medication was prepared.
- (2) The beyond-use date.
- (3) The established name of the drug.
- (4) The quantity of each active ingredient.
- (5) Special storage or handling requirements.
- (6) The lot number or control number assigned by the centralized hospital packaging pharmacy.
- (7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

- (1) The components used in the drug product.
- (2) The expiration date of each of the drug's components.
- (3) The National Drug Code Directory number.

(Amended by Stats. 2015, Ch. 241, Sec. 3. (AB 486) Effective September 2, 2015.)

4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile compounding.

(Amended by Stats. 2016, Ch. 484, Sec. 28. (SB 1193) Effective January 1, 2017.)

4128.7. A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

(Added by Stats. 2012, Ch. 687, Sec. 2. (AB 377) Effective January 1, 2013.)