AMENDED IN SENATE APRIL 9, 2015

SENATE BILL No. 587

Introduced by Senator Stone

February 26, 2015

An act to amend Section ~~4127.1~~ *4052.2* of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 587, as amended, Stone. Pharmacy: ~~compounding.~~ *drug regimens: hypertension and hyperlipidemia.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. ~~The law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board, and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding.~~ *That law authorizes a pharmacist to perform listed procedures or functions as part of the care provided by specified health care entities, including initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care entity.*

~~This bill would make a nonsubstantive change to that licensing provision.~~

This bill would specifically include the treatment of hypertension and hyperlipidemia in the authorized initiation or adjustment of a patient's drug regimen.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.2 of the Business and Professions Code is amended to read:

4052.2. (a) Notwithstanding any other ~~provision of~~ law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours. *This function may include, but is not limited to, treatment of hypertension and hyperlipidemia.*

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, ~~and shall,~~ *and,* at a minimum, *shall* do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

~~SECTION 1. Section 4127.1 of the Business and Professions Code, as added by Section 5 of Chapter 565 of the Statutes of 2013, is amended to read:~~

~~4127.1. (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.~~

~~(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.~~

~~(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.~~

~~(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:~~

~~(1) Reviews a current copy of the pharmacy's procedures and policies for sterile compounding.~~

~~(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.~~

~~(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.~~

~~(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.~~

~~(e) A pharmacy licensed pursuant to this section shall do all of the following:~~

~~(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.~~

~~(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.~~

~~(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.~~

~~(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.~~

~~(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:~~

~~(1) The sterile powder was obtained from a manufacturer.~~

~~(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.~~

~~(h) This section shall become operative on July 1, 2014.~~

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