Frequently Asked Questions

from ask.inspector@dca.ca.gov

As part of its licensee education efforts, the board restored a service whereby a board inspector and board staff are available to respond to verbal and written inquiries from the board and board licensees. To ensure that all licensees receive the benefits of service, the board has developed these FAQs.

It is important to note that the questions and answers below are not intended, nor should they be construed, as legal advice. The answers provided are intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment in determining the appropriate course of action. Should you require legal advice or detailed research, you will need to contact an attorney or another source.

Question: Does a pharmacist have to perform a final verification by physically inspecting the patient's medication if it was filled by a pharmacy technician or an intern?

Answer: There are a few sections of law that address this question and the answer varies based on various factors: Relevant legal references include:

- 1. With respect to interns, section 1726 of title 16 of the California Code of Regulations states a pharmacist supervising an intern be responsible for all professional activities performed by the intern under his or her supervision, including the correct dispensing of a prescription.
- 2. With respect to pharmacy technicians, section 1793.7 of title 16 of the California Code of Regulations states any function performed by a pharmacy technician in connection with dispensing of a prescription, including repackaging from bulk, must be verified and documented in writing by a pharmacist. Except certain situations, the pharmacist must initial the prescription label as verification of the pharmacy technician's work.

Question: What is the pharmacist to intern pharmacist ratio?

Answer: Business and Professions Code Section 4114(b) provides that a pharmacist may not supervise more than two interns at one time.

Question: What is the pharmacist to pharmacy technician ratio in a community pharmacy?

Answer: Business and Professions Code section 4115(f)(1) specifies that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing pharmacy technician functions. The ratio of pharmacy technicians increases for each additional pharmacist to a ratio not to exceed 2 technicians to 1 pharmacist for pharmacy technicians performing duties specified as pharmacy technician duties.

Question: How do I identify the dates of the renewal period within which I must earn 30 units of continuing education (CE) to renew my pharmacist license?

Answer: Pharmacists must earn 30 units of continuing education each renewal cycle.

Example: A pharmacist's license expires October 31, 2017. The current renewal period runs November 1, 2015 through October 31, 2017, within which the pharmacist must have earned 30 units of CE to renewal the license in an active status. The next renewal period will be November 1, 2017 through October 31, 2019. Please note that California law requires pharmacists to keep CE certificates for four years.

Question: Is it possible to purchase pen needles over-the-counter in California?

Answer: Yes, but with a few restrictions and requirements. Please see Business and Professions Code sections 4144.5, 4145.5 and 4146 for the complete requirements.

A pharmacist or physician MAY (but is not mandated to do so) furnish hypodermic needles and syringes for human use without a prescription or permit, with the following restrictions: The person is known to the furnisher, and the furnisher has previously been provided with a prescription or other proof of legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

Additionally, as a public health measure, the pharmacist or physician MAY (but is not mandated to do so) furnish hypodermic needles and syringes for human use to a person 18 years or older without a prescription solely for personal use. A pharmacy that furnishes nonprescription hypodermic needles and syringes must counsel the consumer on the safe disposal of syringes or needles and provide the consumer with one or more of the following disposal options:

- 1. Onsite disposal that meets state and federal standards for collection or disposal of medical sharps waste.
- 2. Mail-back sharps containers authorized by the USPS with tracking forms to verify destruction.
- 3. A sharps container that meets applicable standards for collection and disposal of medical sharps waste.

The pharmacy must also provide written information or verbal counseling to the consumer on how to access to drug treatment, testing and treatment of HIV or hepatitis C, and the safe disposal of sharps waste. A pharmacy may accept returned needles and syringes from the public if contained in an acceptable sharps container.

Business and Professions Code sections 4144.5 and 4145.5(c) allow a pharmacy to sell hypodermic needles and syringes without a prescription for industrial and animal use (if the purchaser can establish his or her identification).

Question: Can a Schedule II controlled substance be refilled?

Answer: Health & Safety Code Section 11200 (c) prohibits the refilling of a Schedule II controlled substance.

Question: How long is a controlled substance prescription valid?

Answer: Health & Safety Code Section 11200 (a) specifies that no person shall dispense or refill a controlled substance more than six months (180 days) after the date written.

Question: How many times can a Schedule III or IV controlled substance be filled?

Answer: Health & Safety Code Section 11200 (b) specifies that no prescription for a Schedule III or Schedule IV controlled substance may be refilled more than five times. Further, this section also creates a limit of a 120-day total supply of refills for a Schedule III or Schedule IV controlled substance prescription.

Example: A prescription is written for temazepam 15mg QHS, quantity #30 with 5 refills. The prescription is dispensed on 7/1/2016 for a quantity of 30. The pharmacy refills the prescription on 8/1/2016, 9/1/2016, 10/1/2016, and 11/1/2016, a 30-day supply for each refill and a total of a 120-day supply between the four refills. Although the prescriber wrote for 5 refills, the pharmacy cannot dispense the remaining refill because the 120-day limit was reached after dispensing the refill on 11/1/2016. A new prescription is required for any additional dispenses.

Question: Where is the law that establishes the requirement for a pharmacist to exercise corresponding responsibility?

Answer: A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Health & Safety Code Section 11153 (a) provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon both the prescribing practitioner <u>AND</u> a corresponding responsibility rests with the pharmacist who fills the prescription.

NOTE: Additional information about corresponding responsibility can be found using the following link -- http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf and http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf for the DEA Pharmacist Manual. Information on the board's precedential decision can be found at http://www.pharmacy.ca.gov/enforcement/precedential.shtml and http://www.pharmacy.ca.gov/enforcement/fy1516/sternberg_lexis.pdf.

Question: Am I required to apply for registration to California's prescription drug monitoring program, CURES?

Answer: Health & Safety Code Section 11165.1 (a)(1)(A)(ii) required a pharmacist, on or before July 1, 2016, or upon licensure, to submit an application to the Department of Justice to obtain approval to access the CURES system. The CA Department of Justice website to register for CURES is https://oag.ca.gov/cures

Question: How often does a pharmacy need to report controlled substances dispensing information to CURES?

Answer: Health & Safety Code Section 11165 (d) specifies that a dispensing pharmacy must report information to the Department of Justice as soon as reasonably possible, but not more than one working day after the controlled substance is dispensed.

Question: How do I get on the Board's email distribution list?

Answer: You may sign up for the Board's email distribution list by visiting the following website and signing up: https://www.dca.ca.gov/webapps/pharmacy/subscribe.php

Question: Where can I find prescription drug take back locations?

Answer: Go to the Board's website, <u>www.pharmacy.ca.gov</u>; scroll down to "Important Information for Consumers"; and click on <u>Drug Take-Back: Find a Drop-off Location</u>.