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## BOARD OF PHARMACY

### Issue Highlights:

Notification Requirements  
 for Generic Substitution

Licensure Before Practice

Pharmacy Technician Taskforce

Pharmacy Security

### **\*Online Registration Services\***

The Division of Registrations continues to encourage usage of the Registrations Online Services. After a simple registration process, you may now:

- Renew your license using a credit card as soon as your license becomes eligible for renewal
- Update your mailing address and contact information
- Check the status of a pending application

#### **Important requirement affecting your license renewal regarding lawful presence in the USA**

Effective January 1, 2007, all applicants requesting original licensure, renewal of an active license, or reinstatement of a lapsed license must complete and sign the Affidavit of Eligibility Form. No license can or will be issued without this form.

#### **The good news is that you can complete this form online when you use Registrations Online Services!**

You must possess at least one secure and verifiable document and include information about that document on the Affidavit itself (or provide the information during online renewal). The list of secure and verifiable documents is available to you when you renew online. We also have a web page where you can read the law, look at the Affidavit, and see the list of acceptable documents.



**Consumer protection  
 is our mission**

## Satellite Pharmacies

The Board's staff has continued to observe pharmacies, typically located within hospital settings, store additional stocks of large volume prescription intravenous solutions in an area of the hospital not designated as part of the pharmacy's compounding / dispensing area (such as a hospital's materials management department). Board Rule 5.01.30(b) defines "compounding / dispensing area" to mean any area in a prescription drug outlet where "compounding / dispensing" is performed. Board Rule 5.01.30(a), in turn, defines "compounding / dispensing" to mean and include, among other things, "prescription drug storage". Once prescription drug stocks are received by the pharmacy from a Board registered prescription drug wholesaler, they may be distributed from the pharmacy to various recognized patient-care units of the hospital as "floor-stock" (such as the emergency room, intensive care unit, or various automated dispensing machines) without the requirement of a satellite. However, those stocks which simply have been received by the pharmacy (without documented distribution to patient-care units of the hospital) must be stored in the designated compounding / dispensing area of the pharmacy until such time the pharmacy either distributes them to floor-stock or receives a patient-specific order to dispense them. Because physical space is typically limited in a pharmacy's principle compounding / dispensing area, each pharmacy has an option to establish one or more satellite pharmacies for additional storage within the same location as the pharmacy's principle compounding / dispensing area by submitting an application to the Board for approval. Board Rule 5.01.31(a) states that satellite compounding / dispensing areas at the same location must be approved by the Board "prior to" use for compounding / dispensing.

An application for a satellite pharmacy can be viewed and printed from the Board's website at [www.dora.state.co.us/pharmacy](http://www.dora.state.co.us/pharmacy).

### Please contact us:

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## **Notification Requirements for Generic Substitution**

The Colorado State Board of Pharmacy has received several complaints recently alleging that pharmacists are not complying with C.R.S. §12-22-124 (3) when generically substituting medications. This statute requires that when substitution occurs, the purchaser must be notified both orally and in writing of this substitution. Such requirement is not necessary for institutionalized patients. The Board considers institutionalized patients to be those patients that are hospitalized, those that reside in correctional facilities, or in long term care facilities. Residents of assisted living facilities are only considered institutionalized patients if their medications are administered by facility personnel.

In addition, the prescription container must be labeled with the name of the drug dispensed and the file copy of the order must contain both the name of the drug prescribed as well as that of the drug that was actually dispensed.

The Board wishes to eliminate any confusion regarding this issue. The law requires, and the Board expects, that all pharmacists and pharmacies will ensure that oral and written notification of generic substitution is provided when such substitution occurs.

## **Licensure Before Practice**

Board of Pharmacy staff has observed an increasing trend in which persons, while already enrolled in an accredited school or college of pharmacy, are practicing as a pharmacy intern prior to the issuance of pharmacy intern license by the Board. The Board expects all Board-registered in-state pharmacies, pharmacist managers, and preceptors to exercise due diligence to determine that each person practicing as a pharmacy intern in any Board-registered pharmacy located in Colorado has actually been issued a pharmacy intern license number by the Board prior to engaging in the practice of pharmacy. Such due diligence may include confirming such information on ALISON (Automated Licensure Information System Online) from the Board's website at [www.dora.state.co.us/pharmacy](http://www.dora.state.co.us/pharmacy). This system provides you with an on-line, real-time licensing status of any Board licensee or registrant.

## **Medication Error Reporting**

The Colorado State Board of Pharmacy urges pharmacists and pharmacies to report medication errors to the FDA through MedWatch. MedWatch is the FDA's Safety Information and Adverse Event Reporting Program that serves health care professionals and the public by providing information about safety issues involving medical products, including prescription drugs. It is important that all medication errors be reported to MedWatch in order for the FDA to accurately quantify and qualify medication error occurrences. A medication error is defined by the National Coordinating Council for Medication Error Reporting and Prevention as, "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

Reporting to MedWatch can be done online, via phone, or by submitting the MedWatch 3500 form via mail or fax. For more information, select "How to Report" at [www.fda.gov/medwatch/report/hcp.htm](http://www.fda.gov/medwatch/report/hcp.htm).

Please remember that any significant compounding or dispensing errors, such as those that result in serious personal injury or death of a patient must be reported in writing to the Board of Pharmacy

## **Pharmacy Security**

A recent analysis of complaints over the past year has revealed a large number of cases involving the security of a pharmacy's compounding / dispensing area. Some involve instances in which a pharmacist fails to properly secure the compounding / dispensing area (i.e. – a door or a window) when closing for the day but while the general store area remains open. Others involve instances in which a non-pharmacist enters the compounding / dispensing area when a pharmacist is not in the building, particularly due to non-pharmacists having accessibility to a key to enter the area. The Board reminds registrants to assure that all entrances to a compounding / dispensing area are secure when closing for the day while the general store area remains open. In addition, the Board urges you to be cautious about the security and accessibility of additional keys that are typically used to gain access to a pharmacy by "floating" pharmacists.

# Pharmacy Technician Taskforce

## Submitted by Jeannine Dickerhofe, Board Member

The Pharmacy Technician Taskforce that was organized by the Colorado State Board of Pharmacy has met several times since June, 2008. This group, consisting of technician and pharmacist representation, has been charged with exploring issues surrounding the possible regulation of pharmacy technicians and reporting its findings back to the Board. Regulation could involve the licensing, registering or required certification of technicians. Much information has been reviewed, including what requirements other states have implemented. Nationwide, the regulation of pharmacy technicians is rapidly changing. Pharmacy practice has changed significantly in recent years. Pharmacists are participating in more medication management programs, so need to delegate more tasks to the pharmacy technicians. Discussions have centered on the pharmacy technician's scope of practice, age requirements, NABP Technician Taskforce Reports, dispensing errors and completion of board-approved technician education programs. There are currently three programs in Colorado that are accredited by the American Society of Health-System Pharmacists. A fourth is anticipated soon.

## A Reminder about Filing Chart Orders for LTCF Patients

It has recently come to the attention of the Board staff that there is some confusion concerning the proper filing of chart orders for Long-Term Care Facility (LTCF) patients. **REG 11.04.10** states, in part, "The LTCF chart orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing." The Board staff reminds any pharmacy that is filing "according to the date of dispensing" that this practice is only valid when the pharmacy dispenses from LTCF chart orders exclusively.

**REG 11.04.10** continues, in part, "If a prescription drug outlet utilizes both prescription orders and chart orders, assigning serial numbers to both with the same computer system, the orders **must be filed sequentially by serial number.**" In other words, if a prescription drug outlet dispenses prescriptions using **both** LTCF chart orders **and** prescription orders (for example: prescription orders from assisted living patients), using the same computer numbering system, then **ALL** the orders must be filed according to the serial numbers to be considered readily retrievable and available.

## Reminder of Reporting of Criminal Convictions, Deferred Judgments, and Disciplinary Actions by Other States

Colorado Law requires that any licensee or registrant with the Colorado State Board of Pharmacy must notify the Board of any criminal conviction or deferred judgment within thirty days of the conviction or judgment. In addition, disciplinary actions in other states must be reported within thirty days after the effective date of such discipline. Alcohol related convictions, including, but not limited to "Driving Under the Influence" or "Driving While Ability Impaired" are considered criminal convictions.

Notifications of such events are to be made in writing to the Board. Submit a detailed written explanation to the Board outlining the facts and circumstances surrounding the event that resulted in the charge. Also submit documentation from the court detailing the charges, the plea agreement or verdict, and sentence requirements. Include proof of completion of any court ordered requirements, if applicable.

Understand that the Board of Pharmacy can conduct audits of its licensing database against several criminal and national disciplinary databases. This allows the Board to track subsequent criminal and disciplinary conduct after initial licensure.

Licensees or registrants should avoid some of the common excuses for failure to disclose criminal convictions or disciplinary actions such as:

- My attorney told me I didn't have to disclose the criminal conduct or disciplinary actions.
- I didn't think the prior conduct had anything to do with the profession.
- I didn't think the disciplinary action, arrest, charges, or conviction was still on my record.
- I didn't think it was subject to disclosure because I received a deferred sentence/judgment.

***Remember, there is no excuse not to disclose disciplinary actions and criminal conduct.***