Supplemental Information

Administrative Hearing Commission Process **(Back to top)**

The Administrative Hearing Commission (AHC) is an independent state agency comprised of hearing commissioners who conduct hearings in cases in which a licensing board has denied licensure to an applicant and the applicant chooses to contest the board's decision. The AHC also conducts hearings in a number of other types of cases involving state agencies.

If the Board requests its legal counsel to file a formal complaint with the AHC, the filing of the complaint is the first step in the process. The Board, through its attorney, will then be required to present evidence at a hearing, which will attempt to prove the facts alleged in the complaint. The attorney will also file written arguments in which the attorney explains why these facts are a violation of the law. The licensee may be represented by an attorney at the hearing or may represent him/herself. Corporations must be represented by legal counsel.

The AHC will issue a written decision following the hearing, indicating what facts were proven by the evidence and whether or not the facts indicate the licensee has violated the law and is subject to discipline. The AHC does not impose discipline. The Board imposes discipline.

If the AHC decides in favor of the Board indicating that the licensee is subject to discipline, the Board will conduct a disciplinary hearing.

The disciplinary hearing is a formal hearing on the record. The Board will have a court reporter present and all witnesses will be sworn. Following the hearing, the Board must issue a written decision setting forth the disciplinary action, which is taken against the licensee.

CE Providers **(Back to top)**

Providers of continuing education programs that desire to have programs approved by the Board of Pharmacy for purposes of licensure renewal must submit the proper application and receive approval prior to offering the continuing education program. No post-approval is provided for by law. Applications must be received by the Board office no less than ten (10) days prior to the scheduled program date and reviewed for approval purposes.

Consumer Product Safety Commission **(Back to top)**

The Board of Pharmacy has signed an agreement with the Consumer Product Safety Commission to assist in enforcing childproof container laws in the state of Missouri.

It is important to note that all prescription drugs, which are dispensed to patients, must be packaged within a childproof container. There are certain exemptions to child-proof containers such as the dispensing of oral contraceptives, sublingual nitroglycerin preparations, along with several other drugs not exceeding a particular milligram strength. It is worth noting here that significant violations of the childproof container laws are to be reported to the Consumer Product Safety Commission by this office for their use in investigations concerning violations of federal laws. Under the federal act, the Consumer Product Safety Commission may impose criminal sanctions on violators. The Act also provides for a private right of action by someone who has been injured due to a violation of the Consumer Product Safety Rules.

Pharmacists should note that they may accept requests for exemptions from patients who desire to have their medication supplied in non-childproof containers. The law does not preclude a pharmacist from relying upon a specific request from a patient, preferably in writing, to have all of his or her medications placed in noncompliant packaging, i.e., a blanket waiver. However, a single request from a patient to dispense a specific prescription in non-CRP is not a basis for the pharmacist to infer the patient wants all subsequent prescriptions to be dispensed in non-CRP. Such a request is not a blanket waiver.

A pharmacist can also utilize non-childproof containers if a physician specifically requests on a prescription that they not be used. However, it is not permissible for a pharmacist to honor a blanket request from a prescriber never to use safety caps for any drugs dispensed.

Pharmacists who wish to update themselves on the current regulations of the poison prevention packaging act as it relates to pharmacy may find specific information on these laws by referring to 16 CFR 1700.14.

Dentists, veterinarians, podiatrists and optometrists-prescribing (Back to top)

These entities are only allowed to prescribe medications as a direct result of the care in which they are licensed to provide, and may not prescribe drug products outside their normal expertise and area of licensure, i.e., a dentist or optometrist prescribing amphetamines, etc. It should be noted that all health care practitioners who are licensed to prescribe must have appropriate BNDD and DEA registrations before they are allowed to prescribe or administer controlled substances. Nurses involved in a collaborative practice arrangement are not allowed to prescribe controlled substances. Likewise, physician assistants involved in a supervisory agreement with a physician are not allowed to prescribe controlled substances.

Expiration Dates of Licenses Issued by the Board of Pharmacy (Back to top)

a. Pharmacists - October 31 (biennial)
b. Pharmacy - October 31 (biennial)
c. Drug Distributors - October 31 (biennial)
d. Intern Pharmacists - December 31 (biennial)
e. Pharmacy technicians - May 31 (annual)

Generic Drug Formulary (Back to top)

When a substitution to a generic product is made, the actual name of the drug must be printed on the prescription label. To print a brand name, when a generic product is used, is misleading to the public and is considered misbranding. Within such settings as nursing home practice, where the staff may need brand name information for informational purposes, it is considered acceptable to list the generic product then use the statement "substituted for" and then list the brand name of the product that is being substituted. However, there is no law requiring that a brand name be used on a label when substitution takes place. Substitution of controlled release and enteric-coated products can occur with FDA guidelines and are not prohibited under law. Products that fall into these categories are treated in the same fashion concerning their equivalency or non-equivalency to a parent compound by the Food and Drug Administration. Each product in these classes will be provided the same A or B rating as are all other FDA approved drugs. The FDA does not currently restrict the substitution of any class of drugs but instead, depends upon individual evaluations of each parent and generic drug product.

Medical Practice Statutes of Interest (Back to top)

Chapter 334.100.3 - Collaborative practice arrangements, protocols and standing orders shall be in writing and signed and dated by a physician prior to their implementation.

Physician Prescribing

- It is illegal for a physician to prescribe controlled substances for him/herself, unless it is a medical emergency. (refer to chapter 195.070.4)
- It is not illegal for a physician to prescribe non-controlled drugs for him/herself, but is discouraged by the Board of Healing Arts.

- It is not illegal for a physician to prescribe either controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as h/she would for any other patient.

Misbranding and Adulteration of drugs is defined as follows **(Back to top)**

Adulteration

- Drugs prepared or held under unsanitary conditions
- Compounded mixtures do not conform to good manufacturing practice
- Container leaks or causes the decomposition of the drug
- Drug varies from USP standards due to poor storage or dispensing practices, i.e., dispensing outdated drugs

Misbranding

- Dispense legend drugs or refill without authorization or prescription
- Label is false or misleading
- Drug is deteriorated unless its label bears necessary precaution
- Dispensing of a non FDA approved drug (interstate commerce)
- Drug is subject to but not packaged according to Poison Packaging Act of 1970

Physician Assistants:

Section 334.734, amended August 28, 1998, allows a physician assistant, who has a supervisory agreement with a physician, to write prescriptions. However, a physician assistant may not write prescriptions independently of a supervisory agreement; s/he may not write for controlled substances; types of drugs prescribed must be consistent with the scopes of practice of the PA and the supervising physician; all prescriptions must include the name of the PA and the supervising physician; a PA may only dispense a 72 hour starter dose of medication.

Practice of Pharmacy and the Internet **(Back to top)**

A number of pharmacies have designed web sites that offer consumers health care information and can act as a source of communication between pharmacists and their patients. Some sites are initiating pharmacy practice by providing clinical type services over the internet. Other services may include formulary management programs, drug utilization review services and practitioner consultations. Two things are of vital importance with these types of operations as concern compliance.

First, any type of program, service or consultation that involves patient specific services or attempts to directly manage the transactions of a pharmacy must be licensed as a Class I: Consultant pharmacy whether located within the state or in another state. Second, anytime patient specific data or information is transferred over the internet by e-mails, files or video systems, the pharmacist/pharmacy must ensure that appropriate security of the information is always maintained at all levels before, during and after transmissions. Some pharmacies are now attempting to dispense drugs using internet links as communication portals. While there are legitimate ways of dispensing drugs using the internet, pharmacists and pharmacies should be well aware that their duty to

dispense drugs based on legitimate prescriptions is of vital importance. The source and the method by which the prescription was obtained are important. A pharmacist cannot turn a blind eye to violations of drug and/or prescribing laws where the pharmacist knows or should have known that such violations are occurring. An example here could be made of what are called "lifestyle" drug sites. These sites are "combination sites" that allow anyone to complete a brief questionnaire, supply a credit card number and get the drug. Dispensing of these types of prescriptions is inappropriate. There is no bona fide patient/physician relationship due to the lack of an adequate physical exam and/or clinical assessment. There is no way to follow up appropriately on the accuracy of answers to printed questions or on the use of the product. According to the Board of Healing Arts, an online or telephonic evaluation by questionnaire is inadequate and does not comply with the intent of Chapter 334, Practice of Medicine. In addition, any physician providing medical services to a consumer located in this state must be licensed with the Board of Healing Arts. See Section 334.010, RSMo.

Prescriptions from Foreign Physicians **(Back to top)**

A pharmacist may not legally dispense a prescription written by a foreign physician, unless that physician is licensed in a state or territory within the United States.

Repackaging, Federal Registration Required **(Back to top)**

Federal Registration is required for certain types of drug repackaging. In order for a pharmacy to repackage drugs and distribute repackaged drugs to other practitioners or facilities, the pharmacy must be registered with the FDA as a repacker. In addition, the pharmacy must provide FDA with a listing of those products that are being repackaged. This registration is required for both federal legend drugs as well as OTC drugs that are distributed in this fashion.

The repackaging of OTC drugs for retail sale to the public by a pharmacy can be done without FDA registration, however, strict labeling requirements must be utilized for any OTC drugs that are repackaged by a pharmacy and exposed for direct sale to the public. Pharmacists should take note that state and federal Food and Drug Acts hold any repackager of OTC items strictly liable for compliance concerning the appropriate labeling of each container of an OTC drug. Minimum labeling requirements include:

1. The name of the product;
2. The name and address of the manufacturer, packer or distributor;
3. The net contents of the package;
4. The established name of all active ingredients and the quantity of other ingredients, whether active or not;
5. The name of any habit-forming drug contained in the preparation;
6. Cautions and warnings that are needed for the protection of the user; and
7. Adequate directions for safe and effective use.

Any pharmacy may provide copies of proposed labels to the FDA for review and advice. Pharmacies electing to repackage drugs should contact the FDA or Board of Pharmacy office for more information.

Return/Reuse of Controlled Substances **(Back to top)**

Federal law prohibits the return for credit or reuse of any controlled substances from an unregistered location. This means that any controlled substances dispensed from a pharmacy to a nursing home cannot be returned for credit or destruction. All destructions must take place on the premises of the nursing home.

State/Federal Law Variances **(Back to top)**

State drug law differs from federal law in some instances. Any drug mixture or compound that contains Codeine (200mg/100ml), Dihydrocodeine (100mg/100ml) and Ethylmorphine (100mg/100ml) with other non-narcotic ingredients that have medicinal qualities are classified as Schedule IV substances under state law and require a prescription.

Tablet Splitting **(Back to top)**

A number of insurance plans and their agents have begun to require pharmacists to dispense double the strength of a drug prescribed, and then split the tablets in half for the delivery of the original intended dose. The pharmacist then splits the tablets and makes changes to the directions for administration of the drug to coincide with the change in tablet strength. Or, the pharmacist supplies the drug in whole form and changes the label directions to instruct the patient that one-half of a tablet is to be administered for each dose.

These practices by insurance companies may not always be in the best interest of the patient. Some insurance plans are requiring that tablets with coatings or non-scored tablets be dispensed with the expectation that they be split. As a licensed professional, the pharmacist must provide appropriate medications in their proper form to their patients. Only drug products that are scored should be used in any tablet splitting activities. This includes any splitting of a tablet into half tablets or quarter tablets. Drugs that are not scored will likely not split in such a manner as to provide a uniform dose. Tablets that are coated may also present problems, because once the drug is split any effect the coating provides may be compromised. Pharmacists need to make sure of all of the following items before tablet splitting occurs:

1. The literature, or other recognized compendia accompanying the drug recognize that splitting of the specific brand of tablet can be accomplished safely and effectively;
2. If a change in the prescription occurs due to using a strength higher than originally called for, the prescriber must approve the change; and
3. Detailed patient counseling to ensure the patient understands changes to the prescription that have been made and, if the patient is responsible for splitting the tablet, proper counseling on splitting techniques and use of such items as tablet splitters.

Proper medication use is important in accomplishing compliance with dispensing such prescriptions.

Technicians/Interns **(Back to top)**

Pharmacy technicians or interns may accept prescriptions for dispensing when "no pharmacist is on duty" but cannot fill, compound, prepare or hand-out a finished product to patients, even if it has been checked by a pharmacist, when there is no pharmacist on duty.

Tips for Prevention of Noncompliant Situations (Back to top)

There are things that the pharmacist and pharmacist-in-charge can do to prevent problems or avoid their escalation into serious noncompliance situations by practicing some of the following steps:

1. Be as familiar as you can be with state and federal drug laws. Every pharmacy is required by law to have a set of the current edition of statutes and rules governing pharmacy practice. Be familiar with the contents of this reference since most of it will have some impact on the lawful practice of pharmacy. Every pharmacist-in-charge should periodically review 20 CSR 2220-2.090, which sets up the overall responsibilities of that position. Knowing ahead of time what a pharmacist-in-charge will be held accountable for can be helpful in designing your overall management scheme of a pharmacy department.
2. Avoid complacency. In addition to keeping up with state and federal laws governing the practice of pharmacy, maintain communications with your colleagues over issues surrounding drug laws and pharmacy practice. Share your successes and your questions with fellow colleagues who may be able to help you in any unfamiliar areas.
3. Establish a quarterly cycle or some other prescribed time interval, when all pharmacists review the inspection report to see if each area is being maintained in compliance. While it is important for the pharmacist-in-charge to review the report, a team effort by all pharmacists employed within a pharmacy often makes for better voluntary compliance since all pharmacists are involved. In addition to the inspection report, periodic staff meetings should include reviews of newsletters that are published by the Board with emphasis on review of any information noting changes or additions to laws affecting practice.
4. Pharmacists on staff should spot check for daily recordkeeping requirements. They should also review pharmacy records with other pharmacists and technicians to ensure compliance in this area is maintained.
5. Maintain a method for periodic review of the inventory in order to separate out expired drugs on a timely basis.
6. Fully utilize the time you have with the inspector. Both the pharmacist-in-charge and the staff pharmacist(s) should take every opportunity to interact with the inspector to clear up any matters of the law or facilitate education concerning compliance issues.

Following these simple steps and making a commitment to take just a little time on a periodic basis to appropriately review records, drugs and practice habits within a pharmacy can go a long way in preventing compliance problems from occurring.

Transfer of Drugs to Foreign Country (Back to top)

An FDA registration is required when a practitioner or pharmacy desires to transfer drugs to a foreign country, or is involved in exporting drugs through a charitable organization. In addition, any transfer of prescription drugs which exceeds five percent (5%) of a pharmacy's gross legend drug sales requires that the pharmacy obtain licensure by the Board of Pharmacy as a drug distributor. Also note that in order to be in compliance with federal law when exporting drugs, you must be in compliance with the drug laws of the country into which the drugs are being shipped. Misbranded or adulterated drugs cannot be exported, even for charitable purposes; this also includes outdated drugs.

Transfer of Prescriptions (Back to top)

State and federal regulations require that all prescriptions be voided when they are transferred to other pharmacies for further dispensing. When a pharmacy utilizes a computer recordkeeping system that can

effectively void the prescription, it is not necessary to go back and also void the original hard copy. The key in this situation is that the computer must fully prevent any further dispensing of a prescription that has been voided.