

Continuing Education for Pharmacy Technicians

Pharmacy Law

An Introduction for the Pharmacy Technician

Ronda H. Lacey, JD, RPh
Adjunct Assistant Professor Pharmaceutical
Sciences
McWhorter School of Pharmacy
Birmingham, AL

Goal: To help pharmacy technicians understand and identify the major legal rules and regulations dealing with the practice of pharmacy.

Objectives:

1. Identify the three general areas of law that regulate the practice of pharmacy.
2. Identify whether a specific area of law is criminal, civil or administrative.
3. Identify the Federal Agency responsible for enforcement of the Controlled Substances Act.
4. Identify the requirements for a valid prescription for a Controlled Substance.
5. Distinguish between OBRA and HIPAA.

The practice of pharmacy is highly regulated. The legal rules and regulations dealing with drugs, pharmacies, pharmacists and technicians can seem overwhelming. This outline and summary will serve as a guide or mini-guide to introduce you to the legal system and assist you in understanding these laws.

THE LEGAL SYSTEM

Although the legal system and how it regulates drugs, pharmacies, pharmacists and technicians cannot be explained in a few pages; general concepts can be provided to ensure not only compliance but the best interest of the public whom we serve.

Pharmacy laws can be generally classified as Federal, State or Administrative. Each legal classification is further subdivided but our emphasis in this program is to introduce you to the major regulations; and provide you the tools to access additional information.

Federal Laws: apply uniformly to each state. The Food Drug and Cosmetic Act, 21 U.S.C § 301 et seq., and its amendments serve as the regulatory system for food, drugs, cosmetics and medical devices in the United States.

State Laws: Apply only to a particular, individual state. States are given the authority to pass laws specific to the citizens of their state. For example, each state

established legal standards as to who can practice pharmacy, assist a pharmacist, practice medicine, assist a medical practitioner; practice law, etc.

Administrative Laws: Established by Administrative Agencies which are established and granted special powers by each state legislature. These administrative laws apply to a restricted number of people, professions or businesses within a particular state. Each state has an administrative agency known as a Board of Pharmacy that regulates the practice of pharmacy within that particular state.

The Boards of Pharmacy establish licensing requirements for manufacturers, distributors, pharmacies, pharmacists and pharmacy technicians within the state. In addition to licensing requirements and registration requirements, the Boards of Pharmacy set standards for professional conduct for pharmacists and pharmacy technicians. It is important that you become familiar with the requirements of the particular state in which you are registered as a pharmacy technician. Most Boards of Pharmacy have their licensing requirements and registration requirements available online at their website.

Criminal, Civil and Administrative Laws

Concerns often arise as to whether a law is criminal, civil or administrative. Criminal cases, whether federal or state, are those brought in the name of the government or state and where an individual's liberty or freedom is at stake. For example: a murder case is a criminal case. If an individual is convicted in a criminal case they could face imprisonment [loss of freedom].

Civil cases, whether federal or state, generally involve a claim known as a lawsuit. In the lawsuit one person, known as a plaintiff, seeks monetary damage from another person, known as a defendant. A plaintiff alleges or claims that a defendant did an act that caused the plaintiff harm, and claims monetary relief. For example: Jane Doe sues Neighborhood Pharmacy for monetary damages; accusing Neighborhood Pharmacy of negligence for placing the wrong drug in a prescription bottle and causing her physical harm. If a judge or jury rules in favor of the plaintiff money damages will be awarded and the defendant faces the loss of money.

Administrative cases can result in fines or loss of a professional license, registration or privilege. For example: John Doe, pharmacy technician, fails to complete the required number of continuing education credits required by the Board of Pharmacy. If the Board of Pharmacy finds John Doe guilty, he could have his registration revoked,

suspended and/or a fine imposed for failure to comply with the rules of the Board of Pharmacy.

The revocation of a professional license or registration can be considered a loss of privilege.

The Food Drug and Cosmetic Act

Laws and regulations for drug manufacture, distribution, and the practice of pharmacy exist in order to protect the public health and welfare. To insure this protection, Federal Laws apply nationwide. The Food, Drug and Cosmetic Act, FDCA, provides, among other things, that drugs cannot be marketed until they are proven safe and effective for use; that certain good manufacturing practices exist; that products cannot be misbranded or adulterated [contaminated]; and that penalties apply for violations.

The FDCA regulates additional matters dealing with drugs and pharmacies including key items that you will see every day as a pharmacy technician:

- Product Labeling
- Product Packaging
- Product Warnings, such as pregnancy warnings
- Product Recalls

The primary consideration for each rule and regulation of the FDCA is the protection of the public.

Poison Prevention Packaging Act

The Poison Prevention Packaging Act (PPPA) was enacted to prevent the accidental poisoning of children with "household substances". Household substances are defined as any substance that is customarily produced for or used in the household.

The PPPA requires the use of child resistant containers for most OTC (Over the Counter) drugs and nearly all prescription drugs. A child resistant container is one manufactured so that 80 percent of children less than five years of age cannot open the container; whereas at least 90 percent of adults can open the container.

The PPPA directs that a drug be dispensed only one time in a child resistant container or vial. In other words the PPPA does not allow (as a general rule) for prescription vials and lids to be re-used because of the concern over the effectiveness of the container.

There are exceptions to the PPPA. The most common exceptions seen in retail pharmacy are:

- Sublingual dosage forms of nitroglycerin

- Medrol dose packs

Patients may request that their prescription be dispensed in a non child resistant package. Although the request may be verbal it is recommended that the patient sign a request for the noncompliant container.

State Regulation

Each state also has the right to enact additional laws and regulations to protect the public within their jurisdiction. These state laws are generally more specific or detailed than federal laws. It is important to remember that state laws cannot be more liberal than federal laws; State laws can be and often are more restrictive than federal laws.

State law makers grant authority to Administrative agencies to enact and enforce even more specific laws to professions that involve public health and welfare; in our case, the practice of pharmacy. Boards of pharmacy are established to determine the specific requirements for who can practice pharmacy; requirements for who can be a pharmacy technician; and their standards for conduct.

The Board of Pharmacy established registration requirements for pharmacy technicians in your state and further established the number of continuing education credits required annually to maintain your registration.

Some states allow pharmacy technicians to perform more tasks within a pharmacy if they successfully take and pass the Pharmacy Technician Certification Board Exam (PTCB). Successful completion of this exam shows your pharmacy and the Board of Pharmacy that you have taken additional training to not only improve your knowledge and skills but help insure patient care and safety.

Almost all states prohibit an individual from being a pharmacist or a pharmacy technician if they have been convicted of a crime involving moral turpitude. A crime involving moral turpitude is one that arises from an act that is intentionally evil [law.com]. Shoplifting is an example of a crime involving moral turpitude because it involves an intentional act that is evil (or known to be against the law).

CLASSES OF DRUGS AND REGULATIONS

Drugs fall within two major categories, prescription and over the counter (OTC Drugs). Prescription drugs are those that require use under medical supervision and require a prescription or physician's order. OTC drugs can be purchased without a prescription or order from a physician.

Prescription drugs can be further classified as legend or controlled. Although a prescription is required before either can be dispensed, controlled substances (as the name suggests) are subject to more stringent regulations and control than legend medications.

The Drug Enforcement Administration (DEA) was established in 1973 to serve as

the primary federal agency responsible for enforcement of the Controlled Substances Act (CSA) (21 U.S.C §§ 801-970). Controlled substances are divided into five (5) schedules:

Schedule I Substances: have no currently accepted medical use in treatment in the United States. Example: heroin, ecstasy.

Schedule II Substances: have a high potential for abuse with severe psychological or physical dependence. Examples: methadone, oxycodone and fentanyl.

Schedule III Substances: have a potential for abuse less than substances in Schedules I or II. Examples: Vicodin® and Tylenol with codeine.

Schedule IV Substances: have a lower potential for abuse relative to substances in Schedule III. Examples: alprazolam [Xanax®] and diazepam [Valium®].

Schedule V Substances: have a lower potential for abuse relative to substances listed in Schedule IV. Example: Robitussin AC®.

In addition, each state may place stricter controls on a controlled substance than is required under the Controlled Substances Act. A state may not place more lenient (or lesser) controls on a controlled substance than is required under the Controlled Substances Act.

Controlled Substance Refills

No Schedule III or Schedule IV prescription may be filled or refilled more than six (6) months after the date of the issuance of the prescription or more than five times, whichever comes first. 21. C.F.R. § 1306.22. Each state determines the restrictions on Schedule V medications.

The date of issuance is the date the prescription is written.

Multiple Schedule II Prescriptions

Federal law prohibits the pre-dating or post-dating of prescriptions. To minimize the hardship on patients and physicians that use certain Schedule II medication on a continuing basis, the DEA permits multiple Schedule II prescriptions for the same drug and patient under certain circumstances:

- The total quantity prescribed cannot exceed a 90 day supply
- Practitioner determines there is a legitimate legal purpose
- Practitioner is acting within the usual course of their professional practice
- Practitioner must write instructions on each prescription (other than 1st prescription) as to the earliest date the prescription may be filled
- Multiple prescriptions must not create an undue risk of diversion or abuse
- Must be permissible under state law
- Practitioner must comply with all other provisions of the Controlled Substance Act and state laws.

Prescriptions

A prescription for a controlled substance

may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner or other registered practitioner who is:

- Authorized by their state to prescribe
- Registered with the DEA
- Agent or employee of a hospital or approved institution

The prescription for a controlled substance must be dated and signed on the date when issued and include:

- Patient's full name and address
- Practitioner's full name, address & DEA registration number
- Drug name
- Strength
- Dosage form
- Quantity prescribed
- Directions for use
- Number of refills

The prescription must be written in ink, indelible pencil, or typewritten and signed by the practitioner on the date when issued. The restrictions are to minimize alterations or changes to the prescription.

The prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her profession. For example a dentist would not be acting within the usual course of his/her profession if they issued a prescription for a pain medication for lower back pain.

DEA Registration Numbers

Prescribers will be assigned a registration number by the Drug Enforcement Administration (DEA). A DEA registration number is a nine-character number consisting of two (2) letters followed by seven (7) digits. Initially, registration numbers began with the letter "A". After all registration numbers starting with the letter "A" were exhausted, the DEA began using the letter "B". During 2008 all registration numbers beginning with the letter "B" were exhausted and the DEA began using the letter "F".

The second alphabet letter is usually the first letter of the registrant's last name. Registration numbers for mid-level practitioners begin with the alphabet letter "M" and distributor registration numbers begin with the alphabet letter "R".

Keep in mind that each individual state specifies which prescribers may prescribe controlled substances.

Counseling & Patient Confidentiality

OBRA 90

The law that requires a patient be offered counseling is **OBRA 90**, Omnibus Budget Reconciliation Act. Although OBRA 90 is a Federal law, individual Boards of Pharmacy actually oversees compliance with OBRA. Most pharmacies have guidelines established to ensure compliance.

OBRA 90 requires **Drug Use Review (DUR)**. Under OBRA 90 there are three (3) parts of the DUR provisions that deal

primarily with health care outcomes and they are:

1. Retrospective review
2. Educational programs
3. Prospective review

It is the “**prospective review**” that is seen in the pharmacy setting on a daily basis. The prospective review also has three (3) main components and they are:

1. A screen of prescriptions before dispensing
2. Patient counseling by the pharmacist
3. Pharmacist documentation of relevant information

It is important that each pharmacy technician work closely with their pharmacist(s) to understand federal requirements and their state requirements in dealing with the prospective review. Many states actually allow the pharmacy technician to make the offer to counsel to the patient. If the offer is accepted by the patient, the pharmacist or approved pharmacy intern will be the individual responsible for counseling. It is important to note that the patient may refuse counseling.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 [HIPAA]

deals with several issues including a patients’ confidential personal and medical information.

Under HIPAA the protected information is called **protected health information** or PHI and it includes all forms of health information that:

1. Relates to past, present or future physical or mental health; the provision of care or payment for care; and
2. Identifies the patient or could reasonably be expected to identify the patient.

Prescriptions and all related information of a patient is covered under protected health information.

Conclusion

The information provided is intended to introduce you to the legal system dealing with pharmacy and its primary purpose of protecting the public. Due to the large number of laws and regulations that govern the practice of pharmacy, it would be impossible to address each in this outline. I do want to provide you with several reference sites that have manuals available for download that will assist you as a pharmacy technician in your day-to-day practice.

Remember that as a pharmacy technician, you are a tremendous asset to the practice of pharmacy and the public whom we each serve. Thank you.

Reference Material for the Pharmacy Technician:

1. DEA [Drug Enforcement Administration]: <http://www.usdoj.gov/dea/index.htm>
 - i. Pharmacist’s Manual
 - ii. Prescriber’s Manual
2. FDA [Food and Drug Administration]: <http://www.fda.gov/>
 - i. FDCA
 - ii. Resource Links
3. NABP [National Association of Boards of Pharmacy]: <http://www.nabp.net/>
 - i. Listing for Boards of Pharmacy
 - ii. Listings for Schools of Pharmacy
 - iii. Resource links
4. PTCB [Pharmacy Technician Certification Board]: <https://www.ptcb.org>
 - i. Testing information
 - ii. Resources

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Continuing Education Quiz

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An Introduction for the Pharmacy Technician

- The practice of pharmacy is highly regulated to ensure:
 - Patient compliance
 - Patients receive counseling
 - Protection of the public
 - Lower medication costs
- Pharmacy laws can be generally classified as:
 - Federal, state and administrative
 - Federal and state
 - Criminal and civil
 - Administrative
- Federal pharmacy laws apply to which of the following:
 - Federal medical facilities and military bases
 - Uniformly to all states
 - Medicaid
 - Medicare
- An individual is prohibited from being a pharmacy technician if they have been convicted of a crime involving moral turpitude. Which of the following offenses is an example of a crime involving moral turpitude?
 - Shoplifting
 - Parking meter violation
 - Failing to recycle aluminum cans
 - All of the above
- Which of the following is an example of an Administrative agency granted special powers by the state legislature:
 - PTA – Parent Teachers Association
 - Board of Pharmacy
 - American Red Cross
 - American Cancer Association
- Which law or act provides that drugs cannot be marketed until they are proven safe and effective for use?
 - FDCA – Food Drug and Cosmetic Act
 - Federal Drug Act
 - State Drug Act
 - Constitution
- States can make laws dealing with the practice of pharmacy that are more restrictive than federal law.
 - True
 - False
- Which agency establishes registration requirements for pharmacy technicians?
 - FDA – Food and Drug Administration
 - PTCB – Pharmacy Technician Certification Board
 - NABP – National Association of Boards of Pharmacy
 - State Boards of Pharmacy
- The Drug Enforcement Administration is responsible for enforcement of the Controlled Substances Act.
 - True
 - False
- The Controlled Substances Act divides controlled substances into how many schedules:
 - Two
 - Three
 - Four
 - Five
- Schedule II drugs have no currently accepted medical use in treatment in the United States.
 - True
 - False
- Which law or act deals with a patient's confidential personal and medical information?
 - FDCA
 - OBRA 90
 - CSA
 - HIPAA
- A physician can legally write a prescription for a Schedule I drug.
 - True
 - False
- Alprazolam is an example of a Schedule ____ drug under the Controlled Substances Act?
 - Schedule I
 - Schedule II
 - Schedule III
 - Schedule IV
- Under the Controlled Substances Act a veterinarian is not an authorized practitioner allowed to write for controlled substances.
 - True
 - False
- A pharmacy technician is allowed to make the offer to counsel to a patient under OBRA 90.
 - True
 - False
- Prescriptions are not considered to be protected health information under HIPAA.
 - True
 - False
- A prescription for a controlled substance in Schedule III expires ____ months from the date of issue:
 - 6 months
 - 12 months
 - 90 days
 - Does not expire
- The DEA allows for multiple Schedule II prescriptions to be written as long as the quantity does not exceed:
 - 90 tablets
 - 180 tablets
 - 180 day supply
 - 90 day supply
- The PPPA does not allow a patient to request their medication be dispensed in non compliant containers.
 - True
 - False
- The administrative agency responsible for establishing the professional responsibility of pharmacy technicians is known as:
 - DEA
 - Board of Pharmacy
 - Medical Association
 - None of the above
- A Board of Pharmacy may suspend the registration of a pharmacy technician for which of the following:
 - Crime involving moral turpitude
 - Theft of controlled substances
 - Shop lifting
 - All of the above
- A prescriber DEA Registration Number consists of 2 alphabet characters followed by 9 digits.
 - True
 - False
- The PPPA requires that a child resistant container comply with which of the following:
 - 80% of adults can open the container
 - 90 % of adults can open the container
 - 100 % of children cannot open the container
 - 95% of children cannot open the container