# Pharmacy Laws

AN APOTHECARY was a person (or a store) that prepared and dispensed medicines and drugs, along with medical advice to customers. Before the 20th century, medicines did not have to prove they were safe or effective to be marketed. Most drugs were still created by hand in a local pharmacy. Today, pharmacy laws protect the health and safety of patients and customers. In addition, pharmacists are able to assure consumers of the efficacy and safety of medicinal products.


## Objective:

Summarize the laws that affect pharmacy practice.

## Key Terms:

adulterated
child-resistant packaging
controlled substance
Controlled Substances Act (CSA)
Drug Enforcement Agency (DEA)
drug utilization review (DUR)
Food and Drug Administration (FDA)
HIPAA
investigational new drug application (INDA)
legend
National Formulary (NF)
new drug application (NDA)
non-legend
orphan drug
over-the-counter (OTC)
sublingual
U.S. Pharmacopoeia (USP)

## Understanding Pharmacy Laws

The laws in terms of regulating medicine and the pharmaceutical industry have changed quite a bit in the past 100 years.

## HISTORY OF PHARMACY LAW

Pharmacy law impacts the way manufacturers package pills (and other pharmaceutical items), the manner in which labs create drugs, the way prescriptions are handled, and more.

### *USP–NF*

Before the 20th century, there was no direct federal regulation of drugs or other consumer products in the United States. Medicines did not have to prove to be safe or effective to be marketed. Most drugs were still created by hand in a local pharmacy. Efforts to create uniformity in drugs began in 1820 with the creation of the **U.S. Pharmacopoeia (USP)**—a private, voluntary undertaking of physicians and pharmacists who compiled detailed information about substances typically kept by pharmacists. They regularly revised the USP as new and better drugs were discovered and created.

In 1888, pharmacists compiled the **National Formulary (NF)**, which was a book of standards for chemical and biological drug substances, dosage forms, compounded preparations, medical devices, and dietary supplements. To fight abuse in drug formulation, labeling, and marketing claims, the United States Congress passed a series of 20th century laws to regulate the development, compounding, distribution, storage, and dispensing of drugs.

### *Pure Food and Drug Act of 1906*

The Pure Food and Drug Act of 1906 prohibits the interstate transportation or sale of adulterated foods and drugs. **Adulterated** is substandard, or failed, in terms of conforming to quality, strength, or purity. The act also addressed misbranded foods and drugs and prohibited labels from containing false information about a drug's strength and purity.

### *Food, Drug, and Cosmetic Act of 1938*

One of the most important pieces of legislation in pharmaceutical history is the Food, Drug, and Cosmetic Act of 1938. The act created the **Food and Drug Administration (FDA)**, which is the federal agency responsible for monitoring safety standards in the food and drug industries. The act requires that drug manufacturers file a **new drug application (NDA)**—information about the composition and manufacture of the drug and test results of safety—with the FDA before the drug can be marketed. Manufacturers must prove that the drug is safe for use by humans. Under this act, the FDA has the power to approve or deny any new drug. Also, the act details labeling requirements for foods and drugs.

### *Durham-Humphrey Act of 1951*

The Durham-Humphrey Act of 1951 requires all products to have adequate directions for use, unless they contain the federal legend: "Caution: Federal law prohibits dispensing without a prescription." Also, the act authorizes the taking of prescriptions verbally, rather than in writing, and the refilling of prescriptions over the telephone. This act separates drugs into two cat-

egories: legend and non-legend. **Legend** are drugs that require a prescription. **Non-legend** are drugs that do not require a prescription.


**FIGURE 1. Durham-Humphrey separates drugs into two categories: legend (drugs that require a prescription) and non-legend (drugs that do not require a prescription). How would you classify an over-the-counter drug?**

### *Comprehensive Drug Abuse Prevention and Control Act of 1970*

The Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly known as the **Controlled Substances Act (CSA)**, is the federal law enacted to combat and control drug abuse. The act classifies drugs with potential for abuse as a **controlled substance** (a drug with a risk for abuse) and places each into one of five categories or schedules based on potential for abuse and accepted medical use. Schedule I drugs are the most dangerous, and Schedule V drugs are the least dangerous. The **Drug Enforcement Agency (DEA)** is the organization responsible for enforcement and prevention related to the abuse of controlled substances.


**FIGURE 2. The Controlled Substance Act combined more than 200 drug laws into one comprehensive law that regulates the manufacture and distribution of controlled substances in an effort to reduce drug abuse.**

### *Kefauver-Harris Amendment of 1972*

The Kefauver-Harris Amendment of 1972 requires drug manufacturers to file an **investigational new drug application (INDA)**, which is an exemption from the FDA to ship or transport the drug to clinical investigators in many states with the intent of proving that the new drug is safe and effective for humans. The INDA is an exemption submitted to the FDA to allow the drug to cross state lines for the purpose of conducting those investigations.

## POISON PREVENTION PACKAGING ACT

To prevent accidental poisoning in children, the Poison Prevention Packaging Act (PPPA) was signed into law in 1970 by President Richard Nixon. The purpose of the act is to protect children under the age of five from poisonings and death that occur when they open containers of hazardous products and eat or drink the contents.

### Over-the-Counter (OTC) Drugs

The act requires that most **over-the-counter (OTC)**—medicines sold directly to the consumer without a prescription—and legend drugs be packaged in child-resistant containers. **Child-resistant packaging** is a container that cannot be opened by 80 percent of children younger than five, but it can be opened by 90 percent of adults.


**FIGURE 3. Special packaging is used to reduce the risk of children ingesting dangerous substances. This is often accomplished with the use of a special safety cap.**

### Accessibility Exceptions

There are some exceptions to the child-resistant packaging specifications because of concerns about accessibility of medication to the elderly and handicapped. A patient may request that his or her medication be dispensed in a non-child-resistant container.

Manufacturers may package any OTC substances in non-child-resistant containers if the packages contain one of these warnings: "This Package for Households Without Young Children" or "Package Not Child Resistant." Examples of medications that do not require child-resistant containers are:

- Oral contraceptives taken cyclically in the manufacturer's dispensing package
- **Sublingual** (below the tongue) nitroglycerine tablets
- Inhalation aerosols
- Hormone replacement therapy
- Powdered unflavored aspirin
- Single time dispensing of product as ordered by prescriber

## LAWS THAT AFFECT PHARMACY PRACTICE

To abide by the law, it is critical to be knowledgeable of relevant laws.

### Orphan Drug Act of 1983

An **orphan drug** is a medication for treatment of diseases or conditions of which there are fewer than 200,000 cases in the United States. Because medical research and development of drugs to treat these diseases is financially difficult, pharmaceutical companies fail to do much

research to develop treatments. To encourage companies to pursue treatment for these diseases, the federal government passed the Orphan Drug Act of 1983. The act provides tax incentives and exclusive licensing of products for manufacturers to develop and market orphan drugs.

## *Omnibus Budget Reconciliation Act of 1987*

The Omnibus Budget Reconciliation Act of 1987 is also known as the Federal Nursing Home Reform Act. It was enacted to protect the rights of patients in long-term care facilities (e.g., nursing homes, skilled nursing facilities, and assisted living homes). Prior to passage of the act, many treatment practices were considered unethical by today's standards. The act places emphasis on a resident's quality of life as well as quality of care.

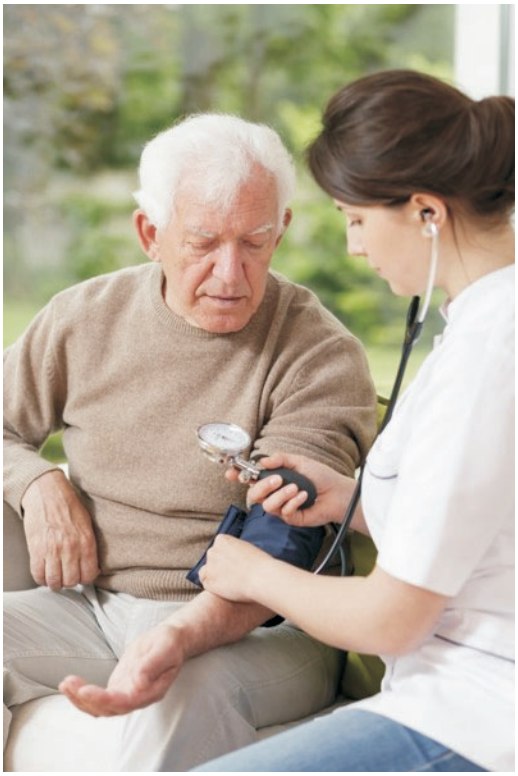

**FIGURE 4. In 1986, the Institute of Medicine conducted a study that found that residents of nursing homes were being abused. The basic objective of the Omnibus Budget Reconciliation Act of 1987 is to ensure that residents of long-term care facilities receive quality care.**

## *Omnibus Budget Reconciliation Act of 1990*

The Omnibus Budget Reconciliation Act of 1990 placed expectations on the pharmacist about how to interact with the patient/customer. The act requires that states establish standards of practice for drug utilization review. A **drug utilization review (DUR)** is an authorized, structured, ongoing review of healthcare providers prescribing, pharmacists dispensing, and patients using medication.

The act requires a review of drug therapy before each prescription is filled or delivered to an individual. Under the law, a pharmacist or technician must make an offer to counsel the patient or customer. If the customer refuses the offer, it must be documented.

## *Health Insurance Portability and Accountability Act (HIPAA) of 1996*

**HIPAA** is the first comprehensive federal regulation designed to safeguard the privacy of protected health information, improve portability and continuity of coverage, combat waste and fraud, and simplify the administration of health insurance.

Title I protects health insurance coverage for workers and their families when they change or lose their jobs. This allows for the portability of moving health insurance from one employer to another without denial or restrictions. Title I requires the coverage and limits restrictions that group health plans can place on benefits for preexisting conditions.

# FURTHER EXPLORATION...

## ONLINE CONNECTION: Compassionate Care Act

The Compassionate Care Act allows healthcare providers to recommend the medical use of marijuana—under carefully controlled circumstances—to patients who are suffering from serious illnesses or debilitating conditions. Visit the following website to read "Medical Marijuana in Illinois—Compassionate Care Act" at http://www.barringtonleads.org/medical-marijuana/. Then participate in a class discussion about the pros and cons of the use of medical marijuana.


**Some of the beneficial uses of medical marijuana are illustrated here.**

Title II defines policies, procedures, and guidelines for maintaining the privacy and security of health information as well as outlining the penalties for violations. The act created several programs to control fraud and abuse within the healthcare system. Title II also created rules aimed at increasing the efficiency of the healthcare system by creating standards for the use and distribution of healthcare information.


**FIGURE 5. An individual's health insurance information is protected by the privacy guidelines set forth in HIPAA. The law sets rules and limits about who can look at and receive your health information.**

## Summary:

For more than 70 years, the practice of pharmacy has been impacted by federal legislation. The purpose of this legislation has been to protect the health, safety, and welfare of patients. Many of the laws that have been enacted are in response to issues and concerns at a certain point in time. Laws such as the Food, Drug, and Cosmetic Act and the Durham-Humphrey Act have improved public safety by requiring drugs to have accurate labeling and ensuring their safety and efficacy. The CSA classifies drugs into categories based on medical use and the potential for abuse to combat and control drug abuse. HIPAA ensures that all of our healthcare information remains confidential and that health insurance coverage is available without restrictions or denials for employees.

## Checking Your Knowledge:

1. Explain the Food, Drug, and Cosmetic Act of 1970 and the agency created under it.
2. Describe how the Controlled Substance Act is used to combat drug abuse.
3. Explain the Poison Prevention Packaging Act. List six examples of substances exempted from the act.
4. Explain the importance of the orphan drug program.
5. Explain the ways HIPAA protects the privacy of health consumers.

## Expanding Your Knowledge:

Schedule a time to interview a local representative from the state board of pharmacy organization about past, present, and future state legislation being considered that impacts the practice of pharmacy. Make sure you do research and prepare questions prior to the interview.

## Web Links:

**Loss of Controlled Substances**
http://www.uspharmacist.com/article/dea-form-106-and-loss-of-controlled-substances

**Safe and Effective Drugs**
http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100years/

**Rights Under HIPAA**
http://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html