

# Law and Ethics: What the Pharmacy Professional Should Know

3 Contact Hours

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**Author Disclosure:** Katie Ingersoll and Elite do not have any actual or potential conflicts of interest in relation to this lesson.

**Universal Activity Number (UAN):** 0761-9999-18-002-H03-P

**Activity Type:** Knowledge-based

**Initial Release Date:** January 11, 2018

**Expiration Date:** January 11, 2020

**Target Audience:** Pharmacists in a community-based setting.

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## Learning objectives

- Discuss the federal pharmacy laws that govern pharmacy practice.
- Describe the Comprehensive Drug Abuse, Prevention, and Control Act of 1970 and its impact on the dispensing of controlled substances.
- Discuss the ethical principles that apply to pharmacy practice.
- Discuss the code of ethics for pharmacists.

## Overview of federal pharmacy laws<sup>4,5,6</sup>

Many federal and state laws govern the practice of pharmacy, and these laws are constantly changing. It is important for pharmacy professionals to familiarize themselves with both the federal and state regulations governing their daily responsibilities in the pharmacy, and keep up to date on new laws as well as amendments to existing laws.

### Pure Food and Drug Act of 1906

This act was enacted in 1906 to address public concerns about improperly labeled and unsanitary food and medications. It prohibited food and medications from being misbranded or adulterated if they are bought and sold across state lines. This was the first act to address the safety risks associated with contaminated and inappropriately labeled food and drug products, but it was not found to be comprehensive enough.

### The Harrison Narcotics Tax Act of 1914

Because of the increasing abuse and trafficking of opium, the International Opium Convention met in 1912 to discuss potential international limitations on its use and transport. In 1914, the U.S. passed its own regulations to regulate opium and narcotic use.

The Harrison Narcotics Tax Act gave authority to the Internal Revenue Service (IRS) to collect tax on opiates, and anyone that produced, dispensed, or sold opiates had to be registered with the IRS. This act also required a prescription for opium to be given to patients as well as

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

This act was created to attempt to correct some of the pitfalls of the Pure Food and Drug Act of 1906. The passing of this act established that the FDA must approve all new medications that are to be sold in the U.S., and that drugs will not be approved until they have been determined to be safe to use.

It also moved cosmetics under the jurisdiction of the FDA. It established greater authority for the FDA to oversee the safety of drugs, food, and cosmetics, in an effort to improve medication safety and prevent further disasters like the sulfanilamide tragedy. This act allowed medications marketed before 1938 to be exempt from the requirement to prove their safety.

The Food, Drug, and Cosmetic Act also established clear definitions for adulteration and misbranding, and established that these actions are

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Federal laws may be more or less restrictive than state laws; the more stringent law should always be followed. Pharmacy professionals are responsible for knowing the state laws in the states they work in, and are responsible for ensuring laws are followed in the workplace.

Drug safety issues continued, because false or incorrect claims of efficacy were not prohibited, labeling was not regulated, safety was not required to be proven, and the FDA did not have the right to ban unsafe products. This resulted in the sulfanilamide tragedy of 1937, when the toxic solvent diethylene glycol was used to make sulfanilamide elixir, resulting in 107 deaths. This tragedy, as well as other safety issues, prompted a more comprehensive act to be passed in 1938.

requiring providers to be registered to prescribe opium. Prescriptions for and the dispensing of opium had to be documented, and restrictions on the sale, importation, and distribution of opium and narcotic derivatives were implemented.

While the Comprehensive Drug Abuse, Prevention, and Control Act of 1970 largely replaced this act, it was the first of its kind to attempt to regulate and decrease the prevalence of narcotic use and addiction.

illegal. It required medication labels to state adequate directions for using the product as well as warnings if the medication is habit forming to avoid misbranding. In addition, it established that labeling must include the quantities of active ingredients, alcohol content, and name and location of the manufacturer.

Products were considered adulterated if they contained any dirty or decayed substances, were manufactured in an unsanitary environment, contained any dangerous coloring additives, were prepared in containers created of unsafe materials, or if they did not have consistent purity. This legislation brought vast improvements to the safety of medications sold in the United States.

## The Durham-Humphrey Amendment of 1951

Many medications were unable to establish appropriate directions for use under the Food, Drug, and Cosmetic Act of 1938, because use under the direction of a prescriber was not considered adequate.

The Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act was passed in 1951 to resolve this issue. It established two classes of medications, prescription (legend) drugs that require a prescriber's order to dispense, and over-the-counter (non-legend) drugs that can be purchased without a prescription. After passing this act into

## Kefauver-Harris Amendment of 1962

Another medication tragedy that occurred in the late 1950s prompted the establishment of the Kefauver-Harris Amendment in 1962. The medication thalidomide (Thalomid), a popular sedative, was marketed in Europe, and the manufacturers sought approval for sale in the United States as well. The FDA withheld approval pending further information on the safety of the drug, which turned out to be a great decision when safety information showed it was linked to birth defects.

Pregnant women who had taken thalidomide gave birth to children with short or missing limbs, known as phocomelia, and thousands of children around the world were born with this condition. Because the FDA did not grant approval, the number of children born with phocomelia in the U.S. was low, but this worldwide disaster prompted the government to reconsider the regulations in place to prevent similar tragedies.

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

Commonly known as the Controlled Substance Act, this act was the first to establish regulations on the prescription and dispensing of controlled substances as well as their importation, possession, and use. It was created to prevent drug abuse and dependence as well as to strengthen the authority of law enforcement on drug abuse. It led to the creation of the Drug Enforcement Agency (DEA), which is supervised by the Department of Justice.

### Registration

The Controlled Substance Act established that every facility dispensing controlled substances and every provider prescribing controlled substances must be registered with the DEA. Pharmacies can register by completing DEA form 224, and registration must be renewed every three years. Registration must also be completed for those who wish to distribute or manufacture controlled substances and those who wish to manage a controlled substance treatment program.

### Scheduling

This legislation established five schedules to categorize controlled substances based on their abuse potential and accepted medical use. This system allowed for stricter regulations for potent and heavily abused medications at the top of the list in Schedule I, and decreasing severity of regulations as the schedule level decreases.

The Controlled Substance Act granted the attorney general the power to move medications between schedules, remove a drug from scheduling, and to add a drug to the scheduling system.

Packaging for scheduled products must contain a symbol or notation identifying the schedule each medication is categorized in.

- **Schedule I:** Extremely high abuse potential and no recognized medical use in the U.S. Prescriptions may not be written for these products.
  - Examples of Schedule I controlled substances include:
    - Marijuana.
    - Heroin.
    - Ecstasy.
    - LSD.
    - PCP.
    - Crack cocaine.
    - Methamphetamine.
    - Psilocybin.
    - Rohypnol.

## Ordering controlled substances

Schedule II controlled substances must be ordered by completing the triplicate DEA form 222 in writing. The 222 form has space to order 10 unique items and is valid for 60 days from the date written on the form.

law, prescription medications were allowed to have the prescriber's directions for use on the label if they had the wording "Caution: Federal law prohibits dispensing without a prescription" on the label.

The Durham-Humphrey Amendment allowed for prescriptions to be called in to the pharmacy over the telephone for ease of receipt at the pharmacy. It also established that prescription drugs could be refilled if indicated by the prescriber.

The Kefauver-Harris Amendment established that drugs must be proven to be effective, in addition to being pure and safe, to receive approval from the FDA for sale in the U.S. This was groundbreaking legislation; no laws prior to this had required proof that medications are effective. This act was also retroactively applied to medications approved by the FDA between 1938 and 1962.

In addition, this amendment gave the FDA the authority to oversee prescription medication advertising, transferring this responsibility from the Federal Trade Commission. It also established good manufacturing practices (GMP) for the manufacture of medications to place the responsibility of creating quality drug products on the drug manufacturers. Lastly, it established more control over clinical trials, requiring informed consent of participants in drug trials and adverse event reporting.

- **Schedule II:** These products have a high abuse potential but have an accepted medical use in the U.S. Prescriptions may be written for these products, but they are regulated by not allowing refills, requiring a new prescription for each order.
  - Examples of Schedule II controlled substances include:
    - Oxycodone.
    - Morphine.
    - Amphetamine salts.
    - Methylphenidate.
    - Cocaine.
- **Schedule III:** These drugs have a lesser abuse potential than schedule I and II controlled substances, and have an accepted medical use in the U.S. These medications may be prescribed for up to six months at a time.
  - Examples of Schedule III controlled substances include:
    - Ketamine.
    - Anabolic steroids.
    - Testosterone.
- **Schedule IV:** These medications have a lesser abuse potential than schedule III drugs, though use is still associated with psychological and physical dependence. They have an accepted medical use in the U.S. These medications may be prescribed for up to six months at a time.
  - Examples of Schedule IV controlled substances include:
    - Clonazepam.
    - Alprazolam.
    - Carisoprodol.
    - Diazepam.
    - Lorazepam.
    - Midazolam.
- **Schedule V:** These drugs have a lower abuse potential than Schedule IV drugs, though still have the potential for abuse and dependence. They have an accepted medical use in the U.S. These medications may be prescribed for up to six months at a time.
  - Examples of Schedule V controlled substances include:
    - Cough syrups containing codeine.
    - Anti-diarrheals containing diphenoxylate.
    - Pregabalin.
    - Lacosamide.

The number of lines completed must be noted at the bottom of the form, and a pharmacist who has authority to order Schedule II medications must sign it.

The pharmacy retains the blue copy of the 222 form and sends the green and brown copies to the wholesaler for ordering. The wholesaler then keeps the brown copy after filling the order, and sends the green copy to the DEA.

Once Schedule II medications are received, the pharmacist must verify that the items received match what was ordered. The pharmacist should initial the quantity received and the date it was received on each item's line on the blue copy of the 222 form. The invoice should be kept with the 222 form and stored for at least two years.

## Maintaining DEA records

All DEA records must be maintained for at least two years, or longer, depending on state law. These include inventory records, records of controlled substances received, and records of controlled substances that left the pharmacy's inventory. They must be maintained separately from other records and be easily retrievable. Defective 222 forms

and those completed incorrectly and not used should be kept for at least two years as well. Pharmacy professionals must be aware of the recordkeeping requirements in their state of employment, because they vary significantly from state to state.

## Controlled substance inventories

The Controlled Substance Act also initiated the requirement to conduct inventories of controlled substances on a regular basis. An initial inventory of all controlled substances must be conducted before the start of business on the first day the pharmacy is open. Biennial controlled substance inventories must be conducted thereafter.

packages of less than 1,000 doses. Records of these inventories must be maintained for at least two years.

When completing controlled substance inventories, an exact count must be completed for Schedule II controlled substances, and an estimated count may be done for Schedule III through V medications in

A perpetual inventory system must be used for Schedule II controlled substances. A perpetual inventory system is a method of recording the quantity of a particular medication continuously as prescriptions are filled so the on-hand count is constantly up to date and accurate. All additions and subtractions from the controlled substance inventory should be recorded as they occur to ensure the on-hand count is accurate.

## Returning controlled substances

Returns of controlled substances can only occur between two entities registered with the DEA. A completed DEA 222 form must accompany any transfer of Schedule II controlled substances with records

maintained at both the receiving and transferring pharmacy, and the green copy of the 222 form should be sent to the DEA field office within 60 days of transfer.

## Destroying controlled substances

Any pharmacy that wants to destroy controlled substances that are damaged or outdated must first apply for permission to destroy these items by completing and submitting DEA form 41. This form should include the date of intended destruction, the name, concentration, and quantity of any controlled substances to be destroyed, the method to

be used for destruction, and the names of the witnesses who will be present for the destruction, and must be sent to the DEA at least two weeks before drug destruction. Hospitals may apply for a "blanket authorization" to destroy damaged products and unused portions of injectable controlled substances.

## Controlled substance theft

If a pharmacy discovers controlled substances have been stolen from the pharmacy, the pharmacy must inform the closest DEA diversion office as well as the local police, and complete DEA form 106. This form should include the pharmacy's DEA registration information,

the purchase value of the products, and the name, dose, and quantity of all controlled substances that were stolen. The original copy of this form should be sent to the DEA and a copy should be maintained at the pharmacy along with its controlled substance records.

## Filling prescriptions for controlled substances

The Controlled Substance Act also created regulations for filling controlled substances. Schedule II medications must be ordered on paper prescriptions that are handwritten or printed from a computer, and must be signed in ink by the prescriber. Refills are not allowed on Schedule II medications.

order. Schedule II prescriptions may also be faxed for products that need to be compounded.

If the pharmacy does not have the full quantity of a Schedule II controlled substance on hand, a partial fill can be given if the remaining quantity of medication is made available within 72 hours. If the remaining quantity cannot be supplied to the patient within 72 hours, a new prescription must be obtained from the patient's prescriber.

Schedule III through V medications can be handwritten or computer generated and signed in ink, or transmitted to the pharmacy orally or by fax. The prescription may be refilled up to five times within six months of the written date on the prescription.

Under emergency conditions, an oral prescription may be used for Schedule II medications if the following conditions are met:

Partial fills may be given on Schedule III through V medications as long as the total amount dispensed does not exceed the quantity ordered by the prescriber and no fills are given out more than six months after the written date on the prescription.

- The pharmacist makes every possible effort to identify the prescriber.
- The quantity is limited to that needed to treat the patient during the emergency period.
- The pharmacist must record the oral prescription in writing.
- The prescriber must provide a written prescription for the emergency order to the pharmacy within seven days of dispensing the emergency order.

Certain Schedule V cough syrups and antidiarrheal agents may be purchased without a prescription, depending on state law. The following requirements must be met when dispensing Schedule V drugs without a prescription:

Schedule II prescriptions may be faxed to the pharmacy for patients in long-term care facilities or those who are terminally ill, and the faxed copy may be maintained as the original written prescription. To be accepted as a fax, the prescription must have a notation that the patient is terminally ill or in a long-term care facility.

- Dispensing may only be completed by a pharmacist.
- The person purchasing Schedule V drugs must be at least 18 years old.
- The pharmacy must obtain identification from the purchaser and record in a logbook the name and address of the person purchasing the medication, the date purchased, the name and quantity of the product purchased, the price, and the pharmacist's signature.
- No more than 240 mL or 48 dosage units of opiate-based products and no more than 120 mL or 24 dosage units of other controlled substances may be purchased within 48 hours.

Partial fills can be completed for these prescriptions, as long as the remaining quantity is dispensed within 60 days of the issue date of the

## Transferring prescriptions for controlled substances

The Controlled Substance Act allows prescriptions for Schedule III to V controlled substances to be transferred between pharmacies one time, unless the pharmacies share a real-time online database. If a database is shared between pharmacies, prescriptions may be transferred up to the maximum number of refills given by the prescriber.

The transfer must occur between two licensed pharmacists. The pharmacy transferring the prescription out must write the word VOID on the face of the prescription to invalidate it, and must record on the back of the prescription the name, address, and DEA number of the receiving pharmacy as well as the transfer date and the name of the pharmacist transferring the prescription.

## Poison Prevention Packaging Act of 1970

This act was created to decrease the risk of accidental poisoning in children and prevents hundreds of deaths that were occurring annually from children accidentally ingesting medications and household chemicals.

It requires that most prescription and over-the-counter products be packaged in materials that are resistant to opening by children. Containers are considered by this act to be child-resistant if they cannot be opened by 80 percent of children under 5 but can be opened by 90 percent of adults.

There are some exceptions to the requirement for child-resistant packaging. These include:

- If the patient requests non-child-resistant packaging in a signed statement, a blanket authorization may be given for all of a patient's medications.
- If the prescriber requests non-child-resistant packaging, a blanket authorization may be given for all of a patient's medications.
- Over-the-counter products that contain the warning "This Package for Households Without Young Children" or "Package Not Child Resistant."

## Occupational Safety and Health Act of 1970 (OSHA)

The enactment of this law created the Occupational Safety and Health Administration to ensure employees have the right to a safe and healthy workplace. It allowed for the development of employee health and safety standards and a reporting system for injuries that occur on the job.

It also was created to aid in the reduction of hazardous working environments and allows the Occupational Safety and Health Administration to audit workplaces to ensure they remain in compliance with the law.

## Drug Listing Act of 1972

This act created the requirement of a distinct 11-digit number to identify each medication, known as the National Drug Code (NDC) number. The first five digits of this number comprise the labeler code, used to identify the drug manufacturer. The next four digits are for the product

## Orphan Drug Act of 1983

Orphan drugs are those used to treat conditions that affect fewer than 200,000 people worldwide. Because many drug manufacturers create products based on potential profitability, products for these conditions were not being developed at the same speed as products for more prevalent conditions.

The Orphan Drug Act created the allowance for tax incentives for companies that produce orphan drug products, as well as allowing

## Drug Price Competition and Patent Term Restoration Act of 1984

Also known as the Hatch-Waxman Amendment, this legislation amended the Food, Drug, and Cosmetic Act to help streamline the generic drug approval process to encourage the development of new generic products.

It allowed for drug companies to file an abbreviated new drug application (ANDA) when applying for FDA approval of generic drugs, to allow generic medications to be approved without the generic manufacturers conducting their own clinical trials to prove the medication's efficacy.

The receiving pharmacy must write the word "Transfer" on the face of the prescription, as well as the original date of the prescription, the original number of refills, the original date of dispensing, the number of refills remaining and the dates of previous refills, the prescription number given at the transferring pharmacy, the name, address, and DEA number of the pharmacy sending the prescription, and the name of the pharmacist responsible for transferring the prescription.

Both pharmacies involved in the transfer must keep their copy of the prescription for at least two years from the last refill date.

- Medications that are administered to patients in an institution, if administered by an employee of the facility.
- Specific medications do not require child-resistant packaging, including:
  - Less than 12.6 mg of betamethasone per package.
  - Less than 16 g of erythromycin ethylsuccinate tablets per package.
  - Aerosol sprays for inhalation.
  - Less than 600 mg of mebendazole per package.
  - Less than 85 mg of methylprednisolone tablets per package.
  - Oral contraceptives.
  - Pancrelipase products.
  - Cholestyramine powder.
  - Colestipol power in packets up to 5 g.
  - Less than 105 mg prednisone per package.
  - Less than 264 mg sodium fluoride per package.
  - Chewable or sublingual isosorbide dinitrate in 10 mg doses or less.
  - Nitroglycerin sublingual tablets.

In the pharmacy environment, this act requires the use of material safety data sheets to inform employees of the risks associated with chemicals they come in contact with. It establishes standards for communicating hazardous issues, and addresses contaminants in the air as well as combustible and flammable materials. It requires eye and skin protection when working with hazardous materials, such as when compounding sterile products.

The Occupational Safety and Health Administration also publishes the Guidelines for Cytotoxic (Anti-neoplastic) Drugs. This publication discusses the potential hazards of working with cytotoxic products and provides recommendations to decrease the risk of hazards.

code, used to represent the specific drug product. The last two digits represent the package code, used to identify the package size and type. The product and package codes are developed by the drug company to differentiate their products.

them exclusive licensing rights to their products for seven years after approval by the FDA. Research assistance and grants were also made available to drug manufacturers under this act.

Companies that produce drug products for diseases that affect more than 200,000 people could also qualify for assistance if they can prove that the development costs for creating a new medication could not be recovered by its sales.

This decreased the amount of time necessary for the FDA to approve generic drugs, as well as decreasing costs for manufacturers of generic products, allowing for increased competition among generic drug manufacturers and inevitably decreasing costs to consumers.

It also allows the first company to file an ANDA for the right to exclusively market their generic product for 180 days before other companies may market their generic versions. Lastly, it encouraged the development of new drugs by defining the conditions for patent extensions.

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## Prescription Drug Marketing Act (PDMA) of 1987

This act was created to solidify the supply chain of prescription medications and reinforce the standard route that drug products follow from drug manufacturers to wholesalers to pharmacies. It was developed to prevent counterfeit products from entering the supply chain and to decrease the diversion of prescription products.

It prevents hospitals and medical facilities from reselling medications to outside businesses, and prevents the reimportation of drug products that have been exported unless the original manufacturer reimports them.

This act also bans the distribution of medication samples to anyone other than those licensed to prescribe medications.

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## FDA Modernization Act of 1997

Because of the high burden of the drug approval process, the FDA Modernization Act was created to streamline the FDA's regulatory process to allow for more rapid approval of new drugs.

This act created a mission statement for the FDA to publicly define its responsibilities and required the creation of a compliance plan to reduce the backlog of medications in the approval process. It also created a fast-track approval process for medications for life-threatening conditions, a database of clinical trial information, and gave drug

manufacturers expanded rights in distributing information on unlabeled uses of drugs.

The FDA Modernization Act increased the FDA's oversight of over-the-counter medications and required inactive ingredients to be listed on labels. This act also changed the requirement for the statement "Federal law prohibits the dispensing of this medication without a prescription" to be replaced by the abbreviation "Rx" on the packaging of prescription products.

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## Omnibus Budget Reconciliation Act of 1987 (OBRA-87)

The Omnibus Budget Reconciliation Act of 1987 was an extensive piece of legislation affecting many different government programs. Because of increasing concerns about substandard care for patients in nursing homes, legislation was incorporated into this act to address the quality of health care available for the elderly under Medicare.

The enactment of OBRA required many changes to the Medicare and Medicaid conditions of participation for pharmacies and long-term care institutions that service Medicare and Medicaid patients, reforming nursing home care.

Standards of care for Medicare and Medicaid patients living in nursing homes were established by OBRA-87. It prevents the use of medications that are not necessary to treat a patient's medical condition and establishes requirements for the use of anti-psychotic agents. It

requires that psychiatric medications can only be used to treat patients with a specific documented psychiatric condition. Doses of anti-psychotics must be gradually tapered to ensure the correct dosage is used, and drug holidays and behavioral modifications should be used regularly to assess appropriateness of medication discontinuation.

OBRA-87 also established that residents of long-term care facilities should be free of significant medication errors, and must be provided routine and emergency medications as needed.

Medications must be labeled as required by law, and stored in a locked storage area under recommended storage conditions. Lastly, it established that long-term care facilities must be serviced by a consultant pharmacist to ensure patients are receiving proper medication therapy.

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## Anabolic Steroid Control Act of 1990

This act was created to introduce regulations for anabolic steroids to establish penalties for those who abuse and misuse these products in an attempt to curb abuse and amended the Comprehensive Drug Abuse, Prevention, and Control Act of 1970 to revise the definition of anabolic steroids.

It defines anabolic steroids as any medication chemically related to testosterone. It listed the medications that are to be considered anabolic, and set aside money for education about the harmful effects of anabolic steroids and to help athletes avoid steroid use. The enactment of this legislation moved anabolic steroids to Schedule III, allowing for greater government oversight of these medications.

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## Omnibus Budget Reconciliation Act of 1990 (OBRA-90)

OBRA-90 was a large bill concerned with many aspects of government funding. Only a small portion affected the practice of pharmacy, but that small portion had a significant impact on pharmacy practice. This bill was the first to recognize that the duties of pharmacists include identifying and resolving drug therapy issues, expanding the standards of practice for pharmacy professionals.

This act states that prospective drug utilization evaluations must be conducted before a prescription is filled to ensure safety for every patient, and must include a review of appropriateness of medication, contraindications, potential drug interactions, and accuracy of dosage and treatment duration. It established that drug utilization reviews (DUR) should be completed by pharmacists and are composed of three steps: verification and screening of prescriptions before they are dispensed, patient counseling, and documentation of relevant information. DURs are also required to include computer programs that can create alerts to notify the pharmacist of potential interactions, adverse events, and pertinent safety issues that may affect the patient.

The act also established a DUR board to retrospectively review whether ideal drug therapies are actually used. The DUR board can also recommend educational programs based on problems that it has identified in its retrospective reviews.

It also required that every patient be offered consultation with a pharmacist on their medications at the time of purchase, and that

records must be maintained to track consultations. The act established standards for patient counseling, in which the pharmacist must offer to discuss significant drug therapy points, including:

- Drug name and description.
- Dosage, administration route, and duration of therapy.
- Special precautions or directions for use.
- Common adverse effects, interactions, and contraindications including how they may be avoided and what to do if they occur.
- Directions for self-monitoring medication therapy.
- Medication storage information.
- How and when to refill the medication.
- What to do if a dose is missed.

Pharmacists must rely on their professional judgment to determine what information should be included in counseling. Patients have the right to refuse counseling.

Failure to comply with these regulations may result in the loss of Medicaid funding and reimbursement for services rendered.

OBRA-90 also established a board to develop and review strategies to decrease costs, manage drug purchasing, and improve patient care for Medicaid patients. The act stated that manufacturers must use the lowest pricing for Medicaid patients. This pricing can be accomplished by refunding the state Medicaid agency the difference between the average and lowest price on each product.

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## Dietary Supplement Health and Education Act (DSHEA) of 1994

This act allowed the creation of regulations for herbal products. It requires the labeling of herbal products to list the ingredients and quantities of

each ingredient, as well as the plant and part of the plant used to create the product, and a statement that the product is a dietary supplement.

Herbal products must meet standards for purity, quality, and composition, and production of these products must comply with standards set by any official compendium. Guidelines were created to

require manufacturers of herbal products to follow good manufacturing practices and prevent adulteration of these products.

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

The enactment of HIPAA set out to acknowledge the basic privacy rights of all patients, and to require health care professionals to explain those rights to patients. It ensures the confidentiality of protected health information (PHI), requires the use of only the minimum amount of PHI necessary, and gives patients the right to see who has accessed their PHI. It also requires that all pharmacy staff and any other facility employees who have access to PHI must receive formal training on HIPAA.

HIPAA applies to all covered entities, which include any person or group who provides health care to a patient, bills for health care services, or is paid for health care services. It established the responsibility of health care workers to protect a patient's PHI. Examples of PHI include:

- Name, address, and other demographic information.
- Date of birth.
- Social Security number.
- Payment history.
- Account, license, and record numbers.
- Prescription and medical history.
- Email address.
- Device identifiers, such as an IP address.
- Genetic information.

Written PHI must be handled, stored, and disposed of in a way that protects it against potential unauthorized releases of information. HIPAA-compliant channels must be used to electronically transmit health information, and computerized patient information must be protected through passwords and protection measures for computer systems. PHI communicated orally must also be protected from potential disclosures, and should be discussed at low volumes to prevent potential unauthorized disclosures.

When disclosing PHI, only the minimum necessary amount of information should be given to decrease the amount of PHI available for

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## Drug Addiction Treatment Act (DATA) of 2000

This act was passed in 2000 to broaden the rights of providers prescribing controlled substances for the treatment of opiate addiction. It allows providers to prescribe medications in Schedules III through V to patients who are undergoing detoxification for or maintenance of opiate addiction.

It applies to controlled substances that have been shown to decrease cravings for opiates and prevent symptoms of withdrawal, such as buprenorphine. It does not apply to methadone.

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## Medicare Drug, Improvement, and Modernization Act (MPDIMA) of 2003

This was one of the first acts that set out to modernize aging the Medicare system that was first established in 1965. When Medicare was first founded, the role of prescription drugs in health care was minimal compared to what it is today.

With time, seniors began taking more and more prescription medications to control their chronic and acute disease states, greatly increasing their medical costs to often unaffordable levels. It was clear that a prescription drug benefit was needed to control drug costs for patients enrolled in Medicare.

The Medicare Modernization Act, as it is commonly known, was responsible for adding a prescription drug benefit to the Medicare system that seniors can choose to sign up for, Medicare Part D. This plan allows seniors to enroll in regional or national insurance plans to

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## Isotretinoin Safety and Risk Management Act of 2004

Isotretinoin (Accutane) is a powerful medication used to treat acne that has been linked to major birth defects, spontaneous abortions, and psychiatric side effects, including suicidal thoughts and attempts.

To promote the safe use of isotretinoin, the Isotretinoin Safety and Risk Management Act was passed to enact the following requirements for prescribing and using isotretinoin:

- All pharmacists, patients, and practitioners involved in the use of isotretinoin must be registered.

potential unauthorized disclosures, unless disclosures are made to the patient themselves.

Disclosures to other individuals can be made under special circumstances, such as:

- For use by law enforcement.
- To the Drug Enforcement Administration (DEA) for investigations.
- To the Board of Pharmacy for investigations.
- For adverse event reporting.
- To workers compensation if needed.
- For certain public health reasons.

A written and signed authorization letter stating the proposed use of disclosed information must be obtained from the patient if a patient's information is to be used outside of these permitted disclosures.

HIPAA requires that patients must be given a written notice of a covered entity's privacy practices. The notice should include information about the privacy practices of the pharmacy or health care provider, including how they intend to use or disclose a patient's PHI and how they will protect this information.

HIPAA established several rights for patients and their medical records. These are:

- The right to receive a list of all non-routine disclosures of their PHI within the past six years.
- The right to receive a copy of their medical records.
- The right to request changes to their medical records. An example of this would be if a prescription is filled with the incorrect prescriber on the label.

HIPAA also increases the portability and continuity of health insurance; reduces health insurance fraud, waste, and abuse; and encourages the use of health savings accounts.

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Patients undergoing treatment for opiate addiction with controlled substances must be enrolled in a treatment program that provides support services and counseling. Prescribers who wish to prescribe controlled substances to treat opiate addiction must be enrolled with the DEA and complete a required training course to obtain certification to dispense these products. Prescribers who work in private practice settings can treat a maximum of 30 patients at a time for the first year, after which they may apply to treat a maximum of 100 patients.

lower the cost of their prescription medications. Patients are required to pay monthly premiums as well as deductibles, but have a maximum out-of-pocket expense annually to help reign in drug costs.

This act also decreased the reimbursement rates that Medicare will pay for durable medical equipment and created a nationwide competitive bidding program for these items in 2007. In addition, this act altered the payment system for medications that qualify for coverage under Medicare Part B in the outpatient setting. It also introduced a Medicare-approved voluntary discount card program to low-income Medicare patients, which is available under the Medicare Advantage program. This card allows for additional cost savings for Medicare patients, in an attempt to decrease the costs associated with hospitalizations and unaffordable medication treatment.

- All prescribers and pharmacists must receive education on the risks involved with the use of isotretinoin, including psychiatric adverse events and birth defects.
- Isotretinoin may only be prescribed for severe recalcitrant nodular acne that is not responsive to other treatments, including antibiotics.
- Patients must be educated on a monthly basis to avoid pregnancy. A survey must be completed monthly to re-educate the patient on the potential side effects.

- Patients must receive one-on-one counseling and must sign an informed consent form before beginning therapy.
- Prescriber offices must be certified to prescribe isotretinoin.
- Prescriptions may be filled for a maximum of 30 days supply at a time.
- Female patients must take a pregnancy test monthly and receive a negative result before they may receive additional isotretinoin.

## Combat Methamphetamine Epidemic Act of 2005

Because of the increasing use and production of methamphetamine in the United States, this act was passed in 2005 to attempt to decrease the availability of ingredients used to produce this dangerous substance.

Over-the-counter products such as pseudoephedrine, ephedrine, and phenylpropanolamine are used in the production of methamphetamine, and this act set out to regulate manufacturing of these products and establish sales restrictions and recordkeeping requirements for the sale of these substances.

Any products containing pseudoephedrine, ephedrine, and phenylpropanolamine have a sales limit of 3.6 g per day, and 9 g in a 30-day period. These products must be sold in blister packaging under the supervision of a licensed pharmacist. They must be kept in a locked

## Medicaid Tamper-Resistant Prescription Act

Beginning in 2008, all handwritten prescriptions filled for patients who have Medicaid paying any part of the cost must be written on tamper-resistant paper.

The tamper-resistant paper must contain each of the following qualities:

- Must contain at least one recognized feature to prevent copying of the prescription, such as thermochromatic ink or background ink.
- Must contain at least one recognized feature to prevent the patient from erasing or modifying information written by the prescriber, such as penetrating ink.

## USP <797>

These regulations, developed by the United States Pharmacopeia, were created to decrease the transmission of infections to patients through drug products, improve the quality of sterile products, and to protect pharmacy personnel from exposure to potentially hazardous drug products.

It was the first enforceable guideline for the preparation of sterile products that established quality standards for the procedures used to create products using aseptic technique. It contains many requirements for the preparation of sterile products, including training and quality assurance requirements, and affects any facility that prepares, stores, or dispenses sterile products.

## Pharmacy ethics

Ethics refers to the branch of philosophy that concerns itself with distinguishing between right and wrong based on knowledge and not feelings or opinions.

Medical practice has been governed by ethical principles and codes since medicine was first established in ancient Greece. The Hippocratic principles of “doing good and avoiding evil” have combined to form the foundation of the basic ethical principles governing medical practice<sup>3</sup>. Over the years, several more principles have been added, and these can be applied to the practice of pharmacy for both pharmacists and pharmacy technicians.

- Blood testing must be done regularly during treatment and 30 days after.
- Treatment centers must be evaluated annually to maintain program compliance.
- All adverse reactions associated with isotretinoin must be reported on a quarterly basis, and patient deaths related to isotretinoin must be reported within 15 days of death.

cabinet on the sales floor within view of the cashier, or behind the counter.

A logbook of purchases must be kept for these products, and must include the product name, strength, and quantity sold, the name, address, and signature of the person purchasing the product, and the date and time of the sale. The logbook may be electronic or written; written logbooks must be bound. Photo identification must be shown in order to purchase these products.

Records of pseudoephedrine sales information must be maintained for at least two years. State laws on pseudoephedrine sales may be more restrictive than federal regulations; it is imperative to know the applicable state regulations before selling pseudoephedrine products.

- Must contain at least one recognized feature to prevent counterfeit prescription pads from being used, such as serial numbers on prescriptions or microprinting.

Prescriptions that do not meet the tamper-resistant requirement may be verified by calling the prescriber’s office. Prescribers may fax prescriptions to the pharmacy if they are out of tamper-resistant paper. If the prescriber is not available, the pharmacy may fill the prescription as long as it verifies the prescription with the prescriber’s office within 72 hours.

USP <797> requires training and evaluation for all personnel who are to use aseptic technique for preparing sterile products, assigning responsibility to the personnel involved in compounding. Risk levels for compounding were assigned for compounds to help determine expiration dates and compounding requirements.

It also created regulations to govern the air classification levels in clean rooms, the physical construction of clean rooms, and procedures for gowning before compounding sterile products. Standards were set for cleaning and sanitation of compounding workspaces, as well as for maintenance of automatic compounding devices and environmental monitoring.

From these ethical principles, codes of ethics have been developed for each health care profession, including pharmacists and pharmacy technicians. They are designed to direct pharmacy professionals in their daily practice of pharmacy and publicly state the principles that guide their duties. During their training, pharmacy professionals are taught the codes of ethics that govern their professions, and it is important to keep these codes in mind when working in the pharmacy. While they may not provide an answer to every ethical dilemma, they should be applied in individual situations to help pharmacy professionals determine the most appropriate solution.

## ETHICAL PRINCIPLES

### Autonomy

Autonomy is the ethical term used to describe the right for patients to make decisions for themselves. It allows patients to choose what medical treatments are best for them and allows them to take ownership of their own health care.

After receiving all of the information necessary to make an informed decision, health care choices must be made by patients themselves without coercion. When patients are unable to make an informed decision on their own, such as infants, children, and those with

dementia, their responsible family member or caregiver can make decisions for them.

While it can be difficult at times for health care professionals to respect a patient’s decision, especially if they disagree, it is ultimately the patient’s right to decide whether he or she wants to take a medication or have a procedure done. For example, if a patient who has been given all of the information about the side effects of Celebrex decides he or she does not want to take it, the health care professional must respect the person’s decision.

Health care professionals do have the responsibility to provide patients with all of the information they need to make an informed decision, through counseling or other means, but the decision is ultimately up to patients.

## **Beneficence**

Beneficence describes the ethical principle of acting in the best interest of the patient, or “doing good.” This principle encourages health care providers to help patients achieve the best possible outcomes of their medical treatment, through advocating for them and providing them with information to make informed decisions.

## **Nonmaleficence**

The principle of nonmaleficence describes the concept of “doing no harm.” Avoiding harm for patients has been a central idea of health care for millennia, and continues to play an essential role today. Health care providers must constantly keep this concept in mind when providing care to patients to ensure the actions they are taking to help the patient do not end up causing harm.

There are many ways pharmacy professionals can apply the principle of nonmaleficence when assisting patients. Pharmacists can prevent harm in many ways, such as preventing medication errors by checking for the presence of drug interactions, adverse events, and duplicate therapies. Pharmacy technicians can also take an active role in preventing harm to patients by focusing on medication safety and ensuring prescriptions are filled correctly and accurately, as well as by learning from mistakes and preventing their repetition.

## **Confidentiality**

Protecting the privacy of a patient’s medical condition and health information is the definition of confidentiality. It is crucial to achieving the best outcomes for a patient, because patients may be less likely to share personal information if they feel their confidentiality will be violated, which could prevent the pharmacy team from acting in the best interest of the patient.

Private health information is protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and pharmacists

## **Veracity**

Veracity is the principle of being honest with patients and always telling the truth. Both pharmacists and technicians can take an active role in promoting veracity by conveying honest and truthful information to patients. Building trust with patients is essential to creating a solid relationship between the pharmacy and the patient, and this trust comes with continuously being honest with patients.

Building trust also allows the pharmacy to obtain thorough information from patients on their health care, and helps pharmacists act in the best interest of their patients.

## **Justice**

The concept of justice can be applied to pharmacy practice, and refers to the practice of allocating products and services to patients fairly, regardless of race, gender, religion, or any other external factors.

A common example of the principle of justice applies to patients who are waiting for an organ transplant. These patients are added to a waiting list of patients and are served as fairly as possible based on their condition and organ needs. Patients are ranked based on their need, and those ranked at the top of the list are matched with donors as they

## **Fidelity**

The principle of fidelity refers to the duty to do what a person has promised to another. It requires health care professionals to be faithful to their patients and to always keep the patient’s best interest in mind. Keeping promises

## **Codes of ethics**

Both pharmacists and pharmacy technicians have their own codes of ethics to govern their practice of pharmacy, developed by professional organizations. They are comprised of principles based on the moral

Providing patients with an opportunity to consult with a pharmacist to ensure they are informed on the use of their new medication is an example of beneficence. Pharmacy professionals play an important role in encouraging positive outcomes for the patient, and should bear this principle in mind on a daily basis.

Nonmaleficence and beneficence often go hand in hand, because not harming a patient can also be considered to be acting in the best interest of the patient. However, “doing no harm” does not always mean the pharmacy professional is “doing good.”

For example, a patient with high blood pressure comes to the pharmacy counter asking about the side effects of pseudoephedrine. The pharmacist tells the person it can increase the blood pressure but does not recommend an alternate product. In this scenario, the pharmacist prevented harm by letting the patient know it can further increase their blood pressure, which can be dangerous, but did not act in the best interest of the patient by recommending a safer alternative. These concepts are applicable to both pharmacists and technicians alike.

and technicians must both take an active role in preventing unauthorized disclosures of protected information.

Daily duties must be conducted in a way that prevents health information from reaching unauthorized sources, and the pharmacy’s policies and procedures should reflect the importance of maintaining confidentiality. To maintain a patient’s trust, pharmacy personnel should respect the wishes of the patient on who they want their patient information to be disclosed.

Being completely honest with patients is important, and this principle can be violated in several ways. When critical information is left out of a conversation with a patient, it is considered an omission. Commission occurs when a lie is intentionally told.

While pharmacists may need to use professional judgment when assessing what and how much information to disclose to patients, the principle of veracity should be kept in mind at all times. Technicians should refer any confusing situations to the pharmacist to ensure veracity is maintained.

become available. While not always perfect, this system allows patients to receive life-saving transplants fairly.

All patients have the right to be treated fairly by their medical providers, so in the pharmacy environment, medications should be allocated in a first-come, first-served fashion, unless another fair system has been developed. This will ensure all patients have the same ability to access important medications.

to patients helps to maintain and build the patient-pharmacy relationship, allowing a pharmacy staff to better serve its patients.

obligations of pharmacy professionals to their patients, society, and other health care professionals.

## Code of Ethics for pharmacists<sup>2</sup>

The Code of Ethics for pharmacists is made up of eight principles to guide pharmacists in their practice. They form a foundation for pharmacists' professional behaviors, attitudes, and actions.

These principles, as stated by the American Pharmacists Association, are:

- A pharmacist respects the covenantal relationship between the patient and pharmacist.
- A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.
- A pharmacist respects the autonomy and dignity of each patient.

## Code of Ethics for pharmacy technicians<sup>1</sup>

Similar to the code of ethics for pharmacists, this code was developed to guide pharmacy technicians in their professional lives. The pharmacy technician's code is comprised of 10 principles adopted by the American Association of Pharmacy Technicians.

In summary, technicians should:

- Use their knowledge to ensure the patient's safety and health.
- Endorse and support veracity and integrity.
- Assist pharmacists in distributing resources in a safe, effective, and cost-efficient manner.
- Respect the ability of pharmacists and other health professionals.
- Continuously improve their pharmacy expertise and knowledge.

## Ethical dilemmas

Ethical dilemmas are complex situations involving a conflict between morals. They have no right or wrong answer, and are often confusing, frustrating situations that require careful consideration to resolve. Many situations involve both ethical and legal considerations, and can be difficult to resolve without guidance.

Identifying the problem is the first step towards finding a solution. The situation should then be assessed completely, and as much information as possible should be gathered to help with the decision-making process. Ethical principles can then be considered to help develop a final decision.

**An ethical dilemma example:** *You are working in a busy retail pharmacy with your friend, Stacy. One day after dinner, you stop by Stacy's house to drop off her lab coat that she forgot in your car. When you use the bathroom at her house, you notice a stock bottle of diazepam on a shelf by the mirror, without a prescription label on it. You remember that there was a missing bottle of diazepam at work two*

## References

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- A pharmacist acts with honesty and integrity in professional relationships.
- A pharmacist maintains professional competence.
- A pharmacist respects the values and abilities of colleagues and other health professionals.
- A pharmacist serves individual, community, and societal needs.
- A pharmacist seeks justice in the distribution of health resources.

A detailed explanation of each principle can be found at <http://www.pharmacist.com/code-ethics>.

- Respect patient dignity, privacy, and individuality.
- Respect the privacy of patient medical records and disclose information only when authorized.
- Refrain from promoting and distributing products of subpar quality or that do not meet standards required by law.
- Refrain from taking part in activities that may disgrace the profession of pharmacy.
- Take an active role in professional pharmacy organizations.

The complete code of ethics for pharmacy technicians can be found at <http://www.nationaltechexam.org/pdf/code-of-ethics.pdf>.

*weeks ago, but no one found it, and it was assumed to be a mistake on the wholesaler's part.*

*Stacy asks you not to tell anyone at the pharmacy; she is your best friend and you do not want her to get in trouble. She says that she accidentally took the bottle when she was packing up her things to leave at the end of her shift today, and that she will take it back to the pharmacy on her next shift. What should you do?*

In the above example, there is a conflict between the fidelity you feel towards your friend Stacy, and concept of justice. It seems as though Stacy may have intentionally stole the diazepam, a crime for which there are consequences, and lied about it. Removing this medication from the pharmacy's shelf is not only a crime, but it unfairly removed this medication from those available to patients in need.

While there may not be a clear right or wrong answer, using ethical principles and seeking advice when appropriate will help to resolve ethical dilemmas.

## LAW AND ETHICS: WHAT THE PHARMACY PROFESSIONAL SHOULD KNOW

### Final Examination Questions

Choose the best answer for questions 1 through 10 and mark your answers online at [Pharmacy.EliteCME.com](http://Pharmacy.EliteCME.com)

- Which of the following pieces of legislation established two classes of medications, prescription (legend) drugs that require a prescriber's order to dispense, and over-the-counter (non-legend) drugs that can be purchased without a prescription?
  - The Harrison Narcotics Tax Act.
  - The Food, Drug, and Cosmetic Act.
  - The Durham-Humphrey Amendment.
  - Kefauver-Harris Amendment.
- According to the Comprehensive Drug Abuse, Prevention, and Control Act of 1970, if the pharmacy does not have the full quantity of a Schedule II controlled substance on hand, a partial fill can be given if the remaining quantity of medication is made available within \_\_\_\_\_ hours.
  - 24.
  - 48.
  - 72.
  - 96.
- \_\_\_\_\_ created the requirement of a distinct 11-digit number to identify each medication, known as the National Drug Code (NDC) number.
  - Orphan Drug Act.
  - Occupational Safety and Health Act.
  - The Food, Drug, and Cosmetic Act.
  - The Drug Listing Act.
- Standards of care for Medicare and Medicaid patients living in nursing homes were established by the \_\_\_\_\_.
  - FDA Modernization Act.
  - Omnibus Budget Reconciliation Act of 1987.
  - Omnibus Budget Reconciliation Act of 1990.
  - Health Insurance Portability and Accountability Act.
- The Omnibus Budget Reconciliation Act of 1990 was the first to recognize that the duties of pharmacists include \_\_\_\_\_.
  - Ordering medications.
  - Verifying the accuracy of prescriptions.
  - Identifying and resolving drug therapy issues.
  - Preventing medication theft.
- \_\_\_\_\_ is the ethical term used to describe the right for patients to make decisions for themselves.
  - Autonomy.
  - Beneficence.
  - Fidelity.
  - Confidentiality.
- The principle of \_\_\_\_\_ describes the concept of "doing no harm."
  - Nonmaleficence.
  - Beneficence.
  - Autonomy.
  - Fidelity.
- Protecting the privacy of a patient's medical condition and health information is the definition of \_\_\_\_\_.
  - Autonomy.
  - Veracity.
  - Fidelity.
  - Confidentiality.
- \_\_\_\_\_ refers to the practice of allocating products and services to patients fairly.
  - Autonomy.
  - Fidelity.
  - Justice.
  - Confidentiality.
- The principle of fidelity refers to \_\_\_\_\_.
  - Allocating products and services to patients fairly.
  - The duty to do what a person has promised to another.
  - "Doing no harm."
  - Acting in the best interest of the patient.