

Controlled Substance Act

THE CONTROLLED SUBSTANCE ACT (CSA) of 1970 was created to combat and control drug abuse. The CSA combined all prior federal laws into one single law that was easier to enforce. The agency responsible for enforcing the law is the Drug Enforcement Agency (DEA). The act classifies drugs with the potential for abuse into five categories or schedules. The act has improved public safety by classifying drugs into categories and ensuring their safety and efficacy.



Objective:



Explain the Controlled Substance Act.

Key Terms:



abuse	dependency	inventory
biennial	dispense	narcotics
controlled substance	disposition	physical
Controlled Substance Act (CSA)	Drug Enforcement Administration (DEA)	psychological
		schedule

Understanding Controlled Substances

Throughout its history, the United States has made many attempts to outlaw addictive drugs and enact laws to protect consumers. The Food and Drug Act of 1906 was the start of more than 200 laws concerning public health and consumer protections. These laws were hard to track and did not effectively meet the country's drug problem. In 1970, President Richard Nixon signed The Comprehensive Drug Abuse Prevention and Control Act of 1970 into law. It is commonly referred to as the Controlled Substance Act (CSA).

EXPLAIN THE CONTROLLED SUBSTANCE ACT

The **Controlled Substance Act (CSA)** is the federal statute under which the manufacture, importation, possession, uses, and distribution of certain substances is regulated. The CSA combined all prior existing federal laws into a single new statute. The CSA categorizes drugs based on their potential for abuse as well as the benefits they provide from a medical standpoint. The act classifies drugs with a potential for abuse as a controlled substance.



FIGURE 1. The Controlled Substance Act is the federal statute that regulates the manufacture, importation, possession, uses, and distribution of certain substances in the United States.

A **controlled substance** is a drug with a risk for abuse and physical or psychological dependence. **Physical** is the dependence related to the body. **Psychological** is the dependence related to the mental and emotional state of a person. The controlled substances are ranked into five categories or schedules. The schedules list the drugs the government considers to be controlled—available only by prescription—with the most dangerous in schedule I and the least dangerous in schedule V. The act consists of two subchapters.

- ◆ Subchapter I defines Schedules I through V; lists chemicals used in the manufacture of controlled substances; and differentiates the lawful and unlawful manufacture, distribution, and possession of controlled substances. This subchapter also specifies the fines and duration of prison terms for violations.
- ◆ Subchapter II describes the laws for exporting and importing controlled substances. This subchapter specifies the fines and duration of prison terms for violations.

The Drug Enforcement Administration (DEA) Role

The **Drug Enforcement Administration (DEA)** is the federal agency responsible for enforcing laws and regulations governing narcotics and controlled substances. **Narcotics** are drugs or other substances affecting mood or behavior that are sold for nonmedical purposes. The DEA was established in 1973 and is responsible for enforcement and prevention related to the abuse of controlled substances. The DEA may initiate proceedings to change a drug's schedule or to add or erase any drug from a certain schedule. The CSA law requires every entity that manufactures, distributes, imports, and exports any drug to register with the DEA.

The DEA works with state and local law enforcement to help stop drug trafficking and gang-related drug violence. Possession or distribution of controlled substances is considered a crime under federal and state laws that can result in criminal prosecution. The manufacturing of illegal controlled substances can result in criminal prosecution.

SUMMARIZE THE CSA DRUG SCHEDULES

The Controlled Substance Act created five schedules with varying qualifications for substance inclusion. The DEA determines which substances are added to or removed from the various schedules. By placing all controlled substances into schedules, it makes it easier to enact criminal statutes by referring to the schedule rather than having to list all substances. It makes it easier for drugs to be added and removed from a schedule rather than having to change an entire drug law.

A **schedule** is a categorical list of controlled substances/drugs based on acceptable medical use and the drug's abuse or dependency potential. Drugs, substances, and certain chemicals used to make drugs are classified into five schedules, depending upon the drug's acceptable medical use and the drug's **abuse** (improper use of) or dependency potential. **Dependency** is the body's physical need for something (e.g., caffeine). The abuse rate is a determinate factor in the scheduling of a drug. Schedule I drugs are considered most dangerous with a high potential for abuse, whereas Schedule V drugs are considered least dangerous with the least potential for abuse.

Schedule I

Schedule I drugs, substances, or chemicals are drugs or substances with no currently accepted medical use in the United States. The drug or substance has a high potential for abuse, with potentially severe psychological or physical dependence. There is a lack of accepted safety for use of the drug or other substance under medical supervision. No prescriptions may be written for Schedule I substances, and such substances are subject to production quotas by the DEA. Schedule I substances include heroin, crack cocaine, LSD, PCP, and opium.

Schedule II

Schedule II drugs, substances, or chemicals are drugs or substances that have currently accepted medical use in the United States or currently accepted medical use with severe restrictions. The drug or substance has a high potential for abuse, with use potentially lead-



FIGURE 2. Schedule I and Schedule II drugs have few accepted medical uses.



FURTHER EXPLORATION...

ONLINE CONNECTION: Just Think Twice

The DEA recognizes that reducing the desire for controlled substances is vital to solving the issue of drug abuse in our country. One of the initiatives to help reduce drug abuse is the DEA's teen website "Just Think Twice" at <https://www.justthinktwice.com/>. The site includes true stories of teens that had drug problems. Visit the website, and click on true stories. Select one of the stories to read. When you are finished, read the additional information about the drug featured in the article.



A drug's potential for abuse (improper use of) or dependency (the body's physical need for) is a determining factor in the drug's placement as a controlled substance.

ing to severe psychological or physical dependence. These drugs or substances are considered dangerous. Schedule II drugs may not be dispensed without the written prescription of a practitioner. Schedule II substances include Fentanyl, morphine, hydrocodone, oxycodone, and amphetamines.

Schedule III

Schedule III drugs, substances, or chemicals are drugs or substances that have currently accepted medical use in the United States. The drug or substance has a moderate to low potential for physical dependence or a high potential for psychological dependence. Schedule III drugs may not be dispensed without the written or oral prescription of a practitioner. Schedule III drugs include Barbiturates, codeine, anabolic steroids, and hormones.

Schedule IV

Schedule IV drugs, substances, or chemicals are drugs or substances that have currently accepted medical use in the United States. The drug or substance may lead to limited physical or psychological dependence. Schedule IV drugs may not be dispensed without the written or oral prescription of a practitioner. Schedule IV drugs include Benzodiazepines, phenobarbital, Ambien®, and Xanax®.

Schedule V

Schedule V drugs, substances, or chemicals are drugs or substances that have currently accepted medical use in the United States. The drug or substance may lead to limited physical or psychological dependence. Schedule V drugs may not be dispensed without the written or

oral prescription of a practitioner. Schedule V drugs include cough suppressants with small amounts of codeine, anticonvulsants, antidiarrheals, and appetite suppressants

INVENTORY, REFILL, AND DISPENSE PROTOCOLS

Every pharmacy must maintain complete, accurate, and current records for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process, through the dispensing pharmacy, to the consumer.

Inventory

An **inventory** is a complete and accurate list of all stocks and forms of controlled substances. An actual physical count is required for schedule II substances, and an estimated count or measure of the contents of schedule III, IV, and V controlled substances is required. The CSA mandates that all inventory records be maintained at the location in a readily retrievable manner for at least two years from the date the inventory was conducted. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances. Every inventory must include:

- ◆ The date the inventory was conducted
- ◆ Timeframe the inventory was taken (at beginning or at the close of business)
- ◆ Name of each controlled substance inventoried
- ◆ Finished form of each substance (e.g., 10mg *tablet*).
- ◆ Number of dosage units of each finish form in the commercial container (e.g., 100-tablet *bottle*)
- ◆ Number of commercial containers of each finished form (e.g., *four 100-tablet bottles*)
- ◆ **Disposition** (disposal) of the controlled substances.

Following the initial inventory, the pharmacy is required to take a **biennial** (every two years) inventory that requires the same information as the initial inventory.

Refills

Controlled substance prescriptions have greater requirements at federal and state levels than other prescriptions. Schedule II prescriptions must contain the physician's DEA number and the patient's full street address. The prescription must be handwritten or computer generated and signed in ink by the practitioner. There are no allowable refills for a schedule II drug. A partial filling is allowed if the remaining quantity is available to the patient within 72 hours.

Federal and state requirements for schedules III through V are less stringent. The prescription may be handwritten or computer generated and signed in ink by the practitioner. The physician's office may telephone or fax the prescription depending on state law. Schedule III to V drugs may be refilled up to five times within six months of the date the prescription was

written. Partial fillings are permitted as long as refills are indicated on the original prescription. The refills cannot exceed the total quantity prescribed.

Dispense

To **dispense** is to count, label, and disperse (cause to disappear) multiple quantities of a medicine at a single time. Pharmacies dispensing controlled substances must be registered with the DEA, and registration must be renewed every three years. All records of controlled substances must be kept for two years. A pharmacy may not employ a person who will have access to controlled substances if he or she has been convicted of a felony offense relating to controlled substances. The pharmacist dispensing a controlled substance must affix to the container a label including the following information:

- ◆ Pharmacy name and address
- ◆ The serial prescription number
- ◆ Date of initial dispensing
- ◆ Name of the patient
- ◆ Name of the prescribing practitioner
- ◆ Directions for use
- ◆ Cautionary statements, if any
- ◆ The warning statement: “CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”

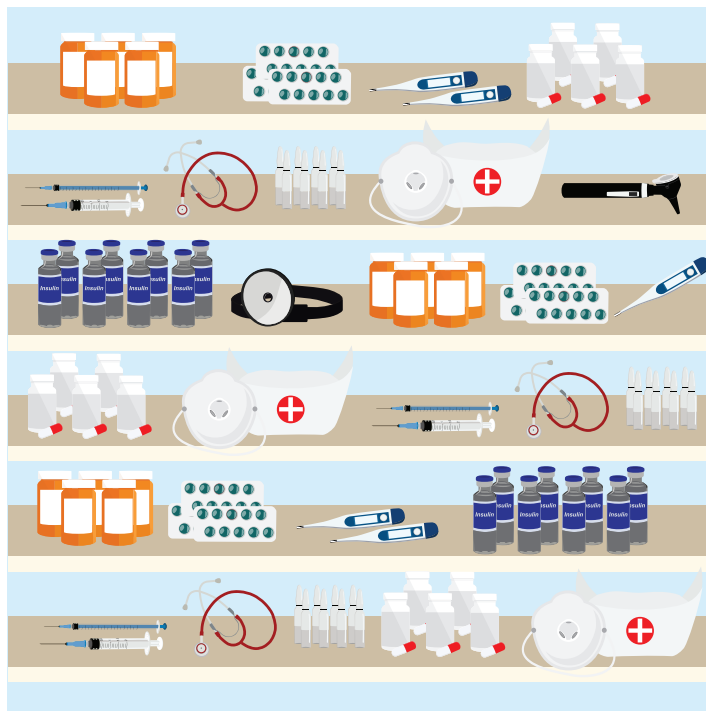


FIGURE 3. Every pharmacy must perform a complete and accurate inventory of all controlled substances and follow all standard protocols for refilling and dispensing medications.

The pharmacist may partially dispense a schedule II drug provided that the remaining portion is dispensed within 72 hours.

The pharmacist may partially dispense schedule III to V drugs providing that the total quantity dispensed does not exceed the total quantity prescribed.

DETECT A FRAUDULENT PRESCRIPTION

Pharmacists must be vigilant against forged or altered prescriptions. They can be held legally responsible for knowingly filling them. In addition, pharmacists have a legal responsibility to be familiar with the state and federal requirements for dispensing controlled substances. They must be aware of the potential situations where drug diversion can occur and the safeguards that can be enacted to prevent this diversion. Pharmacists and pharmacy technicians should be aware of the various kinds of fraudulent prescriptions that may be presented for dispensing.

Types of Fraudulent Prescriptions

- ◆ Legitimate prescription pads are stolen from physician's offices, and prescriptions are written for fictitious patients.
- ◆ Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription.
- ◆ Some drug abusers will have prescription pads from a legitimate doctor printed with a different call-back number that is answered by an accomplice to verify the prescription.
- ◆ Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctor's prescriptions.

Characteristics of Forged Prescriptions

- ◆ The prescription looks "too good;" the prescriber's handwriting is too legible.
- ◆ Quantities, directions, or dosages differ from standard medical usage.
- ◆ The prescription does not comply with acceptable standard abbreviations.
- ◆ The prescription appears to be photocopied.
- ◆ Directions are written in full with no abbreviations.
- ◆ Zeroes have been added to the quantities.
- ◆ A refill is indicated for a schedule II drug.

Preventing Fraudulent Prescriptions

- ◆ Know the prescriber and his or her signature.
- ◆ Know the prescriber's DEA registration number.
- ◆ Know the patient, and check the date the prescription was written.
- ◆ Request proper identification any time there is doubt.
- ◆ If you believe a forged, altered, or counterfeited prescription is offered for dispensing, do not dispense the medication. Then contact the local police.
- ◆ If a pattern of prescription abuse is discovered, contact the state board of pharmacy or the local DEA office.



FIGURE 4. Pharmacies must be aware of the various types of fraudulent prescriptions and the strategies used when presented with one.

Summary:



The Controlled Substance Act is the federal law that regulates the manufacture, importation, possession, uses, and distribution of all controlled substances in the United States. Controlled substances are classified into five categories based on

their medical use and potential for abuse. Schedule I substances have the highest potential for abuse, and schedule V substances have the lowest potential for abuse.

Pharmacies have strict guidelines pertaining to the inventory and dispensing of controlled substances. Controlled substances must be completely inventoried every two years. Inventory records must be readily available at all times and kept on location for at least two years from the initial date of inventory. Strict guidelines regulate the refilling of controlled substances to which all pharmacies must adhere. Also, all controlled substances must be properly labeled.

The dispensing pharmacist must maintain constant vigilance against forged or altered prescriptions. Pharmacists and pharmacy technicians must be aware of the various types of fraudulent prescriptions used to illegally obtain controlled substances. Pharmacy staff is trained to recognize the characteristics of fraudulent prescriptions and the techniques to prevent the dispensing of controlled substances.

Checking Your Knowledge:



1. Explain how the Controlled Substance Act seeks to prevent drug abuse.
2. List the five drug schedules and three examples of drugs in each schedule.
3. Describe the inventory guidelines all pharmacies must adhere to.
4. List the information that must be affixed to the label of a controlled substance.
5. Describe the refill requirements for Schedule I to V controlled substances.

Expanding Your Knowledge:



Schedule a time to interview a law enforcement officer, a recovering teen, or a pharmacist about the dangers of drug abuse. Post a drug-free message on your social media site so others know that you are proud to be drug free.

Web Links:



Abusive Prescribing of Controlled Substances

<http://www.nejm.org/doi/full/10.1056/NEJMp1308222>

DEA Reschedules Hydrocodone

<http://www.ashp.org/Menu/News/PharmacyNews/NewsArticle.aspx?id=4123>

ADHD Medicines and Controlled Substances

<http://www.webmd.com/add-adhd/features/adhd-medicines-controlled-substances>