



## II. Controlled Substances Act

### CONTROLLING DRUGS OR OTHER SUBSTANCES THROUGH FORMAL SCHEDULING

The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. The Act also provides a mechanism for substances to be controlled (added to or transferred between schedules) or decontrolled (removed from control). The procedure for these actions is found in Section 201 of the Act (21U.S.C. §811).

Proceedings to add, delete, or change the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration (DEA), the Department of Health and Human Services (HHS), or by petition from any interested party, including:

- » The manufacturer of a drug
- » A medical society or association
- » A pharmacy association
- » A public interest group concerned with drug abuse
- » A state or local government agency
- » An individual citizen

When a petition is received by the DEA, the agency begins its own investigation of the drug. The DEA also may begin an investigation of a drug at any time based upon information received from law enforcement laboratories, state and local law enforcement and regulatory agencies, or other sources of information.

Once the DEA has collected the necessary data, the DEA Administrator, by authority of the Attorney General, requests from HHS a scientific and medical evaluation and recommendation as to whether the drug or other substance should be controlled or removed from control. This request is sent to the Assistant Secretary for Health of HHS.

The Assistant Secretary, by authority of the Secretary, compiles the information and transmits back to the DEA: a medical and scientific evaluation regarding the drug or other substance, a recommendation as to whether the drug should be controlled, and in what schedule it should be placed.

The medical and scientific evaluations are binding on the DEA with respect to scientific and medical matters and form a part of the scheduling decision.

Once the DEA has received the scientific and medical evaluation from HHS, the Administrator will evaluate all available data and make a final decision whether to propose that a drug or other substance should be removed or controlled and into which schedule it should be placed.

If a drug does not have a potential for abuse, it cannot be controlled. Although the term "potential for abuse" is not defined in the CSA, there is much discussion of the term in the legislative history of the Act. The following items are indicators that a drug or other substance has a potential for abuse:

- (1) There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.
- (2) There is significant diversion of the drug or other substance from legitimate drug channels.
- (3) Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner.
- (4) The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the

health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

In determining into which schedule a drug or other substance should be placed, or whether a substance should be decontrolled or rescheduled, certain factors are required to be considered. These factors are listed in Section 201 (c), [21 U.S.C. § 811 (c)] of the CSA as follows:

(1) *The drug's actual or relative potential for abuse.*

(2) *Scientific evidence of the drug's pharmacological effect, if known.*

The state of knowledge with respect to the effects of a specific drug is, of course, a major consideration. For example, it is vital to know whether or not a drug has a hallucinogenic effect if it is to be controlled due to that effect.

The best available knowledge of the pharmacological properties of a drug should be considered.

(3) *The state of current scientific knowledge regarding the substance.*

Criteria (2) and (3) are closely related. However, (2) is primarily concerned with pharmacological effects and (3) deals with all scientific knowledge with respect to the substance.

(4) *Its history and current pattern of abuse.* To determine whether or not a drug should be controlled, it is important to know the pattern of abuse of that substance.

(5) *The scope, duration, and significance of abuse.* In evaluating existing abuse, the DEA Administrator must know not only the pattern of abuse, but whether the abuse is widespread.

(6) *What, if any, risk there is to the public health.* If a drug creates dangers to the public health, in addition to or because of its abuse potential, then these dangers must also be considered by the Administrator.

(7) *The drug's psychic or physiological dependence liability.* There must be an assessment of the extent to which a drug is physically addictive or psychologically habit forming.

(8) *Whether the substance is an immediate precursor of a substance already controlled.* The CSA allows inclusion of immediate precursors on this basis alone into the appropriate schedule and thus safeguards against possibilities of clandestine manufacture. After considering the above listed factors, the Administrator must make specific findings concerning the drug or other substance. This will determine into which schedule the drug or other substance will be placed. These schedules are established

by the CSA. They are as follows:

### Schedule I

- » The drug or other substance has a high potential for abuse.
- » The drug or other substance has no currently accepted medical use in treatment in the United States.
- » There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- » Examples of Schedule I substances include heroin, gamma hydroxybutyric acid (GHB), lysergic acid diethylamide (LSD), marijuana, and methaqualone.

### Schedule II

- » The drug or other substance has a high potential for abuse.
- » The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- » Abuse of the drug or other substance may lead to severe psychological or physical dependence.
- » Examples of Schedule II substances include morphine, phencyclidine (PCP), cocaine, methadone, hydrocodone, fentanyl, and methamphetamine.

### Schedule iii

- » The drug or other substance has less potential for abuse than the drugs or other substances in Schedules I and II.
- » The drug or other substance has a currently accepted medical use in treatment in the United States.
- » Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
- » Anabolic steroids, codeine and hydrocodone products with aspirin or Tylenol®, and some barbiturates are examples of Schedule III substances.

### Schedule IV

- » The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
- » The drug or other substance has a currently accepted medical use in treatment in the United States.
- » Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.
- » Examples of drugs included in Schedule IV are alprazolam, clonazepam, and diazepam.

## Schedule V

- » The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
- » The drug or other substance has a currently accepted medical use in treatment in the United States.
- » Abuse of the drug or other substances may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.
- » Cough medicines with codeine are examples of Schedule V drugs.

When the DEA Administrator has determined that a drug or other substance should be controlled, decontrolled, or rescheduled, a proposal to take action is published in the Federal Register. The proposal invites all interested persons to file comments with the DEA and may also request a hearing with the DEA. If no hearing is requested, the DEA will evaluate all comments received and publish a final order in the Federal Register, controlling the drug as proposed or with modifications based upon the written comments filed. This order will set the effective dates for imposing the various requirements of the CSA.

If a hearing is requested, the DEA will enter into discussions with the party or parties requesting a hearing in an attempt to narrow the issue for litigation. If necessary, a hearing will then be held before an Administrative Law Judge. The judge will take evidence on factual issues and hear arguments on legal questions regarding the control of the drug. Depending on the scope and complexity of the issues, the hearing may be brief or quite extensive. The Administrative Law Judge, at the close of the hearing, prepares findings of fact and conclusions of law and a recommended decision that is submitted to the DEA Administrator. The DEA Administrator will review these documents, as well as the underlying material, and prepare his/her own findings of fact and conclusions of law (which may or may not be the same as those drafted by the Administrative Law Judge). The DEA Administrator then publishes a final order in the Federal Register either scheduling the drug or other substance or declining to do so.

Once the final order is published in the Federal Register, interested parties have 30 days to appeal to a U.S. Court of Appeals to challenge the order. Findings of fact by the Administrator are deemed conclusive if supported by “substantial evidence.” The order imposing controls is not stayed during the appeal, however, unless so ordered by the Court

## Emergency or Temporary Scheduling

The CSA was amended by the Comprehensive Crime Control Act of 1984. This Act included a provision which allows the DEA Administrator to place a substance, on a temporary basis, into Schedule I, when necessary, to avoid an imminent hazard to the public safety.

This emergency scheduling authority permits the scheduling of a substance which is not currently controlled, is being abused, and is a risk to the public health while the formal rulemaking procedures described in the CSA are being conducted. This emergency scheduling applies only to substances with no accepted medical use.

A temporary scheduling order may be issued for one year with a possible extension of up to six months if formal scheduling procedures have been initiated. The notice of intent and order are published in the Federal Register, as are the proposals and orders for formal scheduling. [21 U.S.C. § 811 (h)]

## Controlled Substance analogues

A new class of substances was created by the Anti-Drug Abuse Act of 1986. Controlled substance analogues are substances that are not controlled substances, but may be found in illicit trafficking. They are structurally or pharmacologically similar to Schedule I or II controlled substances and have no legitimate medical use. A substance that meets the definition of a controlled substance analogue and is intended for human consumption is treated under the CSA as if it were a controlled substance in Schedule I. [21 U.S.C. § 802(32), 21 U.S.C. § 813]

## International treaty obligations

United States treaty obligations may require that a drug or other substance be controlled under the CSA, or rescheduled if existing controls are less stringent than those required by a treaty. The procedures for these scheduling actions are found in Section 201(d) of the Act. [21 U.S.C. § 811 (d)]

The United States is a party to the Single Convention on Narcotic Drugs of 1954, which was designed to establish effective control over international and domestic traffic in narcotics, coca leaf, cocaine, and cannabis. A second treaty, the Convention on Psychotropic Substances of 1971, which entered into force in 1976 and was ratified by Congress in 1980, is designed to establish comparable control over stimulants, depressants, and hallucinogens.

## REGULATION

The CSA creates a closed system of distribution for controlled substances.

The cornerstone of this system is the registration of all those authorized by DEA to handle controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories, and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.

### Registration

Any person who handles or intends to handle controlled substances must obtain a registration issued by DEA. A unique number is assigned to each legitimate handler of controlled drugs such as importer, exporter, manufacturer, distributor, hospital, pharmacy, practitioner, and researcher.

This number must be made available to the supplier by the customer prior to the purchase of a controlled substance.

Thus, the opportunity for unauthorized transactions is greatly diminished.

### Recordkeeping and Reporting

The CSA requires that complete and accurate records be kept of all quantities of controlled substances manufactured, purchased, and sold. Each substance must be inventoried every two years. Some limited exceptions to the recordkeeping requirements may apply to certain categories of registrants.

From these records it is possible to trace the flow of any drug from the time it is first imported or manufactured, through the distribution level, to the pharmacy or hospital that dispensed it, and then to the actual patient who received the drug. The mere existence of this requirement is sufficient to discourage many forms of diversion. It actually serves large drug corporations as an internal check to uncover diversion, such as pilferage by employees.

There is one distinction between scheduled items for record keeping requirements. Records for Schedule I and II drugs must be kept separate from all other records maintained by the registrant. Records for Schedule III, IV, and V substances must be kept in a “readily retrievable” form, or maintained separately from all other records.

### Distribution

Maintaining records is required for distribution of a controlled substance from one manufacturer to another, from manufacturer to distributor, and from distributor to dispenser. In the case of Schedule I and II drugs, the supplier must have a special order form from the customer. This order form (DEA Form 222) is issued by DEA only to persons who are properly registered to handle Schedule I and II controlled substances.

The form is preprinted with the name and address of the customer. The drugs must be shipped to this name and address. The use of this form is a special reinforcement of the registration requirement; it ensures that only authorized individuals may obtain Schedule I and II drugs.

### Controlled Substance Ordering System (CSOS) – Electronic Order Forms

**Any registrant permitted to order Schedule II controlled substances may do so electronically via the DEA Controlled Substance Ordering System (CSOS). The use of electronic orders is optional; registrants may continue to issue orders on a paper DEA Form 222. CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The adoption of the CSOS standards is the only allowance for the electronic transmission of Schedule II controlled substance orders between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized entities. CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must**

**be signed using a digital signature issued by a Certification Authority (CA) operated by DEA.**

Digital certificates can be obtained only by registrants and individuals granted power of attorney by registrants to sign orders. A registrant must appoint a CSOS coordinator who will serve as that registrant’s recognized agent regarding issues pertaining to issuance of, revocation of, and changes to, digital certificates issued under that registrant’s DEA registration. A CSOS digital certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. Certificates will be revoked if the certificate

holder is no longer authorized to sign Schedule II orders for the registrant, if the information on which the certificate is based changes, or if the digital certificate used to sign electronic orders has been compromised, stolen, or lost.

Another benefit of the form is the special monitoring it permits. The form is issued in triplicate: the customer keeps one copy; two copies go to the supplier, who, after filling the order, keeps a copy and forwards the third copy to the nearest DEA office. For drugs in Schedules III, IV, and V, no order form is necessary. The supplier in each case, however, is under an obligation to verify the authenticity of the customer. The supplier is held fully accountable for any drugs that are shipped to a purchaser who does not have a valid registration. Manufacturers must submit periodic reports of the Schedule I and II controlled substances they produce in bulk and dosage forms.

They also report the manufactured quantity and form of each narcotic substance listed in Schedule III. Distributors of controlled substances must report the quantity and form of all their transactions of controlled drugs listed in Schedules I and II, narcotics listed in Schedule III, and GHB. Both manufacturers and distributors are required to provide reports of their annual inventories of these controlled substances. This data is entered into a system called the Automated Reports and Consolidated Orders System (ARCOS). It enables the DEA to monitor the distribution of controlled substances throughout the country, and to identify retail level registrants that receive unusual quantities of controlled substances.

### Dispensing to Patients

The dispensing of a controlled substance is the delivery by a practitioner of the controlled substance to the ultimate user, who may be a patient or research subject. Special control mechanisms operate here as well. Schedule I drugs are those that have no currently accepted medical use in the United States; therefore, they may be used in the United States only in research situations. They generally are supplied by only a limited number of firms to properly registered and qualified researchers. Controlled substances may be dispensed by a practitioner by direct administration, by prescription, or by dispensing.

Records must be maintained by the practitioner of all dispensing of controlled substances and of certain administrations.

The CSA does not require the practitioner to maintain copies of prescriptions, unless, such substances are prescribed in

the course of maintenance or detoxification treatment of an individual. Certain states require the use of multiple-copy prescriptions for Schedule II and other specified controlled substances.

The determination to place drugs on prescription is within the jurisdiction of the FDA. Unlike other prescription drugs, however, controlled substances are subject to additional restrictions. Schedule II prescription orders must be written and signed by the practitioner; they may not be telephoned into the pharmacy except in an emergency. In addition, a prescription for a Schedule II drug may not be refilled. For Schedule III and IV drugs, the prescription order may be either written or oral (that is, by telephone to the pharmacy). In addition, the patient may (if authorized by the practitioner) have the prescription refilled up to five times and at any time within six months from the date the prescription was issued.

Schedule V includes some prescription drugs and many narcotic preparations, including antitussives and antidiarrheals. Even here, however, the law imposes restrictions beyond those normally required for the over-the-counter sales; for example, the patient must be at least 18 years of age, must offer some form of identification, and have his or her name entered into a special log maintained by the pharmacist as part of a special record.

### Electronic Prescriptions

On March 31, 2010, DEA published in the Federal Register the Electronic Prescriptions for Controlled Substances interim final rule which became effective June 1, 2010. The rule provides practitioners with the option of writing prescriptions for controlled substances electronically and also permits pharmacies to receive, dispense, and archive these electronic prescriptions.

Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. As of June 1, 2010, only those electronic applications that comply with all of DEA's requirements as set forth in 21 C.F.R. §1311 may be used to electronically create, transmit, receive/archive controlled substances prescriptions, and dispense controlled substances based on those prescriptions.

### Ryan Haight online pharmacy consumer protection act of 2008

On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, often referred to as the Ryan Haight Act. This law amends the CSA

by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called “rogue Internet sites” that unlawfully dispense controlled substances by means of the Internet. The Ryan Haight Act applies to all controlled substances in all schedules. An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy.

### Quotas

DEA limits the quantity of Schedule I and II controlled substances that may be produced in the United States in any given calendar year. By utilizing available data on sales and inventories of these controlled substances, and taking into account estimates of drug usage provided by the FDA, the DEA establishes annual aggregate production quotas for Schedule I and II controlled substances.

The aggregate production quota is allocated among the various manufacturers who are registered to manufacture the specific drug. DEA also allocates the amount of bulk drug that may be procured by those companies that prepare the drug into dosage units.

### Security

DEA registrants are required by regulation to maintain certain security for the storage and distribution of controlled substances. Manufacturers and distributors of Schedule I and II substances must store controlled substances in specially constructed vaults or highly rated safes, and maintain electronic security for all storage areas. Lesser physical security requirements apply to retail level registrants such as hospitals and pharmacies. All registrants are required to make every effort to ensure that controlled substances in their possession are not diverted into the illicit market. This requires operational as well as physical security. For example, registrants are responsible for ensuring that controlled substances are distributed only to other registrants that are authorized to receive them, or to legitimate patients.

### Controlled Substance Theft or Significant Loss

Should a theft or significant loss of any controlled substance occur, a registrant must implement the following procedures within one business day of the discovery of the theft or loss.

#### A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA.

A pharmacy must notify in writing the local DEA Diversion Field Office within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

#### B. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. A paper version of the form may also be obtained by writing to the Drug Enforcement Administration. If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office and keep a copy for its records.

### PENALTIES

The CSA provides penalties for unlawful manufacturing, distribution, and dispensing of controlled substances. The

penalties are basically determined by the schedule of the drug or other substance, and sometimes are specified by drug name, as in the case of marijuana. As the statute has been amended since its initial passage in 1970, the penalties have been altered by Congress. The following charts are an overview of the penalties for trafficking or unlawful distribution of controlled substances. This is not inclusive of the penalties provided under the CSA.

### User Accountability/Personal Use Penalties

On November 19, 1988, Congress passed the Anti-Drug Abuse Act of 1988, P. L. 100-690. Two sections of this Act represent the U.S. Government's attempt to reduce drug abuse by dealing not just with the person who sells the illegal drug, but also with the person who buys it. The first new section is titled "User Accountability," and is codified at 21 U.S.C. § 862 and various sections of Title 42, U.S.C. The second involves "personal use amounts" of illegal drugs, and is codified at 21 U.S.C. § 844a.

### User Accountability

The purpose of User Accountability is to not only make the public aware of the Federal Government's position on drug abuse, but to describe new programs intended to decrease drug abuse by holding drug abusers personally responsible for their illegal activities, and imposing civil penalties on those who violate drug laws.

It is important to remember that these penalties are in addition to the criminal penalties drug abusers are already given, and do not replace those criminal penalties.

The new User Accountability programs call for more instruction in schools, kindergarten through senior high, to educate children on the dangers of drug abuse. These programs will include participation by students, parents, teachers, local businesses and the local, state, and Federal Government.

User Accountability also targets businesses interested in doing business with the Federal Government. This program requires those businesses to maintain a drug-free workplace, principally through educating employees on the dangers of drug abuse, and by informing employees of the penalties they face if they engage in illegal drug activity on company property. There is also a provision in the law that makes public housing projects drug-free by evicting those residents who allow their units to be used for illegal drug activity, and denies federal benefits, such as housing assistance and student loans, to individuals convicted

of illegal drug activity. Depending on the offense, an individual may be prohibited from ever receiving any benefit provided by the Federal Government.

### Personal Use Amounts

This section of the 1988 Act allows the government to punish minor drug offenders without giving the offender a criminal record if the offender is in possession of only a small amount of drugs. This law is designed to impact the "user" of illicit drugs, while simultaneously saving the government the costs of a full-blown criminal investigation. Under this section, the government has the option of imposing only a civil fine on individuals possessing only a small quantity of an illegal drug. Possession of this small quantity, identified as a "personal use amount," carries a civil fine of up to \$10,000.

In determining the amount of the fine in a particular case, the drug offender's income and assets will be considered. This is accomplished through an administrative proceeding rather than a criminal trial, thus reducing the exposure of the offender to the entire criminal justice system, and reducing the costs to the offender and the government.

The value of this section is that it allows the government to punish a minor drug offender, gives the drug offender the opportunity to fully redeem himself or herself, and have all public record of the proceeding destroyed. If this was the drug offender's first offense, and the offender has paid all fines, can pass a drug test, and has not been convicted of a crime after three years, the offender can request that all proceedings be dismissed.

If the proceeding is dismissed, the drug offender can lawfully say he or she had never been prosecuted, either criminally or civilly, for a drug offense.

Congress has imposed two limitations on this section's use. It may not be used if (1) the drug offender has been previously convicted of a Federal or state drug offense; or (2) the offender has already been fined twice under this section.