

CRS Report for Congress

The Controlled Substances Act: Regulatory Requirements

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James E. Nichols
Law Clerk
American Law Division

Brian T. Yeh
Legislative Attorney
American Law Division



Prepared for Members and
Committees of Congress

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Summary

This report highlights certain non-criminal regulatory requirements of the Controlled Substances Act (CSA). The CSA and its implementing regulations establish a framework through which the federal government regulates the use of controlled substances for legitimate medical, scientific, research, and industrial purposes, and prevents these substances from being diverted for illegal purposes. The CSA assigns various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) to one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. Schedule I contains substances that have no currently accepted medical use and cannot safely be made available to the public under a prescription, while Schedules II, III, IV, and V include substances that have recognized medical uses and may be manufactured, distributed, and used in accordance with the CSA. The order of the schedules reflect substances that are progressively less dangerous and addictive — and progressively more beneficial. To restrict access to chemicals used in the illicit manufacture of certain controlled substances, the CSA also regulates 40 “listed chemicals.” Furthermore, the CSA regulates controlled substance “analogues,” which are substances that are not controlled but are structurally or pharmacologically similar to substances found in Schedule I or II and have no accepted medical use.

Unless specifically exempted by the CSA, any person who handles controlled substances or listed chemicals (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers) must register with the Drug Enforcement Administration (DEA) in the U.S. Department of Justice, which administers and enforces the CSA. Registrants must keep accurate and complete records of all transactions involving controlled substances, maintain detailed inventories of the substances in their possession, and periodically file reports with the DEA, as well as ensure that controlled substances are securely stored and safeguarded in accordance with DEA regulations.

Between 10%-11% of all drug prescriptions written in the United States are for pharmaceutical controlled substances. Only licensed medical practitioners (who are registered with the DEA) are authorized to prescribe controlled substances listed in Schedules II-V to patients; such prescriptions may only be issued by a practitioner who is “acting in the usual course of his professional practice,” and for a “legitimate medical purpose.” The CSA authorizes the DEA Administrator to suspend or revoke a physician's prescription privileges upon a finding that he has “committed such acts as would render his registration ... inconsistent with the public interest.”

While the CSA provides criminal sanctions for *illicit* possession, manufacture, or distribution of controlled substances, the statute also contains a few noteworthy penalty provisions that are specifically applicable to persons who are authorized by the DEA to handle controlled substances lawfully. The CSA sets forth certain offenses involving listed chemicals and DEA registration and other prohibited acts relating to registrants who manufacture, distribute, and dispense controlled substances.

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The Controlled Substances Act: Regulatory Requirements

The Controlled Substances Act (CSA or the act)¹ is the statutory framework through which the federal government regulates the lawful production, possession, and distribution of controlled substances. The CSA places various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. Further, the act requires persons who handle controlled substances or listed chemicals (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers) to register with the Drug Enforcement Administration (DEA) in the U.S. Department of Justice, which administers and enforces the CSA. Registrants must maintain detailed records of their respective controlled substance inventories as well as establish adequate security controls to minimize theft and diversion.² Although the CSA sets forth criminal provisions³ for the unlawful manufacture, possession, and distribution of controlled substances, this report will instead focus on the act's non-criminal regulatory requirements⁴ for those who legitimately produce, distribute, and dispense controlled substances.

Formal Scheduling

The placement of drugs or other substances into schedules under the CSA is based upon the substance's medical use, potential for abuse, and safety or dependence liability.⁵ The act further provides a mechanism for substances to be

¹ 21 U.S.C. §§ 801 et seq.

² See 21 C.F.R. § 1304.11(a) ("Each inventory shall contain a complete and accurate record of all controlled substances on hand ..."); see also 21 C.F.R. § 1301.74(a) ("All applicants and registrants shall provide effective controls to guard against theft and diversion of controlled substances ...").

³ For a detailed summary of the CSA's criminal provisions, see CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Charles Doyle and Brian T. Yeh.

⁴ This report does not cover all the requirements under the CSA, nor does it address state controlled substances regulations. Although federal and state governments both regulate controlled substances, federal law preempts state law when state law conflicts with the CSA. 21 U.S.C. § 903.

⁵ 21 U.S.C. §§ 811-812.

controlled,⁶ or added to a schedule; decontrolled, or removed from the scheduling framework altogether; and rescheduled or transferred from one schedule to another.⁷

The proceedings to add, delete, or change the schedule of a drug or substance may be initiated by the DEA, the U.S. Department of Health and Human Services (HHS), or by petition by any interested person.⁸ When a petition is received by the DEA, the agency initiates its own investigation of the drug or substance. The DEA may also initiate an investigation at any time in response to information received from law enforcement laboratories, state and local law enforcement and regulatory agencies, or other sources of information.

After the DEA's initial investigation, the DEA Administrator (Administrator)⁹ requests from the Assistant Secretary of Health of HHS (Assistant Secretary of Health) a scientific and medical evaluation and recommendation as to whether the drug or substance should be controlled or removed from control.¹⁰ The Assistant Secretary of Health in turn solicits information from the Commissioner of the Food and Drug Administration, and obtains evaluations and recommendations from the National Institute on Drug Abuse. The Assistant Secretary of Health then consolidates the requested information and transmits back to the DEA a medical and scientific evaluation regarding the drug or substance, along with a recommendation as to whether the drug or substance should be controlled and into which schedule it should be placed.¹¹

The Administrator then evaluates all of the relevant data and makes a final determination as to whether the drug or substance should be controlled or removed entirely from control.¹² In making a determination regarding the control of a drug or substance, the Administrator must consider factors such as the drug's actual or relative potential for abuse; scientific evidence of its pharmacological effect; the current state of scientific knowledge regarding the drug or substance; the risk to the public health; and whether the substance is an immediate precursor of a substance

⁶ For the purposes of the CSA, the term "control" as defined by 21 U.S.C. § 802(5) means "to add a drug or other substance, or immediate precursor, to a schedule under [§ 812 of the act], whether by transfer from another schedule or otherwise."

⁷ The procedures for these actions are found at 21 U.S.C § 811.

⁸ 21 U.S.C. § 811(a).

⁹ Although the CSA grants to the Attorney General the authority to enforce its provisions, 21 U.S.C. §§ 801 et seq., the Attorney General has delegated this authority to the DEA Administrator at 21 C.F.R. § 0.100. Accordingly, the term "Administrator" will be used instead of the term "Attorney General" for the remainder of this report.

¹⁰ 21 U.S.C. § 811(b).

¹¹ The medical and scientific evaluations are binding on the DEA with respect to such matters and form a part of the scheduling decision. The recommendation on the initial scheduling of a substance is binding only to the extent that if HHS recommends that the drug or substance not be controlled, the DEA may not add it to its schedules. *Id.*

¹² *Id.*

already controlled under the act.¹³ After the Administrator makes such a determination, he must make specific findings concerning the drug or substance that dictate the schedule in which the drug or substance will be placed.¹⁴

Congress may also add a substance to a schedule through legislation.

Emergency or Temporary Scheduling. The CSA was amended by the Comprehensive Crime Control Act of 1984¹⁵ to include a provision allowing the Administrator to place a drug or substance, on a temporary basis, into Schedule I when necessary to avoid an “imminent hazard to public safety.”¹⁶ The Administrator, however, may not issue a temporary scheduling order until thirty days after he notifies both the public and the HHS Secretary of his intent to issue the temporary scheduling order and of his justification for issuing the order.¹⁷ Further, the Administrator must consider any of the HHS Secretary’s comments regarding the temporary order.¹⁸

When issuing a temporary scheduling order, the Administrator must consider, with respect to the finding of an imminent hazard to public safety (i) the history of the drug or substance and its current pattern of abuse; (ii) the scope, duration, and significance of the drug or substance’s abuse; (iii) the risk to public health; (iv) diversion of the drug or substance from legitimate channels; and (v) the drug or substance’s “clandestine importation, manufacture, or distribution.”¹⁹ A drug or substance may be temporarily scheduled for one year and possibly longer — up to an additional six months — if formal scheduling procedures have been initiated.²⁰ This emergency scheduling applies only to substances with no accepted medical use in the United States.

Listed Chemicals. In an effort to restrict access to chemicals used in the illicit manufacture of certain controlled substances in violation of the CSA, Congress passed the Chemical Diversion and Trafficking Act (CDTA) in 1988.²¹ The CDTA and its subsequent amendments²² allow the DEA to control 40 chemicals²³ and

¹³ See 21 U.S.C. § 811(c)(1)-(8) (complete listing of factors Administrator must consider when determining control or removal of substances from schedules).

¹⁴ See 21 U.S.C. § 812(b) (“[A] drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance”). For a summary of the findings necessary for Schedules I-V, see Appendix.

¹⁵ P.L. 98-473.

¹⁶ 21 U.S.C. § 811(h)(1).

¹⁷ *Id.*

¹⁸ 21 U.S.C. § 811(4).

¹⁹ 21 U.S.C. § 811(h)(3).

²⁰ 21 U.S.C. § 811(h)(2).

²¹ P.L. 100-690.

²² Domestic Chemical Diversion Control Act of 1993, P.L. 103-200; Comprehensive (continued...)

restrict their diversion. These 40 chemicals are referred to by the CSA as “listed chemicals.”²⁴ Listed chemicals are divided into two categories: List I²⁵ and List II.²⁶ While both categories of chemicals can be used to illicitly manufacture controlled substances, List I chemicals are more strenuously regulated than List II chemicals because List I chemicals are “important to the manufacture of a controlled substance.”²⁷

Controlled Substances Analogues. Controlled substance analogues are substances that are not controlled but are structurally or pharmacologically similar to substances found in Schedule I or II and have no accepted medical use.²⁸ A substance that meets the definition of the term “controlled substance analogue” and is intended for human consumption is treated as if it were a controlled substance in Schedule I.²⁹ Controlled substance analogues are different from listed chemicals because such analogues are typically intended for human consumption as a substitute for a controlled substance, whereas listed chemicals are not intended for human consumption but are instead used as “ingredients” in the manufacture of certain controlled substances.

International Treaty Obligations. The United States is a party to the Single Convention on Narcotic Drugs of 1961, which was designed to establish effective control over international and domestic traffic in narcotics, coca leaf, cocaine, and marijuana. The United States is also party to the Convention on Psychotropic Substances of 1971, which was designed to establish similar control over stimulants, depressants, and hallucinogens. Treaty obligations may require the Attorney General

²² (...continued)

Methamphetamine Control Act of 1996, P.L. 104-237; Methamphetamine Anti-Proliferation Act of 2000, P.L. 106-310; Combat Methamphetamine Epidemic Act of 2005, P.L. 109-177.

²³ The 40 listed chemicals are set forth at 21 C.F.R. § 1310.02(a) and (b).

²⁴ See 21 U.S.C. §§ 802(33) — (35) and 21 C.F.R. §§ 1300.02(b)(17) — (19) (defining listed chemicals).

²⁵ 21 C.F.R. § 1300.02(b)(18) defines the term “List I chemical” as “a chemical specifically designated by the Administrator in [21 C.F.R.] § 1310.02(a) ... that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the [CSA] and is important to the manufacture of a controlled substance.”

²⁶ 21 C.F.R. § 1300.02(b)(19) defines the term “List II chemical” as “a chemical, other than a List I chemical, specifically designated by the Administrator in [21 C.F.R.] § 1310.02(b) ... that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the [CSA].”

²⁷ 21 C.F.R. § 1300.02(b)(18).

²⁸ 21 U.S.C. §§ 802(32)(A) and (B).

²⁹ See 21 U.S.C. § 813 (“A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I”).

to control or reschedule a substance if existing controls are less stringent than those required by a treaty.³⁰

Regulation

The CSA creates a “closed system” of distribution³¹ in which distribution may lawfully occur among registered handlers of controlled substances, referred to as “registrants.”³² Central to this closed system of distribution is the registration of all persons or entities authorized by the DEA to handle controlled substances. All registrants are required by the act to maintain complete and accurate inventories and records of all regulated transactions involving controlled substances and listed chemicals, as well as provide adequate security controls to prevent their diversion.

Registration. The CSA defines who must register with the DEA in order to handle controlled substances.³³ Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any controlled substance, must register with the DEA, unless they are exempt.³⁴ Generally, all manufacturers, distributors, and practitioners who deal with controlled substances must register.

Manufacturers and distributors of controlled substances must register with the DEA annually, and those who dispense controlled substances must obtain registrations that may not be issued for less than one year or more than three years.³⁵ Any person who is required to register in order to manufacture, distribute, or dispense controlled substances, but has not yet registered, may apply for registration at any time.³⁶ Those who already are registered can apply for re-registration not more than 60 days before the expiration date of their current registration.³⁷ Registrations specify the extent to which registrants are authorized to manufacture, possess, distribute, or dispense controlled substances. The Administrator is authorized to charge reasonable fees relating to the registration and control of the manufacturing, distribution, and

³⁰ The procedures for these scheduling actions are found at 21 U.S.C. § 811(d).

³¹ Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances*, 73 Fed. Reg. 36722 (proposed June 27, 2008).

³² According to 21 C.F.R. § 1300.02(b)(24), the term “registrant” means “any person who is registered [with the DEA] pursuant to [21 U.S.C. §§ 823 or 957].”

³³ 21 U.S.C. § 822; 21 C.F.R. Part 1301.

³⁴ 21 C.F.R. §§ 1301.22-1301.24 (exempting agents of registrants, certain military personnel, and law enforcement officials from DEA registration requirements).

³⁵ 21 C.F.R. § 822(a).

³⁶ 21 C.F.R. § 1301.13.

³⁷ *Id.*

dispensing of controlled substances under the act.³⁸ In addition, the Administrator can inspect the establishments of registrants or applicants for registration.³⁹

Registration is granted to applicants only if it would be consistent with the “public interest” to do so.⁴⁰ The Administrator uses several criteria to assess whether registering an applicant is consistent with the “public interest.” The criteria differ depending on the substance involved and whether the applicant is a manufacturer, distributor, or practitioner, but generally include factors such as those relating to public health and safety and compliance with state and local laws.⁴¹

The Administrator also has the authority to deny, revoke, or suspend registrations under certain circumstances but must provide adequate grounds for doing so.⁴² Before the DEA can deny an application, the agency must provide the applicant with an opportunity to demonstrate why the registration should not be denied.⁴³ However, the Administrator can suspend without notice any registration in order to avoid imminent danger to public health and safety.⁴⁴ A revocation or suspension of a registration may be applicable to a particular controlled substance or class of controlled substances. For example, a manufacturer who has been found to have violated the registration provisions regarding a Schedule II substance will still be able to manufacture controlled substances in Schedules III-V because the revocation or suspension relates only to one class of controlled substances.⁴⁵

³⁸ 21 U.S.C. § 821; *see also* 21 C.F.R. § 1301.13(e)(1) (chart detailing specific types of registrations and respective fees).

³⁹ 21 U.S.C. § 822(f); 21 C.F.R. § 1301.31.

⁴⁰ 21 U.S.C. § 823.

⁴¹ 21 U.S.C. §§ 823(a)-(f).

⁴² 21 U.S.C. § 824(a) states in pertinent part: “A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the [Administrator] upon a finding that the registrant —
 (1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;
 (2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical; (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial recommended by competent State authority;
 (4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or
 (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a — 7(a) of [the Social Security Act, which excludes certain individuals and entities from participation in Medicare and State healthcare programs] . . .”

⁴³ 21 U.S.C. § 824(c).

⁴⁴ 21 U.S.C. § 824(d); 21 C.F.R. § 1301.36(e).

⁴⁵ THOMAS C. FOX, CAROL COLBORN LOEPERE & JOSEPH W. METRO, HEALTH CARE (continued...)

The registration of an individual terminates when the person dies, ceases legal existence, or discontinues business or professional practice.⁴⁶ A registrant who ceases legal existence or discontinues business or professional practice must notify the DEA promptly of this occurrence. A registration cannot be transferred to someone else unless the Administrator provides his express, written consent for such a transfer to occur.⁴⁷

In some instances, applicants must apply for several separate registrations in order to comply with the CSA. Separate registrations are required for each principal place of business or professional practice where controlled substances are manufactured, distributed, imported, exported, or dispensed.⁴⁸ For example, a physician who is regularly engaged in dispensing controlled substances at one location must register to dispense controlled substances at other locations if he chooses to dispense controlled substances at these other locations.⁴⁹ However, with the enactment of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, the DEA Administrator must modify existing registrations of pharmacies to authorize them to dispense controlled substances by means of the Internet, unless the Administrator determines that such modification would be inconsistent with the public interest.⁵⁰

Recordkeeping Requirements. In addition to registration requirements, the CSA contains several recordkeeping provisions.⁵¹ A registrant authorized to handle controlled substances must keep accurate records and maintain detailed inventories in compliance with applicable federal and state law. For example, a registrant must maintain a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant.⁵² Furthermore, inventories must be available for inspection for at least two years.⁵³ These records are generally open for inspection by federal authorities and state officers tasked with enforcing state narcotics laws.⁵⁴

⁴⁵ (...continued)

FINANCIAL TRANSACTIONS MANUAL § 20:62 (2005).

⁴⁶ 21 C.F.R. § 1301.52.

⁴⁷ 21 C.F.R. § 1301.52(b).

⁴⁸ 21 C.F.R. § 1301.12.

⁴⁹ *See* United States v. Clinical Leasing Service, Inc., 925 F.2d 120 (5th Cir. 1991).

⁵⁰ Section 3(b) of P.L. 110-425, with an effective date of April 13, 2009, amending 21 U.S.C. § 823(f).

⁵¹ 21 U.S.C. § 827; 21 C.F.R. Part 1304.

⁵² 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a).

⁵³ 21 U.S.C. § 827(b)(3); 21 C.F.R. § 1304.04(a).

⁵⁴ *Id.*

Certain DEA regulations implementing the CSA also apply to listed chemicals.⁵⁵ For example, all registrants authorized to handle listed chemicals (List I and List II) must maintain records of regulated transactions and submit various reports to the DEA.⁵⁶ However, the Administrator has the authority to exempt specified concentrations of listed chemical mixtures from the recordkeeping requirements set forth in section 830 of the act that require registrants to maintain detailed records of every regulated transaction.⁵⁷

Distribution. As a means to ensure that only authorized registrants obtain Schedule I and II drugs from manufacturers and distributors, the CSA requires registrants who legitimately distribute⁵⁸ controlled substances or listed chemicals to keep records of shipments to purchasers.⁵⁹ Manufacturers and distributors must receive a special order form from a purchaser prior to shipping Schedule I and II drugs.⁶⁰ The form is preprinted by the DEA with the name and address of the purchaser and the drugs must be shipped by the supplier filling the order to the purchaser's registered location.⁶¹ All manufacturers must forward copies of completed order forms to the DEA by the close of the month in which the shipment is made.⁶² The CSA also provides for electronic orders of Schedule I and II drugs.⁶³ Manufacturers must also forward copies of filled electronic orders to the DEA within 2 business days.⁶⁴

The DEA further monitors the distribution of controlled substances by requiring manufacturers and distributors of Schedule I and II drugs to file reports⁶⁵ through the Automated Reports and Consolidated Orders System (ARCOS).⁶⁶ Certain narcotics listed in Schedules III and IV are also covered by the ARCOS reporting requirements.⁶⁷

Registered pharmacies that are authorized to dispense controlled substances by means of the Internet must report to the DEA Administrator the total quantity of each

⁵⁵ See generally 21 C.F.R. Part 1310 (records and reports of listed chemicals).

⁵⁶ 21 U.S.C. § 830(a) and (b); 21 C.F.R. §§ 1310.03-06.

⁵⁷ See chart at 21 C.F.R. § 1310.12(c).

⁵⁸ For the purposes of the CSA, the term "distribute," as defined by 21 U.S.C. § 802(11), means "to deliver (other than by administering or dispensing [to an ultimate user or research subject]) a controlled substance or listed chemical."

⁵⁹ 21 C.F.R. Part 1305.

⁶⁰ DEA Form 222 is only issued to customers who are properly registered with the DEA.

⁶¹ 21 C.F.R. § 1305.13(c).

⁶² 21 C.F.R. § 1305.13(d).

⁶³ 21 C.F.R. § 1305 Subpart C.

⁶⁴ 21 C.F.R. § 1305.29.

⁶⁵ 21 C.F.R. §§ 1304.31 and 1304.32.

⁶⁶ 21 C.F.R. § 1304.33.

⁶⁷ 21 C.F.R. § 1304.33(d).

controlled substance that the pharmacy has dispensed each month.⁶⁸ In addition, online pharmacies⁶⁹ must clearly display on their website homepage a statement that they comply with federal and state law concerning the delivery or sale of controlled substances, as well as post certain disclosure information such as

- the name and address of the pharmacy as it appears on the pharmacy's DEA registration certificate,
- the pharmacy's telephone number and email address,
- a list of states in which the pharmacy is licensed to dispense controlled substance,
- the identification and contact information of the pharmacist-in-charge, and
- the following statement: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309."⁷⁰

An online pharmacy must notify the DEA Administrator, and the state boards of pharmacy in any states in which the online pharmacies operate, thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing; such notification must include pharmacy's Internet site address, the information that is required to be posted on the pharmacy's website, and the DEA registration numbers of the pharmacy and practitioners who work for it.⁷¹ Online pharmacies that are already operational as of April 13, 2009, must submit this notification to the DEA Administrator and any applicable state boards of pharmacy no later than May 12, 2009.

⁶⁸ Section 3(c) of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, P.L. 110-425, with an effective date of April 13, 2009, adding new 21 U.S.C. § 827(d)(2). However, pharmacies are exempt from such reporting requirement if they do not exceed in a given month either of two thresholds: (1) 100 or more prescriptions dispensed, or (2) 5,000 or more dosage units of all controlled substances combined. *Id.*

⁶⁹ An "online pharmacy" means 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, but does *not* include, among other things, (1) manufacturers and distributors who do not dispense controlled substances to an unregistered individual or entity, (2) advertisements that do not attempt to facilitate an actual transaction involving a controlled substance, or (3) a registered pharmacy whose dispensing of controlled substances via the Internet consists solely of refilling or filling new prescriptions for controlled substances in schedule III, IV, or V. 21 U.S.C. § 802(52), as added by section 3(a) of P.L. 110-425, with an effective date of April 13, 2009.

⁷⁰ Section 3(d) of P.L. 110-425, with an effective date of April 13, 2009, adding new § 311 to the Controlled Substances Act.

⁷¹ *Id.*

Dispensing to Patients. The CSA further provides special control mechanisms for licensed practitioners and pharmacists who dispense⁷² controlled substances in Schedules II-V to patients for legitimate medical purposes. Because controlled substances classified as Schedule I drugs are deemed to have no accepted medical purpose in the United States, they may only be used for research, and practitioners may not prescribe them to patients. Under the CSA, only licensed medical practitioners⁷³ are authorized to prescribe controlled substances listed in Schedules II-V to patients.⁷⁴ A prescription for a controlled substance must be “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”⁷⁵ Accordingly, practitioners have a responsibility to ensure that the controlled substance is properly prescribed and dispensed.⁷⁶

No controlled substance in Schedules II may be dispensed to a patient by a pharmacist without a written prescription⁷⁷ from a practitioner, except in certain cases where the practitioner administers the controlled substance directly to the patient.⁷⁸ However, in the case of an emergency situation, a practitioner may orally authorize a pharmacist to fill a prescription for a Schedule II controlled substance.⁷⁹ Controlled substances in Schedules III-V may be dispensed by a pharmacy pursuant to either a written or oral prescription, including a facsimile of a written

⁷² According to 21 U.S.C. § 802(10), the term “dispense” means “to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.”

⁷³ According to 21 U.S.C. § 802(21), the term “practitioner” means “a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.”

⁷⁴ See 21 C.F.R. § 1306.03 (persons entitled to issue prescriptions).

⁷⁵ 21 C.F.R. § 1306.04.

⁷⁶ Pharmacists share with practitioners the responsibility to ensure that controlled substances are properly prescribed and dispensed. Both practitioners and pharmacists are subject to the criminal and civil provisions of the CSA for knowingly prescribing and dispensing a controlled substance in a manner inconsistent with the act. *Id.*

⁷⁷ 21 U.S.C. § 829(a); see also 21 C.F.R. § 1306.05 (manner of issuance of prescriptions for Schedule II controlled substances).

⁷⁸ 21 U.S.C. § 829(a); see also 21 C.F.R. § 1306.11(b) (authorizing individual practitioners to administer or dispense controlled substances directly to patients without prescription).

⁷⁹ 21 C.F.R. § 1306.11(d).

prescription;⁸⁰ these substances may also be administered or dispensed directly by the practitioner in the course of his professional practice without a prescription.⁸¹

Pharmacists may partially fill a prescription for Schedule II substances under certain circumstances.⁸² Pharmacists are prohibited from refilling prescriptions for Schedule II substances.⁸³ Prescriptions for controlled substances in Schedules III and IV, however, may be filled or refilled by pharmacists up to five times within six months after the date on which the prescription was issued, unless the prescribing practitioner authorizes a renewal of the prescription.⁸⁴

A controlled substance that is a prescription drug may not be delivered, distributed, or dispensed by means of the Internet without a “valid prescription.”⁸⁵ Only with respect to this provision of the Controlled Substances Act, a “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one medical evaluation of the patient in the physical presence of the practitioner.⁸⁶

Quotas. The DEA limits the quantity of Schedule I and II controlled substances which may be produced in a given calendar year. The CSA authorizes the Administrator to

- establish aggregate production quotas for all manufacturers;
- establish individual production quotas for specific registered manufactures;
- establish individual production quotas for registrants who have not manufactured controlled substances during one or more proceeding years; and
- implement quota increases for individual manufacturers where necessary.⁸⁷

⁸⁰ 21 U.S.C. § 829(b). If the prescription is made orally, the pharmacist must promptly reduce to writing all of the information required to be in a prescription under 21 C.F.R. § 1306.05, except for the signature of the practitioner. 21 C.F.R. § 1306.21(a).

⁸¹ 21 U.S.C. § 829(b); 21 C.F.R. § 1306.21(b).

⁸² See 21 C.F.R. § 1306.13(a) (“The partial filling of a prescription for a substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription.... The remaining portion of the prescription may be filled within 72 hours of the first partial filling”).

⁸³ 21 U.S.C. § 829(a) (“No prescription for a controlled substance in schedule II may be refilled.”).

⁸⁴ 21 U.S.C. 829(b); 21 C.F.R. § 1306.22(a).

⁸⁵ Section 2 of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, P.L. 110-425, with an effective date of April 13, 2009, adding new 21 U.S.C. § 829(e).

⁸⁶ *Id.*

⁸⁷ See 21 U.S.C. §§ 826(a)-(e) (general provisions regarding the establishment of production quotas for Schedule I and II controlled substances).

By regulation, the Administrator must consider the following factors in making his quota determinations: (i) the total disposal of the controlled substance during the current and two preceding years; (ii) trends in the national rate of new disposal of the controlled substance; (iii) total inventories (actual or estimated) of “the class and all substances manufactured from the class [of controlled substances listed in Schedule I or II];” (iv) projected demand for a particular controlled substance; and (v) other relevant factors affecting the use of controlled substances including, changes in the currently accepted medical use of a controlled substance, the economic and physical availability of the raw materials necessary to produce a controlled substance, and recent unforeseen emergencies (i.e., natural disasters).⁸⁸

Security. For the purposes of ensuring the secure storage and distribution of controlled substances and listed chemicals, all applicants and registrants must generally “provide effective controls and procedures to guard against theft and diversion of controlled substances.”⁸⁹ DEA regulations further require all applicants and registrants to substantially comply with specific security standards for storage of controlled substances and List I chemicals.⁹⁰ Applicants and registrants must also be prepared to make adjustments to their security systems in the event that a controlled substance is transferred to another schedule or removed from control under the CSA.⁹¹

DEA regulations also detail specific security requirements for the different types of applicants and registrants. For example, non-practitioners (i.e., manufacturers, distributors, and narcotic treatment programs) are required to store Schedule I and II substances in electronically monitored safes, steel cabinets or vaults that meet or exceed certain specifications.⁹² Licensed practitioners must store controlled substances in a “securely locked, substantially constructed cabinet”⁹³ and must notify the DEA of the theft or significant loss of any controlled substances within one business day of discovering such loss or theft.⁹⁴ Furthermore, all practitioners are prohibited from hiring employees who have been convicted of a drug-related felony

⁸⁸ 21 C.F.R. §§ 1303.11(b)(1)-(5).

⁸⁹ *See* 21 C.F.R. § 1301.71 (general security requirements and standards for measuring compliance).

⁹⁰ 21 C.F.R. § 1301.71(b) states: “Substantial compliance with the standards set forth in §§ 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant.” Section 1301.71(b) also sets forth a list of fifteen discretionary factors for Administrator to consider when evaluating the overall security system of an applicant or registrant; *see also* 21 C.F.R. § 1309.71(a)-(c) (general security requirements for List I chemicals).

⁹¹ 21 C.F.R. § 1301.71(c).

⁹² *See* 21 C.F.R. §§ 1301.72(a)(1)(i)-(iii) (specifications required for safes and steel cabinets storing Schedule I and II drugs or substances); *see also* 21 C.F.R. §§ 1301.72(a)(2) and 1301.72(a)(3)(i)-(vi) (specifications required for vaults storing Schedule I and II drugs or substances).

⁹³ *See* 21 C.F.R. § 1301.75 (physical security controls for practitioners).

⁹⁴ 21 C.F.R. § 1301.76(b).

or who have had a DEA registration denied or revoked.⁹⁵ DEA regulations recommend that non-practitioners carefully screen individuals before hiring them as employees, to ensure that job applicants do not have convictions for crimes or have engaged in unauthorized use of controlled substances.⁹⁶

Penalties. While the criminal provisions of the CSA focus mainly on the *illicit* possession, manufacture, and distribution of controlled substances,⁹⁷ there are a few noteworthy penalty provisions applicable to persons registered with the DEA. The CSA sets forth certain offenses involving listed chemicals,⁹⁸ DEA registration,⁹⁹ and other prohibited acts related to registrants who manufacture, distribute and dispense controlled substances.¹⁰⁰

With respect to DEA registration generally, registrants authorized to distribute or dispense any controlled substance are prohibited from distributing, dispensing, or manufacturing controlled substances that are not authorized by a registrant's registration.¹⁰¹ Registrants must maintain accurate records and furnish them when required to do so by law enforcement officials.¹⁰² Registrants must also maintain a degree of transparency by allowing law enforcement officials access to their premises for inspections authorized by the CSA.¹⁰³ Failure to adhere to the registration requirements of the CSA may subject a registrant to civil fines, imprisonment, or both.¹⁰⁴

The CSA also proscribes certain acts related to the manufacture and distribution of controlled substances and listed chemicals. Registrants who knowingly or intentionally (i) distribute Schedule I and II substances without a valid order form;¹⁰⁵ (ii) use an invalid registration number during the course of handling or acquiring controlled substances;¹⁰⁶ (iii) furnish false or fraudulent material information in a

⁹⁵ 21 C.F.R. § 1301.76(a).

⁹⁶ 21 C.F.R. § 1301.90.

⁹⁷ For a description of the criminal penalty provisions of the CSA, *see* CRS Report RL30722, *Drug Offenses: Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws*, by Charles Doyle and Brian T. Yeh.

⁹⁸ 21 U.S.C. §§ 841(c); (e)-(f).

⁹⁹ 21 U.S.C. § 842.

¹⁰⁰ 21 U.S.C. § 843.

¹⁰¹ 21 U.S.C. § 842(a)(2).

¹⁰² 21 U.S.C. § 842(a)(5).

¹⁰³ 21 U.S.C. § 842(a)(6).

¹⁰⁴ *See generally* 21 U.S.C. § 842(c) (penalties for committing prohibited acts set forth in § 842(a)).

¹⁰⁵ 21 U.S.C. § 843(a)(1).

¹⁰⁶ 21 U.S.C. § 843(a)(2).

record or report required by the act,¹⁰⁷ or (iv) present false or fraudulent identification when receiving a listed chemical,¹⁰⁸ are subject to criminal fines, imprisonment, or both.¹⁰⁹ Additionally, registrants who violate the aforementioned provisions may be subject to injunctive or declarative actions filed by the Attorney General in federal district court.¹¹⁰

Finally, the CSA specifies several offenses regarding listed chemicals. For example, criminal fines and/or imprisonment are available for any person who knowingly or intentionally (i) possesses a listed chemical with the intent to manufacture a controlled substance without proper registration; (ii) possesses or distributes a listed chemical with knowledge or a reasonable belief that the listed chemical will be used to manufacture a controlled substance; or (iii) evades the CSA's recordkeeping and reporting requirements by receiving or distributing listed chemicals in small units.¹¹¹ Also, any person who knowingly possesses or distributes listed chemicals in violation of the CSA, or knowingly violates the CSA's recordkeeping requirements, is subject to criminal fines, imprisonment, or both.¹¹² Furthermore, in addition to the other applicable penalties, violators of the aforementioned provisions may also be enjoined for up to ten years from handling listed chemicals.¹¹³

Exceptions to the Regulatory Requirements Under the CSA

It is important to note that the CSA allows for exceptions and also exempts certain individuals from some or all of its regulatory requirements. For example, individuals exempted from registration requirements include, among others, officers or employees of the DEA, officers of the U.S. Customs Service, officers or employees of the U.S. Food and Drug Administration, and any other federal officers who are authorized to possess, import, or export controlled substances in the course of their official duties.¹¹⁴ Officers or employees of any state, or political subdivision of a state, who are engaged in enforcement of state or local laws relating to controlled substances, are also exempt from registering with the DEA.¹¹⁵ A person who has

¹⁰⁷ 21 U.S.C. § 843(a)(4)(A).

¹⁰⁸ 21 U.S.C. § 843(a)(4)(B).

¹⁰⁹ *See generally* 21 U.S.C. § 843(d) (penalties for committing prohibited acts set forth in § 843(a)).

¹¹⁰ 21 U.S.C. § 843(f).

¹¹¹ 21 U.S.C. §§ 841(c)(1)- (3).

¹¹² *See* 21 U.S.C. § 841(f)(1) and (2) (penalties for offenses involving listed chemicals).

¹¹³ 21 U.S.C. § 841(e).

¹¹⁴ 21 C.F.R. § 1301.24(a)(1).

¹¹⁵ 21 C.F.R. § 1301.24(a)(2). For additional registration exceptions, see 21 C.F.R. §§ 1301.22-1301.23.

lawfully obtained, and who possesses, a controlled substance for his own use is also not required to register.¹¹⁶

In addition, only those actually engaged in activities relating to manufacturing, distributing, and dispensing controlled substances are required to obtain registration, but related or affiliated persons who are not engaged in such activities are not required to register. For example, a stockholder or parent corporation of a corporation that manufactures controlled substances is not required to obtain registration, nor are employees of a registered manufacturer, distributor, or dispenser.¹¹⁷

The DEA Administrator may, by regulation, waive the registration requirement for certain manufacturers, distributors, or dispensers, if he finds it consistent with the public health and safety.¹¹⁸

In certain circumstances, the CSA recordkeeping provisions do not apply. The CSA recordkeeping provisions do not apply to the prescribing or administering of a controlled substance in Schedules II-V by practitioners acting in the lawful course of their professional practice *unless* such substance is prescribed or administered in the course of maintenance or detoxification treatment of an individual.¹¹⁹ For example, the prescribing or administering of methadone for the treatment of narcotic addiction must be in conformity with the CSA's recordkeeping provisions. The CSA also does not apply to research conducted in conformity with the exemption granted under certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) or to preclinical research or teaching.¹²⁰

¹¹⁶ 21 U.S.C. § 822(c).

¹¹⁷ 21 C.F.R. § 1301.11(a); 21 U.S.C. § 822(c).

¹¹⁸ 21 U.S.C. § 822(d).

¹¹⁹ 21 U.S.C. §§ 827(c)(1)(A), 827(c)(1)(B).

¹²⁰ 21 U.S.C. § 827(c)(2).

Appendix. Classification of Controlled Substances

Schedule	CSA Statutory Provision	Examples of Scheduled Substances
Schedule I	Pursuant to 21 U.S.C. § 812(b)(1), a substance will be placed in Schedule I based on specific findings made by the Administrator that “(A) The drug or other substance has a high potential for abuse. (B) The drug or other substance has no currently accepted medical use in treatment in the United States. (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.”	Heroin, lysergic acid diethylamide (LSD), marijuana, MDMA (Ecstasy), methaqualone (Quaalude). ^a
Schedule II	Pursuant to 21 U.S.C. § 812(b)(2), a substance will be placed in Schedule II based on specific findings made by the Administrator that “(A) The drug or substance has a high potential for abuse. (B) 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. (C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.”	Methadone, methamphetamine, methylphenidate (Ritalin®), morphine, oxycodone (OxyContin®), phencyclidine (PCP). ^b
Schedule III	Pursuant to 21 U.S.C. § 812(b)(3), a substance will be placed in Schedule III based on specific findings made by the Administrator that “(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II. (B) The drug or other substance has a currently accepted medical use in treatment in the United States. (C) Abuse of the drug may lead to moderate or low physical dependence or high psychological dependence.”	Anabolic steroids, synthetic delta — 9 tetrahydrocannabinol (THC), codeine, hydrocodone with aspirin or Tylenol®. ^c

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Schedule IV	Pursuant to 21 U.S.C. § 812(b)(4), a substance will be placed in Schedule IV based on specific findings made by the Administrator that “(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III. (B) The drug or other substance has a currently accepted medical use in treatment in the United States. (C) 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.”	Xanax®, Valium®, Equanil®, Talwin®, Darvon®. ^d
Schedule V	Pursuant to 21 U.S.C. § 812(b)(5), a substance will be placed in Schedule V based on specific findings made by the Administrator that “(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV. (B) The drug or other substance has a currently accepted medical use in treatment in the United States. (C) 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 IV.”	Certain cough medicines with codeine, and certain opium preparations. ^e

- a. See 21 C.F.R. § 1308.11(b)-(f) (complete listing of Schedule I drugs and substances); *see also* 21 C.F.R. § 1308.11(g) (temporary listing of substances subject to emergency scheduling in Schedule I).
- b. See 21 C.F.R. § 1308.12(b)-(g) (complete listing of Schedule II drugs and substances).
- c. See 21 C.F.R. § 1308.13(b)-(g) (complete listing of Schedule III drugs and substances).
- d. See 21 C.F.R. § 1308.14(b)-(f) (complete listing of Schedule IV drugs and substances).
- e. See 21 C.F.R. § 1308.15(b)-(e) (complete listing of Schedule V drugs and substances).