



# The Controlled Substances Act: Regulatory Requirements

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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 reflects substances that are progressively less dangerous and addictive. 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 (CSA or the act)<sup>1</sup> 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.<sup>2</sup> Although the CSA sets forth criminal provisions<sup>3</sup> for the unlawful manufacture, possession, and distribution of controlled substances, this report will instead focus on the act's non-criminal regulatory requirements<sup>4</sup> 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.<sup>5</sup> The act further provides a mechanism for substances to be controlled,<sup>6</sup> or added to a schedule; decontrolled, or removed from the scheduling framework altogether; and rescheduled or transferred from one schedule to another.<sup>7</sup>

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.<sup>8</sup> 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)<sup>9</sup> requests from the Assistant Secretary of Health of HHS (Assistant Secretary of Health) a scientific and medical

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<sup>1</sup> 21 U.S.C. §§ 801 et seq.

<sup>2</sup> 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 ...").

<sup>3</sup> 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 Brian T. Yeh.

<sup>4</sup> 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.

<sup>5</sup> 21 U.S.C. §§ 811-812.

<sup>6</sup> 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."

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

<sup>8</sup> 21 U.S.C. § 811(a).

<sup>9</sup> 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 28 C.F.R. § 0.100(b). Accordingly, the term (continued...)

evaluation and recommendation as to whether the drug or substance should be controlled or removed from control.<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup> 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 already controlled under the act.<sup>13</sup> 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.<sup>14</sup>

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 1984<sup>15</sup> 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."<sup>16</sup> 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.<sup>17</sup> Further, the Administrator must consider any of the HHS Secretary's comments regarding the temporary order.<sup>18</sup>

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

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(...continued)

"Administrator" will be used instead of the term "Attorney General" for the remainder of this report.

<sup>10</sup> 21 U.S.C. § 811(b).

<sup>11</sup> 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.*

<sup>12</sup> *Id.*

<sup>13</sup> 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).

<sup>14</sup> 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**.

<sup>15</sup> P.L. 98-473.

<sup>16</sup> 21 U.S.C. § 811(h)(1).

<sup>17</sup> *Id.*

<sup>18</sup> 21 U.S.C. § 811(4).

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."<sup>19</sup> A drug or substance may be temporarily scheduled for two years and possibly longer—up to an additional year—if formal scheduling procedures have been initiated.<sup>20</sup> 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.<sup>21</sup> The CDTA and its subsequent amendments<sup>22</sup> allow the DEA to control 40 chemicals<sup>23</sup> and restrict their diversion. These 40 chemicals are referred to by the CSA as "listed chemicals."<sup>24</sup> Listed chemicals are divided into two categories: List I<sup>25</sup> and List II.<sup>26</sup> 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."<sup>27</sup>

## 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.<sup>28</sup> 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.<sup>29</sup> 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.

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<sup>19</sup> 21 U.S.C. § 811(h)(3).

<sup>20</sup> 21 U.S.C. § 811(h)(2), as amended by the Synthetic Drug Abuse Prevention Act of 2012, P.L. 112-144.

<sup>21</sup> P.L. 100-690.

<sup>22</sup> Domestic Chemical Diversion Control Act of 1993, P.L. 103-200; Comprehensive 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.

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

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

<sup>25</sup> 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."

<sup>26</sup> 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]."

<sup>27</sup> 21 C.F.R. § 1300.02(b)(18).

<sup>28</sup> 21 U.S.C. §§ 802(32)(A) and (B).

<sup>29</sup> 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").

## Synthetic Drugs

Synthetic drugs are chemically produced in a laboratory; their chemical structure can be either identical to or different from naturally occurring drugs, and their effects are designed to mimic or even enhance those of natural drugs.<sup>30</sup> Many synthetic cathinones (central nervous system stimulants) are marketed under household names such as “bath salts” or “plant food” and are stamped with the warning “not intended for human consumption.” This action is intended to circumvent the CSA’s statutory definition of a controlled substance analogue. In October 2011, the DEA used its temporary scheduling authority to place three synthetic cathinones on Schedule I of the CSA.<sup>31</sup> In June 2012, Congress passed the Synthetic Drug Abuse Prevention Act of 2012—Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (P.L. 112-144)—which permanently added two of these synthetic cathinones to Schedule I of the CSA, along with cannabimimetic substances (commonly referred to as synthetic marijuana).<sup>32</sup>

## 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 to control or reschedule a substance if existing controls are less stringent than those required by a treaty.<sup>33</sup>

## Regulation

The CSA creates a “closed system” of distribution<sup>34</sup> in which distribution may lawfully occur among registered handlers of controlled substances, referred to as “registrants.”<sup>35</sup> Central to this closed system of distribution is the registration of all persons or entities authorized by the DEA to handle controlled substances. The DEA has described the movement of a controlled substance from manufacture to the patient as follows:

[A] controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are

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<sup>30</sup> United Nations Office on Drugs and Crime, *Synthetic Drugs*, at [http://www.apaic.org/index.php?option=com\\_content&view=article&id=91&Itemid=63](http://www.apaic.org/index.php?option=com_content&view=article&id=91&Itemid=63).

<sup>31</sup> Drug Enforcement Administration, *Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cathinones Into Schedule I*, 76 Fed. Reg. 65371 (Oct. 21, 2011).

<sup>32</sup> For more information on this law and this topic generally, see CRS Report R42066, *Synthetic Drugs: Overview and Issues for Congress*, by Kristin M. Finklea and Lisa N. Sacco.

<sup>33</sup> The procedures for these scheduling actions are found at 21 U.S.C. § 811(d).

<sup>34</sup> Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances*, 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010).

<sup>35</sup> 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].”

all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.<sup>36</sup>

All registrants are required by the CSA 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. Therefore, a particular controlled substance is always under the control of a DEA-registered person until it reaches the patient or is destroyed, and the CSA's regulatory requirements "ensure that all controlled substances are accounted for from their creation until their dispensing or destruction."<sup>37</sup>

## **Registration**

The CSA defines who must register with the DEA in order to handle controlled substances.<sup>38</sup> 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.<sup>39</sup> Generally, all manufacturers, distributors, and practitioners who deal with controlled substances must register. The CSA refers to an individual patient as an "ultimate user," which it defines as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household."<sup>40</sup> Ultimate users are not required to register with the DEA<sup>41</sup> because the controlled substances in their possession "are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability."<sup>42</sup>

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.<sup>43</sup> 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.<sup>44</sup> Those who already are registered can apply for re-registration not more than 60 days before the expiration date of their current registration.<sup>45</sup> 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 dispensing of controlled

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<sup>36</sup> DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3481 (January 21, 2009).

<sup>37</sup> DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591 (May 2, 2005).

<sup>38</sup> 21 U.S.C. § 822; 21 C.F.R. Part 1301.

<sup>39</sup> 21 C.F.R. §§ 1301.22-1301.24 (exempting agents of registrants, certain military personnel, and law enforcement officials from DEA registration requirements).

<sup>40</sup> 21 U.S.C. § 802(27).

<sup>41</sup> 21 U.S.C. § 822(c)(3).

<sup>42</sup> DEA, *Definition and Registration of Reverse Distributors*, 68 Fed. Reg. 41222, 41226 (proposed July 11, 2003).

<sup>43</sup> 21 C.F.R. § 822(a).

<sup>44</sup> 21 C.F.R. § 1301.13.

<sup>45</sup> *Id.*



substances under the act.<sup>46</sup> In addition, the Administrator can inspect the establishments of registrants or applicants for registration.<sup>47</sup>

Registration is granted to applicants only if it would be consistent with the “public interest” to do so.<sup>48</sup> 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.<sup>49</sup>

The Administrator also has the authority to deny, revoke, or suspend registrations under certain circumstances but must provide adequate grounds for doing so.<sup>50</sup> 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.<sup>51</sup> However, the Administrator can suspend without notice any registration in order to avoid imminent danger to public health and safety.<sup>52</sup> 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.<sup>53</sup>

The registration of an individual terminates when the person dies, ceases legal existence, or discontinues business or professional practice.<sup>54</sup> A registrant who ceases legal existence or discontinues business or professional practice must notify the DEA promptly of this occurrence. A

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<sup>46</sup> 21 U.S.C. § 821; *see also* 21 C.F.R. § 1301.13(e)(1) (chart detailing specific types of registrations and respective fees).

<sup>47</sup> 21 U.S.C. § 822(f); 21 C.F.R. § 1301.31.

<sup>48</sup> 21 U.S.C. § 823.

<sup>49</sup> 21 U.S.C. §§ 823(a)-(f).

<sup>50</sup> 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] . . .”

<sup>51</sup> 21 U.S.C. § 824(c).

<sup>52</sup> 21 U.S.C. § 824(d); 21 C.F.R. § 1301.36(e).

<sup>53</sup> THOMAS C. FOX, CAROL COLBORN LOEPERE & JOSEPH W. METRO, HEALTH CARE FINANCIAL TRANSACTIONS MANUAL § 20:62 (2005).

<sup>54</sup> 21 C.F.R. § 1301.52.

registration cannot be transferred to someone else unless the Administrator provides his express, written consent for such a transfer to occur.<sup>55</sup>

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.<sup>56</sup> 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.<sup>57</sup> 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.<sup>58</sup>

## **Recordkeeping Requirements**

In addition to registration requirements, the CSA contains several recordkeeping provisions.<sup>59</sup> 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.<sup>60</sup> Furthermore, inventories must be available for inspection for at least two years.<sup>61</sup> These records are generally open for inspection by federal authorities and state officers tasked with enforcing state narcotics laws.<sup>62</sup> The CSA declares that it is unlawful for any person to “refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required” by the CSA;<sup>63</sup> it is also unlawful for any person knowingly or intentionally “to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed” under the CSA.<sup>64</sup>

Certain DEA regulations implementing the CSA also apply to listed chemicals.<sup>65</sup> 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.<sup>66</sup> However, the Administrator has the authority to exempt specified concentrations of listed chemical mixtures from the

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<sup>55</sup> 21 C.F.R. § 1301.52(b).

<sup>56</sup> 21 C.F.R. § 1301.12.

<sup>57</sup> See *United States v. Clinical Leasing Service, Inc.*, 925 F.2d 120 (5<sup>th</sup> Cir. 1991).

<sup>58</sup> Section 3(b) of P.L. 110-425, amending 21 U.S.C. § 823(f).

<sup>59</sup> 21 U.S.C. § 827; 21 C.F.R. Part 1304.

<sup>60</sup> 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a).

<sup>61</sup> 21 U.S.C. § 827(b)(3); 21 C.F.R. § 1304.04(a).

<sup>62</sup> *Id.*

<sup>63</sup> 21 U.S.C. § 842(a)(5).

<sup>64</sup> 21 U.S.C. § 843(a)(4).

<sup>65</sup> See generally 21 C.F.R. Part 1310 (records and reports of listed chemicals).

<sup>66</sup> 21 U.S.C. § 830(a) and (b); 21 C.F.R. §§ 1310.03-06.

recordkeeping requirements set forth in section 830 of the act that require registrants to maintain detailed records of every regulated transaction.<sup>67</sup>

## **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 distribute<sup>68</sup> controlled substances or listed chemicals to keep records of shipments to purchasers.<sup>69</sup> Manufacturers and distributors must receive a special order form from a purchaser prior to shipping Schedule I and II drugs.<sup>70</sup> 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.<sup>71</sup> All manufacturers must forward copies of completed order forms to the DEA by the close of the month in which the shipment is made.<sup>72</sup> The CSA also provides for electronic orders of Schedule I and II drugs.<sup>73</sup> Manufacturers must also forward copies of filled electronic orders to the DEA within 2 business days.<sup>74</sup>

The DEA further monitors the distribution of controlled substances by requiring manufacturers and distributors of Schedule I and II drugs to file reports<sup>75</sup> through the Automated Reports and Consolidated Orders System (ARCOS).<sup>76</sup> Certain narcotics listed in Schedules III and IV are also covered by the ARCOS reporting requirements.<sup>77</sup>

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 controlled substance that the pharmacy has dispensed each month.<sup>78</sup> In addition, online pharmacies<sup>79</sup> 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

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<sup>67</sup> See chart at 21 C.F.R. § 1310.12(c).

<sup>68</sup> 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.”

<sup>69</sup> 21 C.F.R. Part 1305.

<sup>70</sup> DEA Form 222 is only issued to customers who are properly registered with the DEA.

<sup>71</sup> 21 C.F.R. § 1305.13(c).

<sup>72</sup> 21 C.F.R. § 1305.13(d).

<sup>73</sup> 21 C.F.R. § 1305 Subpart C.

<sup>74</sup> 21 C.F.R. § 1305.29.

<sup>75</sup> 21 C.F.R. §§ 1304.31 and 1304.32.

<sup>76</sup> 21 C.F.R. § 1304.33.

<sup>77</sup> 21 C.F.R. § 1304.33(d).

<sup>78</sup> Section 3(c) of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, P.L. 110-425, 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.*

<sup>79</sup> 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.

- 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."<sup>80</sup>

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.<sup>81</sup> Online pharmacies that were already operational as of April 13, 2009, had to submit this notification to the DEA Administrator and any applicable state boards of pharmacy no later than May 12, 2009.

## **Dispensing to Patients**

The CSA further provides special control mechanisms for licensed practitioners and pharmacists who dispense<sup>82</sup> 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 practitioners<sup>83</sup> are authorized to prescribe controlled substances listed in Schedules II-V to patients.<sup>84</sup> 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."<sup>85</sup> Accordingly, practitioners have a responsibility to ensure that the controlled substance is properly prescribed and dispensed.<sup>86</sup>

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<sup>80</sup> Section 3(d) of P.L. 110-425, adding new § 311 to the Controlled Substances Act.

<sup>81</sup> *Id.*

<sup>82</sup> 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."

<sup>83</sup> 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."

<sup>84</sup> See 21 C.F.R. § 1306.03 (persons entitled to issue prescriptions).

<sup>85</sup> 21 C.F.R. § 1306.04; *United States v. Moore*, 4223 U.S. 122 (1975).

<sup>86</sup> 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. 21 C.F.R. § (continued...)

No controlled substance in Schedules II may be dispensed to a patient by a pharmacist without a written prescription<sup>87</sup> from a practitioner, except in certain cases where the practitioner administers the controlled substance directly to the patient.<sup>88</sup> 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. DEA regulations define “emergency situation” as those in which the prescribing practitioner determines:<sup>89</sup>

1. that immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
2. that no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the act; and
3. that it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Such an emergency oral authorization for a Schedule II substance may be filled by a pharmacist if the following conditions are met:<sup>90</sup>

1. the quantity of the drug prescribed and dispensed is limited to an amount adequate to treat the patient during the emergency period;
2. the prescription is immediately reduced to writing by the pharmacist and contains all the information that federal regulations require of prescriptions,<sup>91</sup> except for the signature of the prescribing individual practitioner;
3. if the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
4. within seven days after authorizing an emergency oral prescription, the prescribing individual practitioner must deliver a written prescription to the dispensing pharmacist. The practitioner must write on the face of the prescription “Authorization for Emergency Dispensing” and also write the date of the oral order. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. The pharmacist must notify the nearest DEA office if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist

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(...continued)

1306.04(a).

<sup>87</sup> 21 U.S.C. § 829(a); *see also* 21 C.F.R. § 1306.05 (manner of issuance of prescriptions for Schedule II controlled substances).

<sup>88</sup> 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).

<sup>89</sup> 21 C.F.R. § 290.10.

<sup>90</sup> 21 C.F.R. § 1306.11(d).

<sup>91</sup> 21 C.F.R. § 1306.05.

to do so shall void the authority to dispense without a written prescription of a prescribing individual practitioner.

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 prescription;<sup>92</sup> these substances may also be administered or dispensed directly by the practitioner in the course of his professional practice without a prescription.<sup>93</sup>

Practitioners are permitted to sign and transmit electronic prescriptions for controlled substances, assuming that the electronic prescription complies with detailed requirements set forth in the applicable federal regulations.<sup>94</sup>

Pharmacists may partially fill a prescription for Schedule II substances under certain circumstances.<sup>95</sup> Pharmacists are prohibited from refilling prescriptions for Schedule II substances.<sup>96</sup> 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.<sup>97</sup> A pharmacy may process electronic prescriptions for controlled substances if it has satisfied several conditions described in the applicable federal regulations.<sup>98</sup>

A controlled substance that is a prescription drug may not be delivered, distributed, or dispensed by means of the Internet without a “valid prescription.”<sup>99</sup> 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.<sup>100</sup>

## **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;

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<sup>92</sup> 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).

<sup>93</sup> 21 U.S.C. § 829(b); 21 C.F.R. § 1306.21(b).

<sup>94</sup> Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances*, 75 Fed. Reg. 16235, 16307 (Mar. 31, 2010).

<sup>95</sup> 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.”).

<sup>96</sup> 21 U.S.C. § 829(a) (“No prescription for a controlled substance in schedule II may be refilled.”).

<sup>97</sup> 21 U.S.C. 829(b); 21 C.F.R. § 1306.22(a).

<sup>98</sup> Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances*, 75 Fed. Reg. 16235, 16316 (Mar. 31, 2010).

<sup>99</sup> Section 2 of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, P.L. 110-425, adding new 21 U.S.C. § 829(e).

<sup>100</sup> *Id.*

- 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.<sup>101</sup>

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).<sup>102</sup>

## 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.”<sup>103</sup> DEA regulations further require all applicants and registrants to substantially comply with specific security standards for storage of controlled substances and List I chemicals.<sup>104</sup> 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.<sup>105</sup>

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.<sup>106</sup> Licensed practitioners must store controlled substances in a “securely locked, substantially constructed cabinet”<sup>107</sup> 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.<sup>108</sup> Furthermore, all practitioners are prohibited from hiring employees who have been convicted of a drug-related felony or who have had a DEA

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<sup>101</sup> See 21 U.S.C. §§ 826(a)-(e) (general provisions regarding the establishment of production quotas for Schedule I and II controlled substances).

<sup>102</sup> 21 C.F.R. §§ 1303.11(b)(1)-(5).

<sup>103</sup> See 21 C.F.R. § 1301.71 (general security requirements and standards for measuring compliance).

<sup>104</sup> 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).

<sup>105</sup> 21 C.F.R. § 1301.71(c).

<sup>106</sup> 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).

<sup>107</sup> See 21 C.F.R. § 1301.75 (physical security controls for practitioners).

<sup>108</sup> 21 C.F.R. § 1301.76(b).

registration denied or revoked.<sup>109</sup> 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.<sup>110</sup>

## **Disposal of Controlled Substances<sup>111</sup>**

DEA registrants may need to dispose of controlled substances in their possession when they are expired, damaged, contaminated, or otherwise unwanted. Under the CSA and DEA regulations, there are three different options for registrants to dispose of controlled substances:<sup>112</sup>

1. The distributor or dispenser may return the controlled substance to the pharmaceutical manufacturer who accepts returns of outdated or damaged controlled substances.
2. The distributor, dispenser, or manufacturer may itself dispose of the controlled substances under procedures specified by federal regulation.<sup>113</sup>
3. The distributor, dispenser, or manufacturer may transfer the controlled substances to a “reverse distributor” to take custody of the controlled substances for the purpose of returning them to the manufacturer or arranging for their disposal.<sup>114</sup>

## **Penalties**

While the criminal provisions of the CSA focus mainly on the *illicit* possession, manufacture, and distribution of controlled substances,<sup>115</sup> there are a few noteworthy penalty provisions applicable to persons registered with the DEA. The CSA sets forth certain offenses involving listed chemicals,<sup>116</sup> DEA registration,<sup>117</sup> and other prohibited acts related to registrants who manufacture, distribute and dispense controlled substances.<sup>118</sup>

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<sup>109</sup> 21 C.F.R. § 1301.76(a).

<sup>110</sup> 21 C.F.R. § 1301.90.

<sup>111</sup> For information about disposal by patients who possess already dispensed controlled substances (as opposed to DEA registrants that want to dispose of them), see CRS Report R40548, *Legal Issues Relating to the Disposal of Dispensed Controlled Substances*, by Brian T. Yeh. This report discusses the Secure and Responsible Drug Disposal Act of 2010, P.L. 111-273, which, among other things, amended the Controlled Substances Act to allow a patient to deliver controlled substances to an entity that is authorized by federal law to dispose of them, providing that such disposal occurs in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

<sup>112</sup> DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591, 22592 (May 2, 2005).

<sup>113</sup> Under 21 C.F.R. § 1307.21, any person may request permission from DEA to dispose of controlled substances without the need for a DEA or state government witness. If a registrant has a regular need to dispose of controlled substances, the DEA may grant blanket authorization for such disposal; however, “DEA normally requires that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and witness the destruction.” DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591 (May 2, 2005).

<sup>114</sup> A “reverse distributor” is a DEA-registered entity “who receives controlled substances acquired from another DEA registrant for the purpose of—(1) returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or (2) where necessary, processing such substances or arranging for processing such substances for disposal.” 21 C.F.R. § 1300.01(b)(41).

<sup>115</sup> 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 Brian T. Yeh.

<sup>116</sup> 21 U.S.C. §§ 841(c); (e)-(f).



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.<sup>119</sup> Registrants must maintain accurate records and furnish them when required to do so by law enforcement officials.<sup>120</sup> Registrants must also maintain a degree of transparency by allowing law enforcement officials access to their premises for inspections authorized by the CSA.<sup>121</sup> Failure to adhere to the registration requirements of the CSA may subject a registrant to civil fines, imprisonment, or both.<sup>122</sup>

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;<sup>123</sup> (ii) use an invalid registration number during the course of handling or acquiring controlled substances;<sup>124</sup> (iii) furnish false or fraudulent material information in a record or report required by the act;<sup>125</sup> or (iv) present false or fraudulent identification when receiving a listed chemical,<sup>126</sup> are subject to criminal fines, imprisonment, or both.<sup>127</sup> Additionally, registrants who violate the aforementioned provisions may be subject to injunctive or declarative actions filed by the Attorney General in federal district court.<sup>128</sup>

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.<sup>129</sup> 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.<sup>130</sup> 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.<sup>131</sup>

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(...continued)

<sup>117</sup> 21 U.S.C. § 842.

<sup>118</sup> 21 U.S.C. § 843.

<sup>119</sup> 21 U.S.C. § 842(a)(2).

<sup>120</sup> 21 U.S.C. § 842(a)(5).

<sup>121</sup> 21 U.S.C. § 842(a)(6).

<sup>122</sup> *See generally* 21 U.S.C. § 842(c) (penalties for committing prohibited acts set forth in § 842(a)).

<sup>123</sup> 21 U.S.C. § 843(a)(1).

<sup>124</sup> 21 U.S.C. § 843(a)(2).

<sup>125</sup> 21 U.S.C. § 843(a)(4)(A).

<sup>126</sup> 21 U.S.C. § 843(a)(4)(B).

<sup>127</sup> *See generally* 21 U.S.C. § 843(d) (penalties for committing prohibited acts set forth in § 843(a)).

<sup>128</sup> 21 U.S.C. § 843(f).

<sup>129</sup> 21 U.S.C. §§ 841(c)(1)-(3).

<sup>130</sup> *See* 21 U.S.C. § 841(f)(1) and (2) (penalties for offenses involving listed chemicals).

<sup>131</sup> 21 U.S.C. § 841(e).

## 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.<sup>132</sup> 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.<sup>133</sup> A person who has lawfully obtained, and who possesses, a controlled substance for his own use is also not required to register.<sup>134</sup>

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.<sup>135</sup>

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.<sup>136</sup>

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.<sup>137</sup> 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.<sup>138</sup>

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<sup>132</sup> 21 C.F.R. § 1301.24(a)(1).

<sup>133</sup> 21 C.F.R. § 1301.24(a)(2). For additional registration exceptions, see 21 C.F.R. §§ 1301.22-1301.23.

<sup>134</sup> 21 U.S.C. § 822(c).

<sup>135</sup> 21 C.F.R. § 1301.11(a); 21 U.S.C. § 822(c).

<sup>136</sup> 21 U.S.C. § 822(d).

<sup>137</sup> 21 U.S.C. §§ 827(c)(1)(A), 827(c)(1)(B).

<sup>138</sup> 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), synthetic marijuana. <sup>a</sup>
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). <sup>b</sup>
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®. <sup>c</sup>
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®. <sup>d</sup>
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. <sup>e</sup>

- 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).

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