RxLegal

The Federal Controlled Substances Act: Schedules and Pharmacy Registration

*Michael Gabay, PharmD, JD, BCPS**

The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, more commonly known as the Controlled Substances Act, became effective on May 1, 1971.^{1,2} This federal law contains 3 different titles. Title I deals with the establishment of rehabilitation programs for drug abusers, Title II addresses the registration and distribution of controlled substances, and Title III discusses issues related to the importation and exportation of controlled substances.² The main segment of interest to pharmacists is Title II. This *RxLegal* column is the first of a 4-part series that provides an overview of key components of this important federal law.

The goal of the Controlled Substances Act is to improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances.¹ To achieve this goal, manufacturers, distributors, and dispensers of controlled substances must be registered with the Drug Enforcement Administration (DEA), the agency charged with enforcement of the Act on the federal level. Registration of these entities with the DEA results in the formation of a “closed system” for controlled substances distribution. This closed system allows for controlled substances to be traced from initial manufacture to final dispensing to the patient.

Controlled substances are generally defined as medications that are considered easily abusable. Under the Controlled Substances Act, these medications are categorized into 5 schedules.¹ Definitions of each schedule with corresponding examples of medications are presented in **Table 1**. Schedule I medications have the highest abuse potential, while medications in Schedule V have a low abuse potential. In addition to the schedules, the Controlled Substances Act contains information on scheduled listed chemical products or SLCPs. These listed chemicals are products that contain ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed legally in the United States as nonprescription drugs.

Of note, some states have passed laws allowing for the medical or recreational use of marijuana.² These state laws do not alter the fact that marijuana remains a Schedule I medication under federal law. In addition, medications may be removed or added to a schedule or be switched from one schedule to another. The US Attorney General has the authority to add, remove, or switch. The Attorney General generally works with the Secretary of the Department of Health and Human Services to determine a medication’s schedule.

Every pharmacy that dispenses controlled substances is required to register with the DEA.¹ Prior to obtaining a DEA registration, a pharmacy must have a state license for operation. A DEA pharmacy registration is obtained by completing the Application for New Registration (ie, DEA Form-224). Instructions for completing the form are found on the US Department of Justice DEA Office of Diversion Control Web site (http://www.deadiversion.usdoj.gov/drugreg/reg_apps/224/224_instruct.htm).³ Pharmacies can also apply electronically for a new or renewed registration (http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm).⁴ Once approved, a pharmacy must renew registration every 3 years.

Some drug products such as pseudoephedrine, phenylpropanolamine, and ephedrine-containing medications are classified as SLCPs as described previously.¹ These chemicals may be used inappropriately to compound illegal substances such as methamphetamine (ie, crystal). If a pharmacy were to engage in the wholesale distribution of these chemicals, a DEA chemical registration would be required in addition to the registration for handling controlled substances. This is rarely the case, because most pharmacies are retail distributors of these chemicals (ie, regulated sellers) and not wholesale distributors. A regulated seller legally sells the aforementioned chemicals only for personal use either directly to walk-in customers or via other face-to-face transactions.

*Director, Drug Information Group and Prior Authorization Services, Clinical Associate Professor, Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, Illinois

Table 1. Schedules of controlled substances¹

Schedule	Definitions	Examples
Schedule I	High abuse potential with no accepted medical use; medications within this schedule may not be prescribed, dispensed, or administered	Heroin, marijuana, ecstasy, gamma hydroxybutyric acid (GHB)
Schedule II	High abuse potential with severe psychological or physical dependence; however, these medications have an accepted medical use and may be prescribed, dispensed, or administered	Morphine, codeine, hydrocodone, hydromorphone, methadone, oxycodone, fentanyl, methylphenidate, pentobarbital
Schedule III	Intermediate abuse potential (ie, less than Schedule II but more than Schedule IV medications)	Hydrocodone/acetaminophen 5 mg/500 mg or 10 mg/650 mg; codeine in combination with acetaminophen, aspirin, or ibuprofen; anabolic steroids; ketamine
Schedule IV	Abuse potential less than Schedule II but more than Schedule V medications	Propoxyphene, butorphanol, pentazocine, alprazolam, clonazepam, diazepam, midazolam, phenobarbital, pemoline, sibutramine
Schedule V	Medications with the least potential for abuse among the controlled substances	<i>Robitussin AC</i> , <i>Phenergan</i> with codeine

Once granted, a DEA registration may be suspended or revoked by the US Attorney General.¹ Reasons for suspending or revoking a registration include the following:

- Falsifying the application for the registration
- Having a prior conviction of a felony related to a controlled substance or a List I chemical (ie, phenylpropanolamine or pseudoephedrine)
- Having a suspension, revocation, or denial of a state license
- Committing an act that “renders registration inconsistent with the public interest”
- Being excluded from Medicare or Medicaid programs

The Attorney General may also deny registration or renewal.¹ In so doing, he or she determines whether issuing the registration or renewal would be inconsistent with the public interest. This decision is made by weighing factors such as state licensing board or professional disciplinary authority recommendations, compliance with laws regarding controlled

substances, and a prior conviction record related to any aspect of controlled substances (ie, manufacture, distribution, or dispensing). The second article in this series will focus on requirements for controlled substances prescriptions.

REFERENCES

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