

Chapter 5

Controlled Substances Laws

Chapter Outline

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Controlled Substances Laws

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Learning Objectives

1. List the five schedules of controlled substances and examples for each schedule.
2. Compare the five schedules based on risks for abuse, misuse, and dependency.
3. Identify requirements for controlled substance prescriptions, including information required from the physician and the pharmacy.
4. Describe the formula for determining the validity of a DEA number.
5. List the federal Controlled Substances Act requirements for the prescription label that is placed on a patient's container.
6. List the different DEA forms and their uses.

Introduction

Controlled substances are subject to more stringent controls by federal and state laws (and the implementing regulations) than other drugs because of the potential for misuse, abuse, diversion, and addiction. Controlled substances are used to treat a number of medical conditions such as pain, anxiety, seizures, and insomnia. Controlled substances laws and regulations establish a number of requirements for ordering, distribution, storage, recordkeeping, and handling of controlled substances by pharmacists as well as drug manufacturers, drug distributors, physicians, and other health care providers.

This chapter focuses on the *federal* controlled substances laws and regulations including schedules of controlled substances, labeling of controlled substances, prescribing and dispensing of controlled substances, transferring of controlled substance prescriptions, the Drug Enforcement Administration, ordering of controlled substances, and reporting of thefts and losses of controlled substances. The chapter also discusses state prescription monitoring programs and federal and state restrictions over the sales of products containing ephedrine, pseudoephedrine, and phenylpropanolamine. State controlled substances laws and regulations vary from state to state and coverage. Decisions regarding dispensing of controlled substances prescriptions rest with the pharmacist. Pharmacists have responsibilities under controlled substances laws to dispense valid controlled substance prescriptions issued for a legitimate medical purpose. The Drug Enforcement Administration (DEA) Pharmacists' Manual available from the DEA provides information to assist pharmacists' understanding of the federal controlled substances laws. See <http://www.dea diversion.usdoj.gov/pubs/manuals/index.html>. Controlled substances laws and regulations are subject to change, and pharmacy technicians should defer to the pharmacist regarding dispensing of controlled substances.



Key Point

Controlled substances are subject to more stringent controls by federal and state laws (and the implementing regulations) than other drugs because of the potential for misuse, abuse, diversion, and addiction.

Controlled Substances Laws

State and federal controlled substance laws add another layer of controls over drugs classified as controlled substances or regulated chemicals that apply to the practice of pharmacy. The federal Controlled Substances Act of 1970 or CSA,¹ and its regulations (21 Code of Federal Regulations Part 1300) establish comprehensive requirements and controls over the manufacture, import, export, distribu-