



PHARMACYTECH PTCE



Everything you need to know about passing the PTCE



CERTIFICATION



The PTCE

The PTCE is computer based and lasts two hours. It has 90 multiple-choice questions that must be answered in the first hour and fifty minutes. The PTCE offers a "blueprint," with an approximate percentage of questions related to specific content areas. However, there are several versions of the

PTCE exams, and students taking the same test in the same location will receive different versions of the exam. Some may contain more or less of a particular content area than another. Once you have passed the PTCE, you are entitled to use the CPST designation. You must recertify with the PTCE every two years and complete 20 hours of continuing education (CE) per two-year recertification cycle.

Licensure/Registration by State

In addition to the national certification, you may be required to become certified or registered with your state pharmacy board. Each state has different requirements for pharmacy technicians, and some do not require either national certification or state registration.

LAWS

Federal pharmacy laws are listed below. Individual states also have pharmacy laws. Where they differ, always follow the stricter law.

EN: Some medications are considered a controlled substance under state laws, but not federal.

Federal Food, Drug & Cosmetic Act of 1938 (FDCA)

- Effectively created the Food and Drug Administration (FDA), giving them the responsibility to approve all new drugs and ensure purity standards by enforcing the rules against **adulteration** and **misbranding**. Adulteration includes contamination or failure to meet purity and quality standards. Misbranding includes false, inaccurate, improper, or confusing labeling or if the product is harmful when used according to the label directions.
- The FDCA gives the FDA the power to enforce recalls if any product is in violation of these rules. These recalls may occur at the wholesaler, retail, or consumer level. There are three levels of FDA recalls:
 - Class I:** For risk of "serious adverse health consequences or death."
 - Class II:** For risk of "temporarily or medically reversible adverse health consequences" or low-probability of serious adverse health consequences.
 - Class III:** For products unlikely to have adverse health consequences.

Health Insurance Portability & Accountability Act of 1996 (HIPAA)

- HIPAA is far-reaching and regulates the way health care personnel handle Protected Health Information (PHI). HIPAA defines PHI as any individually identifiable health information. Under HIPAA, pharmacies must:
- Ensure the confidentiality of PHI. This includes all manner of transmissions, whether written, electronic, or oral (patient counseling, phone calls with providers, etc.). Under HIPAA, pharmacy staff may not disclose any PHI to anyone other than the patient, including spouses and relatives unless the patient has given express consent.
 - Train pharmacy staff on HIPAA regulations and periodically retrain or update training.
 - Protect against possible breaches with security measures.
 - Dispose of PHI in accordance with HIPAA (through measures such as incineration or shredding).

- Appoint a designated privacy officer.
- Inform patients of their privacy rights and how the pharmacy handles their information.
- Provide patients with their PHI records if requested.

Most importantly, any breach must be reported in a timely manner to the Department of Health and Human Services Office for Civil Rights. If the breach affects fewer than 500 individuals, it must be reported within 60 days of the end of the calendar year. If it affects more than 500 individuals, it must be reported within 60 days of the breach.

Occupational Safety & Health Act of 1970

The Occupational Safety and Health Act of 1970 created the Occupational Safety and Health Administration (OSHA) to ensure the safety of workers nationwide. As it relates to pharmacy, OSHA requires workers to be trained in safety measures, safety sheets to be available for all hazardous substances, and personal protective equipment (PPE) to be worn/used when exposure to hazardous substances is possible.

Controlled Substance Act of 1970

This act created formal scheduling of drugs with the potential for abuse and dependency as **controlled substances**. It led to the creation of the Drug Enforcement Administration (DEA) in 1973 to help with regulatory enforcement.

DEA Number Calculations

A DEA number is required to prescribe controlled substances except for by military practitioners and employees in public-health services, prisons, and certain long-term care facilities. Each DEA number has its own validation within its digits. Each DEA number consists of two letters and seven digits, enabling you to manually validate a DEA number. Here's how:

- The first letter corresponds to the prescriber's registration type.
- The second letter is the first letter of the prescriber's last name.
- The 1st, 3rd, and 5th numbers are added together, and the 2nd, 4th, and 6th letters are added together and multiplied by 2. Add the two resulting figures together, and the final digit should match the 7th digit, also known as the **check digit**.

EN: Dr. James Bryant sends in a prescription with a DEA number of

AB4390667.

6 + 9 + 4 = 19

3 + 0 + 6 = 9 + 2 = 18

19 + 18 = 37

Since the B in the DEA number matches the "B" in Bryant, and the 7 in 37 matches the check digit, this is a potentially valid DEA number.

Schedules (I-V)

Controlled substances are categorized into five different schedules, according to their potential for abuse and dependency:

Schedule I: No accepted medical use-high abuse potential.

EN: Illegal drugs such as LSD and heroin

Note: Cocaine is **not** schedule I, but schedule II, although it is rarely used medically.

Schedule II: High-abuse potential. According to the DEA, use of schedule II drugs potentially leads to "severe psychological or physical dependence."

EN: ADHD drugs such as Ritalin, Concerta, and Adderall; opioid analgesics such as morphine and oxycodone; and synthetic opioids such as fentanyl

Schedule III: Moderate abuse and dependency potential.

EN: Codeine-containing products (less than 90 mg) and testosterone

Schedule IV: Low abuse and dependency potential.

EN: Benzodiazepines and sleep aids such as Ambien

Schedule V: Lowest abuse and dependency potential.

EN: Codeine-containing cough syrups, Lyrica, Vimpat

Poison Prevention Packaging Act of 1970

This act requires child safety caps on all dispensed prescriptions. Easy open caps may be used if requested, and a record must be kept of the request.

Drug Listing Act of 1972

This act established rules for all drug manufacturers to supply a current drug list to the FDA. Each drug is assigned its own NDC (national drug code). The NDC is

unique to the manufacturer and package size; thus, the same medication from different manufacturers (e.g., generics) will each have their own NDC. An NDC is usually broken down into three sections:

- The first section refers to the manufacturer or repackager.
- The second section refers to the specific drug itself (including strength and form).
- The third section refers to the packaging size.

Prescription Drug Marketing Act of 1987

- Requires wholesale distributors to be licensed.
- Samples of prescription medications may only be given to licensed prescribers.
- Exported prescription drugs may not be reimported.

Omnibus Budget Reconciliation Act of 1990 (OBRA-90)

OBRA was a widespread federal deficit reduction budget bill, the pharmacy implications of which initially only pertained to Medicaid recipients. However, as it was up to individual states to determine how to enforce OBRA, most expanded the act to include all patients. Under OBRA, three major requirements are pertinent for pharmacy:

- Pharmacists must offer counseling to all patients, documenting patient referrals for counsel. (Under no circumstances should a technician counsel patients.)
- Pharmacists must perform a "prospective drug utilization review" (DUR) prior to filling each prescription, which evaluates therapy for potential problems (e.g., interactions, allergies, therapeutic duplication, and other adverse effects).
- Record-keeping mandates: Pharmacists must keep patient profiles of medications dispensed for two years on-site.

Combat Methamphetamine Epidemic Act of 2005

- Requires pharmacies to limit sales of over-the-counter medications containing pseudoephedrine or phenylephrine to 3.6 grams per purchaser per day and no more than 7.5 grams within a 30-day period. Products containing these ingredients must be kept behind the pharmacy counter or in a locked cabinet and can only be purchased by customers over the age of 18 with a valid photo ID.
- Pharmacists must maintain a logbook of each regulated purchase, including the customer's signature, address, product purchased, quantity purchased, and date and time of the sale. This logbook may be physical or electronic and must be maintained for a period of two years.

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