Credentialing Guidelines and Requirements

A Candidate Guidebook

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Regulatory Compliance Assessment-Based Certificate Program

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Regulatory Compliance Certificate Program

Scope

PTCB Regulatory Compliance certificate holders have demonstrated expert knowledge of regulatory compliance, including understanding pharmacy laws, regulations, legal requirements, and practice standards.

Eligibility Requirements

A candidate must hold an active PTCB CPhT Certification and complete a PTCB-Recognized Regulatory Compliance Education/Training Program.

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Exam

Candidates are required to pass the Regulatory Compliance Exam to earn the PTCB Regulatory Compliance Certificate. The Regulatory Compliance Exam is a computer-based exam with 70 multiple-choice questions. Be prepared to commit 1 hour and 30 minutes for the exam (5-minute tutorial, 1 hour and 20-minute exam, and 5-minute post-exam survey).

Exam Content Outline

The Regulatory Compliance Exam covers several knowledge areas organized into three domains, as shown in the following table.

Laws, Regulations, and Guidelines (37%)
Roles of various regulatory bodies
Use of USP Standards pertaining to Regulatory Compliance (e.g., appropriate application and interpretation of USP Chapters)
Federal requirements for pharmacy (e.g., non-discrimination; fraud, waste, and abuse; OIG exclusion list; HIPAA; SAMHSA; Nuclear Regulatory Commission (NRC))
Environmental Protection Agency's (EPA) hazardous waste management in the pharmacy
Federal Controlled Substances Act
Federal Food, Drug, and Cosmetic Act (FDCA)
Drug Quality and Security Act (DQSA)—Title I Compounding Quality Act (CQA), Title II Drug Supply Chain Security Act (DSCSA)
Accreditation Standards (e.g., types of accreditations, elements of accreditation, reasons for accreditation)
Legal Requirements and Practice Standards (37%)
Regulatory and accreditation-related terminology (e.g., statute, law, regulation, standard, code, certification, certificate, licensure, registration)

Basic principles that serve as the foundation for pharmacy laws and pharmacy ethics (e.g., evolution of the FD&C Act, other key legislation that has shaped pharmacy practice)
Federal requirements (e.g., DEA, FDA) for controlled substances (i.e., receiving, storing, ordering, labeling, dispensing, reverse distribution, take back programs, and loss or theft of)
Federal requirements for handling and disposal of non-hazardous, hazardous, and pharmaceutical substances and waste
Federal requirements for restricted drug programs and related medication processing (e.g., pseudoephedrine, Risk Evaluation and Mitigation Strategies [REMS])
Laws and/or regulations regarding compliance and auditing functions
Federal requirements pertaining to the medication dispensing process
Federal requirements pertaining to personnel competency
Federal requirements pertaining to compounding sterile preparations (CSP)
Federal requirements pertaining to non-sterile compounding
Licensing and reporting requirements for personnel and facility
Patient Safety and Quality Assurance Strategies (26%)
Elements of compliance programs (e.g., Just Culture, continuous quality improvement (CQI), quality assurance (QA), patient safety organization (PSO))
Methods or techniques to systematically improve accuracy (e.g., barcode scanning, Failure Mode and Effects Analysis (FMEA), Root Cause Analysis (RCA))
Cause and impact of medication dispensing errors (e.g., abnormal doses, early refill, incorrect quantity, incorrect strength, incorrect patient, incorrect drug, incorrect route of administration, incorrect directions, wrong timing, missing dose, misinterpretation of drug concentration)
Cause and impact of other types of quality-related events (e.g., incomplete counseling, patient language barrier, adverse events)
Medication storage requirements (e.g., refrigeration, freezing)
Rules, policies and regulations related to the disposal of pharmaceutical drugs (e.g., prescription drug take back programs; proper medication destruction)
Reporting of medication errors and quality-related events (e.g., internal reporting, MedWatch, VAERS, Board of Pharmacy)
Institute for Safe Medication Practices (ISMP) best practices (e.g., List of High-Alert Medications; Targeted Medication Safety Best Practices for Hospitals; Safe Preparation of Compounded Sterile Preparations; look-alike/sound-alike medications)

Exam Passing Score

A panel of subject-matter experts established a passing score for the Regulatory Compliance Exam using industry best practices. The method used by the panel, as directed by a psychometrician, is the modified-Angoff method. This method requires experts (panel members) to evaluate individual test questions and estimate the percentage of qualified pharmacy technicians that would be able to answer each question correctly. These estimates were analyzed for consistency and averaged to produce the passing score. The passing score and candidate results are reported as scaled scores. The passing scaled score for the Regulatory Compliance Exam is 300. The range of possible scores is 0 to 400.

Advanced Certified Pharmacy Technician Credential

Earning your Regulatory Compliance Certificate takes you one step closer to becoming a PTCB Advanced Certified Pharmacy Technician (CPhT-Adv). Active PTCB CPhTs who have completed at least four of the certificate programs, or three certificate programs and the Compounded Sterile Preparation Technician (CSPT) Certification, and 3 years of work experience will be eligible to earn a CPhT-Adv credential.