2025 | CANDIDATE HANDBOOK

COUNCIL ON PHARMACY STANDARDS

Certification Examination

CRDP

Certified Rare Disease Pharmacist

Council on Pharmacy Standards

COUNCIL ON PHARMACY STANDARDS

CANDIDATE HANDBOOK

Recognition, Value, Expertise...

It is what certification is all about!

ABOUT CERTIFICATION

Competency-based certification allows pharmacists to demonstrate validated, practice-relevant knowledge in a defined specialty. Through CPS certification, candidates attest to professional accountability, lifelong learning, and safe, effective practice.

The Certification Commission for the Council on Pharmacy Standards (CC-CPS) is the independent body that designs, governs, and maintains CPS certification and recertification programs. CC-CPS operates at arm's length from CPS education and operations, with formal conflict-of-interest controls, documented firewalls, and term limits to preserve independence.

CC-CPS follows recognized best-practice frameworks, including ISO/IEC 17024, the Standards for Educational and Psychological Testing (AERA/APA/NCME), and guidance from ICE and NCCA.

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ELIGIBILITY CRITERIA

All eligibility criteria must be met at the time of application

CURRENT LICENSURE

Candidates must hold a Doctor of Pharmacy (Pharm.D.) or Bachelor of Science in Pharmacy (B.S. Pharm.) degree from a program accredited by the Accreditation Council for Pharmacy Education (ACPE). Graduates of programs outside of the U.S. must hold a degree deemed equivalent and/or possess a Foreign Pharmacy Graduate Examination Committee® (FPGEC) Certificate.

PRACTICE EXPERIENCE

Current/active unrestricted licensure as a pharmacist is required. An "unrestricted" license is not currently subject to any limitations, probation, or disciplinary action.

- **U.S. Licensed Pharmacists**: Must possess an active, unrestricted license to practice pharmacy in at least one U.S. state or territory.
- **International Pharmacists**: Must hold an active and unrestricted license in their country of practice. A certified English translation must be provided if the original license is not in English.

Candidates will need to upload their license or a printout of the verification that includes their name, license number, licensing state or country, and the date the license expires.

SPECIALTY QUALIFICATION

To ensure candidates have foundational knowledge in the specialty, one of the following two pathways must be met:

1. **Standard Pathway**: Completion of one year (12 months) of experience comprised of at least 2000 hours of practice time as a licensed pharmacist in one of the above exam specialties must be documented. **This is not an either/or requirement – both time and hours must be met.**
2. **Certificate Pathway**: The specialty experience requirement is met for candidates who hold an active certificate of completion from a nationally recognized provider in a related subject matter. This includes, but is not limited to, the completion of a relevant PGY residency, fellowship, certificate/training program, or a relevant graduate degree. Recognized providers include:
    - American Society of Health-System Pharmacists (ASHP)
    - American Pharmacists Association (APhA)
    - American College of Clinical Pharmacy (ACCP)
    - American Society of Consultant Pharmacists (ASCP)

RESOURCES

CPS Exam Candidates

Use the Study Guides & Preview Tests page as the official and most current source for all exam materials.

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How to find your materials

1. Visit pharmacystandards.org/study-guides.
2. Search by certification name or acronym (e.g., CPOM).
3. Open the items under your credential:
    - **Outline** – Exam content outline & competencies
    - **Guide** – Candidate Guide with policies, sample items, and study tips
    - **Case Study** – Scenario-based practice
    - **Preview** – Short preview quiz
    - **Practice Exam** – Practice test with scoring

Before you register

- Read your Candidate Guide and Testing Guide (remote proctoring rules, ID requirements, system check, reschedule/cancel windows).
- Confirm your name on the account **matches your government ID.**
- Run the **system check** on the device and network you will use on test day.

Need help?

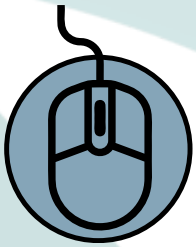
See FAQs or Contact Us from the Study Guides page.

FEES

All fees are non-refundable

Examination Fees

- The total exam fee is $395 (=$50 Application + $345 Examination).
- The $50 application fee is non-refundable.
- If you are found ineligible, CPS refunds the $345 examination portion automatically.
- After you schedule an appointment, reschedule/cancel windows and fees apply (see Administrative Policies, pp. 9–11).
- Payments are online only by Visa, Mastercard, or American Express (U.S. dollars).
- If paid by a third party (e.g., employer), any permitted refund is issued to that payer.
- Applications are not accepted by mail, phone, or fax.



$395

TOTAL EXAM FEE

Application + Examination
Includes a **non-refundable $50 application fee**.

Note: If an applicant is determined ineligible, CPS refunds the $345 examination portion. The $50 application fee is non-refundable.

Group Fee Payments

CPS will accept group payments for certification exams from institutions. Details are on the CPS website.

Other Non-refundable Payment Related Fees

Incomplete Application Fee >
All incomplete applications are subject to a non-refundable $30 reprocessing fee upon the submission of proper documentation. See page 9 for more information.

License Verification >
If licensure information is requested requiring an additional submission, the candidate will have two weeks to provide the license with all the correct information and pay the non-refundable $30 reprocessing fee. If this is not provided within the two weeks, the application will be marked ineligible. Ineligible applicants will receive a refund minus the $50.00 non-refundable application fee. There are no refunds or withdrawals for applications using a bulk code.

Credit Card Chargeback >
Assessed only if a credit-card dispute is resolved in CPS's favor. Future registrations may be blocked until balances are cleared.

FEES

All fees are non-refundable

Computer exam candidates can change their scheduled testing date to a **$50 non-refundable fee**.

Candidates may do this from within their CPS account.

Refer to CPS Testing Guide for details.

Other Exam Related Fees

Reschedule (date/time) — $50 >

Allowed ≥ **48 hours** before your appointment via your CPS account. Changes inside 48 hours are not permitted; the **no-show** policy applies.

Exam Change — $125 >

Administrative change to switch to a different exam (before an appointment is scheduled). May require re-review of eligibility.

Withdrawal — $165 >

Cancel your exam before scheduling or ≥ 7 days before your appointment to withdraw. CPS refunds the examination portion ($345) minus $165. Within 7 days, or after a no-show, the examination portion is forfeited. See Administrative Policies (pp. 9–11) for full timelines.

Retest — $395 >

Retest candidates must pay the full application ($50) and examination ($345) fees and must observe a 45-day wait before reapplying.
See Retest Policy (p. 9).

Refunds

Ineligible Computer Testing Applicants will receive a refund of the $345 examination portion (the **$50 application fee is non-refundable**) minus any outstanding charges.

No refunds

will be issued for the following circumstances:

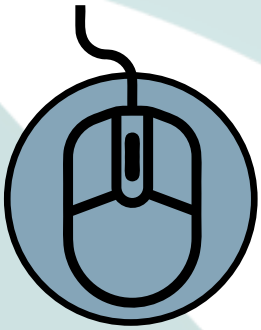
- Candidates who are not successful in achieving certification.
- No-shows or candidates who fail to test.
- Candidates who are unable to schedule within the eligibility period and do not withdraw per policy.
- Once an exam session has started.

COUNCIL ON PHARMACY STANDARDS

CANDIDATE HANDBOOK

STEPS TO REGISTER

HOW TO REGISTER FOR A CPS EXAM (REMOTE, COMPUTER-BASED)



STEP 1

Confirm eligibility

Review the **Eligibility Criteria** for your credential (link to section).

STEP 2

Submit your application

Submit your application online at the CPS website **PharmacyStandards.org**. Applications can only be submitted online. You cannot submit an application by mail, telephone or fax. Payment must be made online by credit card. Individual or group payments can be made.

STEP 3

Prepare your documents

To get prepared to complete the application - *see the application checklist on the next page*. It is a handy listing of all the information you will need to supply.

STEP 4

Email confirmation of your registration

After completing and submitting the application, you will receive an email confirmation within 30 minutes. **This will be the ONLY confirmation notice you will receive for your application. If you do not receive it, please make sure the email in your profile is accurate and check your email folders.**

STEP 5

Application approval procedure

The application will be reviewed to determine qualification to take the examination. This process can take up to two weeks, depending on the volume of applications received at the time of submission. If the application is incomplete, *see page 10* to learn how to resubmit the application and what fees will need to be paid.

STEP 6

Notification of eligibility to take the exam

If approved, an Eligibility Letter will be emailed and posted in your CPS account with instructions to schedule your exam.

Before scheduling:

- Run the system check on the device/network you will use.
- If you need accommodations, submit your request before booking.
- Ensure your account name matches your government ID.

Eligibility period: You must schedule and test within your 365-day eligibility period (see your letter).

CPS is not responsible for lost or misdirected email. ***Please make sure the email in your profile is accurate and check your account 5-7 days after you have registered*** to ensure your application was complete and additional information is not needed. If you do not receive your examination eligibility letter within 2 weeks of your examination application submission confirmation, use the "Contact Us"link on **PharmacyStandards.org** and select "Application I already submitted" from the drop down menu, to inform CPS.

APPLICATION CHECK LIST

Before filing your application look over the below checklist and gather the information needed to complete it.

- [ ] **PERSONAL INFORMATION:**
You have complete contact details (name as it appears on your government ID, address, phone, email). Your CPS profile email is current and monitored.

- [ ] **ELIGIBILITY:**
You reviewed the eligibility requirements and meet one pathway (Standard or Certificate/Training)

- [ ] **LICENSURE:**
You have your pharmacist license or primary-source verification showing name, license number, jurisdiction, type, and expiration date ready to upload. If not in English, include a certified English translation. Non-US grads include FPGEC® Certification (as applicable). Your license name matches your government ID or you have legal name-change proof.

- [ ] **EMPLOYMENT:**
You know your current employer contact info (address, phone, email) and have 5-year work history (titles, dates, specialty area, supervisor/contact). Include gaps/unemployment where applicable.

- [ ] **SPECIALTY QUALIFICATION DOCUMENTS:**
You have documentation for your pathway:
  - Standard: summary of qualifying duties and estimated 2,000 hours/12 months within the stated window (verifiable).
  - Certificate/Training: certificate of completion (or PGY/residency/fellowship/degree) plus syllabus/competency summary.

- [ ] **APPLICATION AGREEMENT:**
You will check the agreement box to e-sign the statements below. Applications cannot be submitted without consent.

I have read and agree to abide by CPS policies in the Candidate Guide and Testing Guide, including fees, reschedule/withdrawal timelines, and conduct rules. I understand and consent to remote proctoring, including room scan, screen share, and audio/video recording for security and audit. I certify the information provided is true and complete; I understand that false or misleading statements may result in denial, invalidation, or revocation. I understand my application is subject to audit and authorize CPS to contact employers, licensing boards, and education providers to verify information. I acknowledge the $50 application fee is non-refundable and that other refunds are governed by the published policy.

ADMINISTRATIVE POLICIES

Incomplete Application Processing

An application is **incomplete** if any of the following apply:

- Missing or incorrect information.
- Licensure proof missing required data (name, license number, jurisdiction, type, expiration date) or is not in English without a certified translation.
- Payment not authorized or reversed (declined card, return, or chargeback).
- Any issue that prevents CPS from determining eligibility.

Process:

Incomplete applications are returned with instructions to upload the missing items and pay a **non-refundable $30 reprocessing fee**. All filing deadlines continue to apply. If the resubmission does not fully resolve deficiencies, the application is declared ineligible (the **$50 application fee is not refundable**).

Retest Policy

Candidates who wish to retake a CPS exam must submit a **new application**, meet the then-current eligibility criteria, and pay the **full application ($50) and examination ($345) fees**. CPS does not limit lifetime attempts, but the maximum number of attempts in a calendar year is **three (3)**. Each retest uses a different form of the exam.

Mandatory waiting period

- A **45-day wait is required from the date/time of the last attempt before submitting a retest application or scheduling a new appointment.**
- The wait applies to all delivery modes of testing and all exam forms.
- Applications submitted before the 45-day mark are **not accepted**. If submitted in error, the **application fee remains non-refundable**.

Interruption / invalid attempt rules

- If an exam session experiences **candidate-side** failure (device, internet, environment, refusal of proctoring/ID), the attempt is **invalid** and a retest after 45 days is required; fees follow the **No-Refunds** policy.
- If CPS or the test vendor causes the outage, CPS will provide a no-cost reschedule of the same attempt (no 45-day wait) or, if the attempt cannot be restored, a retest after 45 days without additional fees beyond the original exam fee.

Result notice

- The 45-day date is shown on the candidate's **results/attempt notice** and in the CPS account.

All timelines and fees are governed by the most current online policy at pharmacystandards.org; online versions supersede print.

All policies and procedures are subject to change without notice

ADMINISTRATIVE POLICIES

CANDIDATE HANDBOOK

Changes & Withdrawals

Reschedule (date/time) — $50 non-refundable

For the same exam, you may change your appointment ≥ 48 hours before the start time via your CPS account.

- Must remain within your 365-day eligibility period.
- Limit: 1 reschedule per registration (additional changes require a withdrawal + new registration).
- No changes allowed < 48 hours before the appointment or on exam day.
- See Fees for no-show rules.

Exam or Eligibility-Window Change — $125 non-refundable

Use this to switch to a different CPS exam or to adjust your eligibility period (no appointment scheduled yet).

- Re-establish eligibility for the new exam; CPS may request additional documentation.
- Any approved change uses the original 365-day period (no reset).
- Request must be submitted ≥ 30 days before the end of your eligibility period.
- Limit: 1 exam/window change per registration.
- No refunds of original fees or the change fee.

Rescheduling (same exam): $50 | Exam change: $125

All candidates requesting a change MUST:

- Submit the change request within one calendar year from the first date of their original assigned eligibility period.
- Cancel their exam date (if they have one scheduled), before submitting a change. Scheduled exams may also be canceled using the "Schedule" link in your account.
- Use the CPS website online Change Request Form.
- Submit a non-refundable fee of $125 with the Change Request Form.

Not permitted

- Changes on exam day or after the appointment start time.
- Switching exams after check-in begins.
- Only CPS pharmacy credentials may be selected.

To change examination category:

- Eligibility must be re-established for the new exam category, and additional documentation and fees may be required.
- The time to consider eligibility for the new category will count toward the original assigned computer testing window.
- ***Examinees must take the exam for which they have been determined eligible. No changes will be permitted on examination day***. If a candidate knowingly or unknowingly takes an examination other than they were found eligible to take, the examination will not be scored. No refunds will be allowed, and all fee policies will apply if the candidate reapplies for an examination.
- Candidates must submit their request at least 30 days prior to the end of their 365-day eligibility period.

ADMINISTRATIVE POLICIES

Withdrawal Policy - Computer Testing

- Only the applicant/candidate may request a withdrawal.
- When you may withdraw:
  - Before scheduling an appointment, or
  - ≥ 7 days before your scheduled appointment time (withdrawal cancels the appointment).
- Refund: CPS refunds the examination portion ($345) minus a $165 withdrawal fee → $180. The $50 application fee is not refundable. Any outstanding charges are deducted from the refund.
- Requests < 7 days before the appointment or after a no-show are not eligible for any refund.

Withdrawal Policy - Bulk Purchase Voucher

Withdrawals are not allowed after eligibility is determined. Refunds are governed by the bulk purchase agreement; CPS does not issue refunds for redeemed codes. (Institutions manage reassignment within their terms.)

Substitution Policy

Candidate substitutions are not allowed. The name on the registration must match the government ID presented on test day. Name changes require legal documentation before scheduling.

Score Cancellation

CPS may cancel scores and/or invalidate an attempt for irregularities (e.g., identity mismatch, prohibited items, coaching, tampering, exam content disclosure, policy violations) with or without proof of intent. Fees are not refunded. CPS may impose waiting periods or bar future testing per policy.

Auditing Applications

Applications are subject to audit. Candidates must provide requested documentation (e.g., licensure, employment verification, training certificates) within 14 days. Failure to respond or verify may result in denial or revocation. By submitting an application, you authorize CPS to contact employers, licensing boards, and education providers for verification.

All policies and procedures are subject to change without notice

GENERAL POLICIES

How Exams are Scored

CPS exams are **criterion-referenced**: your outcome is compared to a predefined performance standard, **not** to other candidates. The passing standard is set through periodic **standard-setting studies** (e.g., Angoff/Bookmark) conducted with subject-matter experts and approved by the CPS Board.

CPS uses **item response theory (IRT)** and **test equating** to place different forms of the exam on a common scale. Because some forms may be slightly harder or easier, equating ensures fairness—candidates meeting the standard on any form receive the **same pass/fail decision**.

Score reports provide:

- Your **overall result** (Pass/Fail).
- **Content-area diagnostics** to guide study. These diagnostics are **not percent correct** and are **not comparable** across candidates or attempts. Labels indicate performance **relative to the standard** (e.g., **Below Target / Near Target / At Target / Above Target**).

The passing standard may be reviewed periodically to reflect current practice and blueprint updates.

Retention of Computer Answer Strings

CPS retains computer answer strings and operational testing data for a minimum of 3 years and may retain longer for quality assurance and legal/regulatory purposes. Identity verification media (e.g., audio/video from remote proctoring) are retained per the CPS Privacy & Data Retention Policy.

Test Disclosure

CPS does not release live test questions, answer keys, or full forms. Using, sharing, soliciting, or possessing exam content—before or after testing—is a security violation and may result in score invalidation, revocation, and suspension of testing privileges.

All policies and procedures are subject to change without notice

GENERAL POLICIES

ADA and Nondiscrimination Policies

CPS does not discriminate on the basis of **age, sex, pregnancy, race, color, religion, national origin, ethnicity, disability, marital status, sexual orientation, gender identity or expression, military/veteran status, or genetic information**.
Testing accommodations. CPS provides **reasonable accommodations** consistent with the Americans with Disabilities Act (ADA) for qualified candidates. Requests must be **submitted with the application and before scheduling** an appointment, using the CPS Accommodation Request Form (see **pharmacystandards.org/accommodations**). Documentation must be **current** and signed by a qualified clinician describing the functional limitations and recommended accommodations. CPS will acknowledge requests within **5 business days** and issue a determination within **15 business days** of receiving complete documentation. Information is **confidential** and used only for accommodation determinations. Denials may be **appealed** per the Appeals Procedure below.

Appeals Procedure

Candidates may appeal eligibility determinations, accommodation decisions, exam administration irregularities, or policy applications. Appeals must be **submitted in writing within 60 days** of the decision or event and should include relevant facts and supporting documents. CPS will acknowledge receipt within **5 business days** and render a written decision within **30 days** (or notify if additional time is required). Appeals are reviewed by the **CPS Policy Review Committee**, independent of the original decision maker, and may be escalated to the **Board of Directors**.
CPS does **not** release exam content or answer keys; score verification involves **administrative/technical re-scoring only**.

Revocation

Certification may be denied, suspended, or revoked for: falsification or misrepresentation; **exam security violations** (cheating, proxy testing, item disclosure); misuse of CPS names, logos, or marks; failure to meet or maintain eligibility/recertification requirements; **loss or restriction of the license to practice pharmacy**; nonpayment of required fees; or other material policy violations.
Prior to action, CPS will provide **written notice** of the allegations and an opportunity to **respond**. A written decision (which may include sanctions and eligibility to reapply after a specified period) will be issued and may be **appealed** under this policy.

Designation Authorization

Certification is a non-transferable, revocable, limited, non-exclusive license to use the certification designation, subject to compliance with the policies and procedures, as may be revised from time to time.

Any use or display of CPS certification marks and/or logos without the prior written permission of the CPS is prohibited. Any candidate or certificant who manufacturers, modifies, reproduces, distributes or uses a fraudulent or otherwise unauthorized CPS certificate, CPS designation or other credential may be subject to disciplinary action, including denial or revocation of eligibility or certification. Any individual who engages in such behavior also may be subject to legal action.

All policies and procedures are subject to change without notice

GENERAL POLICIES

Renew Your Certification

CPS requires **recertification every three (3) years** to verify ongoing competence in each credential's core knowledge areas.

Recertification Steps

Earn the required credit using either:

1. Continuing Education (CE) that fits your topics, or
2. Approved professional activities (e.g., teaching, publications, precepting, quality-improvement/projects, committee work).
3. Finish within 3 years, upload documentation, and keep records for audit.

Lapse & Reinstatement

If requirements are **not met by the deadline**, the credential **expires**. Expired credentials may be regained only through **re-examination**, subject to the then-current eligibility criteria. CE completed **after** expiration cannot be applied retroactively.

Audits & Recordkeeping

CPS randomly audits recertification applications. If selected, you must provide CE certificates and short activity descriptions within the requested timeframe. Maintain CE documentation **throughout the cycle and until approval**.

For further details, visit the CPS website **PharmacyStandards.org** and download the recertification catalog for a full description of the recertification process. Click on **Renew your Certification** on the home page.

Verification of Your Credential

CPS provides **third-party verification** of active credentials on request.

- **When available:** After official results post to your CPS account and your digital certificate is issued.
- **What is verified:** Credential name and ID (if applicable), **status** (active/expired), **original certification date**, and **current expiration date**.
- **How to request:** From the CPS website (see **pharmacystandards.org/verification**), select **Request a Verification**, enter the recipient's email, and submit payment.
- **Fee & delivery: $30 per request.** Verifications are sent by email to the designated party.
- **Notes:** CPS cannot verify until certification is achieved. Ensure your name and profile information are accurate before submitting a request.

All policies and procedures are subject to change without notice

EXAM CONTENT OUTLINE

How to Study

CPS does not provide review courses or study materials for the examination. CPS views the examinations as an evaluative process. Eligibility criteria have been established to identify minimum levels of preparation for the examinations. CPS believes your practice experience is your best preparation. Candidates can review detailed test outlines and suggested resources in the Candidate Guides.

Domain 1: Clinical Management and Pharmacogenomics (30%)

Task 1: Design evidence-based therapeutic plans based on patient-specific clinical and genomic data.

Integrate pathophysiology, natural history, and patient goals to formulate a comprehensive care plan.

Apply pharmacogenomic principles to select appropriate therapies and predict patient response.

Evaluate the clinical significance of variants identified in molecular diagnostic reports (e.g., NGS, WES).

Design a monitoring plan to track efficacy and toxicity using validated clinical endpoints and biomarkers.

Manage complex polypharmacy, assessing for drug-disease and drug-drug interactions.

Task 2: Interpret results from newborn screening, genetic panels, and biomarker assays.

Differentiate between screening and diagnostic genetic tests and assess their clinical validity.

Evaluate the implications of a positive newborn screening result and manage follow-up testing.

Correlate specific genotypes with disease phenotypes, prognosis, and therapeutic eligibility.

Assess the utility of various biomarkers for diagnosis, prognosis, and monitoring of treatment response.

Communicate complex genetic test results and their clinical implications to patients and interprofessional teams.

Task 3: Manage the unique pharmacological challenges of orphan drugs and novel therapeutics.

Analyze the mechanisms of action, pharmacokinetics, and pharmacodynamics of rare disease therapies.

Develop strategies to manage and mitigate the unique adverse effect profiles of orphan drugs.

Apply dosing adjustments for pediatric patients and those with organ dysfunction.

Assess the risk of immunogenicity and manage the clinical implications of neutralizing antibodies.

Evaluate the pharmacology of emerging modalities like antisense oligonucleotides, siRNAs, and enzyme replacement therapies.

Task 4: Develop protocols for the management of treatment-related toxicities and supportive care needs.

Design management plans for acute events such as infusion-related reactions, anaphylaxis, and cytokine release syndrome.

Implement proactive monitoring to detect and manage long-term or cumulative drug toxicities.

Integrate non-pharmacologic and supportive care measures to manage disease symptoms and treatment side effects.

Manage the safe use of REMS drugs with Elements to Assure Safe Use (ETASU).

Differentiate between an adverse drug event and a manifestation of the underlying disease.

Task 5: Apply principles of genetic counseling in patient communication.

Explain patterns of inheritance and recurrence risk to patients and families.

Assess patient understanding of genetic information using health literacy and teach-back principles.

EXAM CONTENT OUTLINE

Manage the ethical, legal, and social implications (ELSI) of genetic testing, including privacy and potential discrimination.

Facilitate informed decision-making regarding genetic testing for at-risk family members.

Collaborate with certified genetic counselors to provide comprehensive patient support.

Task 6: Manage the transition of care for patients with rare diseases across different life stages and care settings.

Design a structured transition plan for adolescent patients moving from pediatric to adult care providers.

Execute a comprehensive medication reconciliation process during any care transition (e.g., hospital admission/discharge).

Ensure continuity of access to critical therapies during changes in insurance or location of care.

Educate receiving care teams who may be unfamiliar with the patient's rare disease.

Coordinate with the multidisciplinary team to address the medical, psychosocial, and logistical aspects of care transitions.

Domain 2: Specialty Logistics and Advanced Therapies (20%)

Task 1: Manage the supply chain for high-cost, limited distribution, and temperature-sensitive medications.

Navigate the operational requirements for procuring drugs from limited distribution drug (LDD) networks.

Design and implement protocols to ensure cold chain integrity from procurement to administration.

Manage inventory of high-cost medications to minimize waste and prevent therapy interruptions.

Troubleshoot supply chain disruptions and coordinate with manufacturers and distributors to resolve issues.

Ensure compliance with all data reporting and contractual requirements of LDD agreements.

Task 2: Oversee the handling, preparation, and administration of Advanced Therapy Medicinal Products (ATMPs).

Apply standards for the safe handling and preparation of gene therapies (e.g., AAV-based) and cell therapies (e.g., CAR-T).

Manage the chain of identity and chain of custody for autologous and allogeneic cell therapies.

Develop institutional protocols for the unique storage requirements of ATMPs, including cryopreservation.

Coordinate just-in-time delivery and administration of patient-specific therapies with infusion centers.

Educate clinical staff on the preparation, administration, and immediate monitoring requirements for ATMPs.

Task 3: Manage long-term safety monitoring and patient registries for novel therapies.

Design patient-specific, long-term follow-up plans to monitor for delayed adverse events from gene and cell therapies.

Manage the operational aspects of patient enrollment and data submission to post-marketing safety registries.

Assess registry data for emerging safety signals or trends in long-term outcomes.

Ensure compliance with regulatory requirements for long-term follow-up (e.g., 15 years for gene therapies).

Communicate the importance of long-term follow-up and registry participation to patients and caregivers.

Task 4: Implement wastage mitigation and financial stewardship programs for ultra-high-cost therapies.

Design protocols for dose rounding and vial sharing to minimize the waste of expensive medications.

Evaluate the financial impact of different dosing strategies and vial sizes.

Implement inventory management systems to track and reduce drug waste.

Collaborate with payers to establish reimbursement policies for unavoidable drug waste.

Analyze and report on the financial savings achieved through stewardship initiatives.

EXAM CONTENT OUTLINE

Task 5: Manage investigational drug services for rare disease clinical trials.

Apply Good Clinical Practice (GCP) principles to the management of investigational drugs.

Oversee the procurement, storage, accountability, and dispensing of study medications.

Design protocols for the sterile or non-sterile preparation of investigational products, including blinding procedures.

Ensure compliance with all sponsor and regulatory requirements for record-keeping and documentation.

Collaborate with the principal investigator and research team to maintain the integrity of the study protocol.

Task 6: Coordinate complex administration across various sites of care.

Evaluate and select appropriate sites of care (e.g., hospital outpatient, infusion suite, home infusion) based on drug and patient needs.

Develop and disseminate detailed administration guidelines for infusion nurses and other healthcare providers.

Manage the logistics of scheduling and coordinating infusions, especially for therapies requiring specialized monitoring.

Troubleshoot administration-related challenges, such as difficult IV access or device malfunctions.

Ensure all sites of care meet the safety and handling requirements for the specific therapy.

Domain 3: Global Patient Access and Health Economics (20%)

Task 1: Design and execute comprehensive strategies to secure medication access and financial assistance.

Manage multi-level prior authorization appeals, including peer-to-peer reviews and external appeals.

Assemble and submit robust clinical arguments to payers, integrating evidence and letters of medical necessity.

Navigate manufacturer patient assistance programs (PAPs), co-pay programs, and independent charitable foundations.

Develop strategies to mitigate the impact of accumulator and maximizer programs on patient out-of-pocket costs.

Challenge restrictive payer policies that conflict with established standards of care or FDA labels.

Task 2: Apply principles of health economics and outcomes research (HEOR) to demonstrate product value.

Evaluate cost-effectiveness and budget impact models for ultra-high-cost therapies.

Interpret value frameworks from organizations like the Institute for Clinical and Economic Review (ICER).

Analyze the concepts of quality-adjusted life-years (QALYs) and their application in rare disease value assessment.

Synthesize real-world evidence to demonstrate the long-term clinical and economic value of a therapy.

Communicate the value proposition of a rare disease therapy to payers and health system decision-makers.

Task 3: Manage market access strategies for novel and high-cost therapies.

Assess the implications of different payment models, such as outcomes-based agreements, for rare disease therapies.

Develop formulary submission dossiers that articulate the clinical and economic value of a new product.

Differentiate between the access and reimbursement pathways for pharmacy versus medical benefits.

Analyze how payer utilization management tools (e.g., step therapy, quantity limits) impact patient access.

Contribute to the development of institutional policies for managing the financial impact of high-cost drugs.

Task 4: Navigate global health policy and cross-border access for rare diseases.

Compare international rare disease frameworks and orphan policies (e.g., FDA, EMA, PMDA, WHO).

Assess the role of international patient registries and advocacy networks in shaping global policy.

Manage the logistical and regulatory challenges of cross-border therapy importation and early access programs.

EXAM CONTENT OUTLINE

Evaluate the impact of World Health Organization (WHO) policies and initiatives on rare disease care.

Advocate for policy changes at the local, national, and international levels to improve access to care.

Task 5: Lead patient advocacy and engagement initiatives.

Collaborate with patient advocacy organizations to develop educational resources and support programs.

Empower patients and caregivers with the skills and knowledge for effective self-advocacy.

Integrate the patient perspective and patient-reported outcomes into clinical care and research.

Connect patients and families with peer support networks and community resources.

Ensure that care delivery is culturally competent and patient-centered.

Task 6: Differentiate global regulatory frameworks for orphan products.

Compare the criteria for orphan drug designation between the FDA (Orphan Drug Act) and the EMA (Regulation EC No 141/2000).

Evaluate the different market exclusivities and financial incentives offered in the US, EU, and Japan.

Assess how different regulatory bodies approach the use of surrogate endpoints and accelerated approvals for rare diseases.

Manage the submission of orphan drug designation applications to global health authorities.

Analyze how global regulatory convergence initiatives impact orphan product development.

Domain 4: Evidence Evaluation and Care Coordination (15%)

Task 1: Critically appraise clinical evidence in the context of rare diseases.

Evaluate the design and limitations of small-population clinical trials.

Assess the validity and applicability of real-world evidence, including patient registries and natural history studies.

Differentiate between statistical significance and clinical meaningfulness of trial endpoints.

Synthesize evidence from disparate sources (e.g., clinical trials, case reports, mechanistic data) to guide clinical decisions.

Analyze clinical practice guidelines and consensus statements for their applicability to individual patients.

Task 2: Lead interprofessional care teams and coordinate complex patient care.

Lead multidisciplinary rare disease care teams, integrating genetic counselors, specialists, and advocacy stakeholders.

Facilitate collaboration between local providers and specialists at national Centers of Excellence.

Design and implement patient-centered, shared care plans that span multiple specialties.

Apply telemedicine, digital health platforms, and remote monitoring tools to coordinate rare disease care.

Ensure seamless communication and care continuity across the entire healthcare team.

Task 3: Design and implement comprehensive patient and caregiver education programs.

Develop educational materials that adhere to health literacy principles for complex topics like genetics and advanced therapies.

Assess patient and caregiver understanding using methods like teach-back.

Provide training on medication administration, including self-injection techniques and infusion management.

Create customized adherence strategies based on an assessment of individual patient barriers.

Empower patients with knowledge to become active participants in their care.

Task 4: Contribute to outcomes research and quality improvement initiatives.

Design and evaluate long-term outcomes in rare disease registries, including patient-reported outcomes and quality-of-life metrics.

EXAM CONTENT OUTLINE

Manage the collection and submission of data to patient registries and other real-world evidence platforms.

Analyze quality improvement data to identify and address gaps in care.

Disseminate research findings through publications and presentations to advance the field.

Use outcomes data to demonstrate the value of specialized pharmacy services for patients with rare diseases.

Task 5: Manage the psychosocial impact of rare diseases on patients and families.

Assess patients and caregivers for psychosocial distress, including anxiety, depression, and caregiver burnout.

Provide empathetic support and connect individuals with mental health professionals and support groups.

Integrate psychosocial assessment into the routine clinical care workflow.

Develop resources to help families navigate the challenges of the diagnostic odyssey and chronic illness.

Collaborate with social workers and case managers to address non-medical barriers to care.

Task 6: Evaluate the ethical frameworks for resource allocation and genetic medicine.

Apply principles of bioethics to clinical dilemmas in rare disease care.

Analyze the ethical considerations surrounding access to ultra-high-cost therapies and resource allocation.

Assess the ethical implications of genetic testing, including pre-symptomatic testing and incidental findings.

Navigate conflicts of interest in a healthcare landscape with significant industry involvement.

Advocate for equitable and just access to care for all patients with rare diseases.

Domain 5: Genomics, Regulatory Pathways, and Emerging Therapies (15%)

Task 1: Apply principles of human genetics and molecular diagnostics in rare disease management.

Differentiate between various types of genetic mutations (e.g., missense, nonsense, frameshift) and their functional impact.

Evaluate the diagnostic yield and limitations of different testing platforms (e.g., single gene, panel, WES/WGS).

Assess the clinical actionability of genetic variants based on established classification guidelines (e.g., ACMG).

Apply genetic findings to confirm diagnoses, predict disease course, and guide therapy selection.

Manage the interpretation of variants of uncertain significance (VUS) in clinical practice.

Task 2: Evaluate global regulatory pathways for orphan drugs and accelerated approvals.

Manage the process for obtaining Orphan Drug Designation from the FDA and the EMA.

Assess a drug's eligibility for expedited pathways such as FDA's Accelerated Approval and EMA's Conditional Marketing Authorisation.

Design post-marketing confirmatory study plans required for converting an accelerated to a full approval.

Analyze the use of novel clinical trial designs (e.g., basket trials, n-of-1 trials) in rare disease drug development.

Differentiate the evidentiary standards for approval among major global health authorities.

Task 3: Manage patient enrollment in clinical trials, registries, and expanded access programs (EAPs).

Assess patient eligibility for participation in interventional clinical trials.

Facilitate patient access to investigational therapies through EAPs ("compassionate use").

Manage the operational requirements for enrolling patients in long-term observational registries.

Differentiate the regulatory frameworks for clinical trials versus EAPs.

EXAM CONTENT OUTLINE

Apply ethical principles to ensure informed consent and protect patient welfare in the research setting.

Task 4: Assess the unique regulatory and clinical requirements for gene and cell therapies.

Evaluate the specific CMC (Chemistry, Manufacturing, and Controls) challenges for ATMPs.

Manage the clinical requirements for long-term follow-up to monitor the durability and safety of gene therapies.

Assess the regulatory pathways for specific ATMPs, such as CAR-T cells and AAV-based gene replacement therapies.

Differentiate the regulatory frameworks for ATMPs between the US (RMAT designation) and EU (ATMP Regulation).

Apply risk management principles to the unique safety profiles of gene and cell therapies.

Task 5: Apply ethical principles to genetic testing and precision medicine in rare pediatric populations.

Manage the ethical complexities of pre-symptomatic and carrier testing in minors.

Assess the challenges of obtaining informed consent and assent from pediatric patients and their families for genomic medicine.

Evaluate the ethical considerations of using novel or off-label therapies in children with rare diseases.

Navigate dilemmas related to the return of secondary or incidental genetic findings.

Advocate for the equitable inclusion of pediatric patients in clinical research.

Task 6: Evaluate emerging therapeutic technologies and their clinical application.

Assess the mechanism of action and therapeutic potential of novel modalities like CRISPR/gene editing and mRNA therapies.

Analyze the clinical development and potential applications of radiopharmaceuticals in rare diseases.

Evaluate the role of digital therapeutics and artificial intelligence in rare disease management.

Monitor the evolving regulatory landscape for these emerging technologies.

Translate the science of novel platforms into understandable concepts for patients and providers.

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