2025 | CANDIDATE HANDBOOK

COUNCIL ON PHARMACY STANDARDS

Certification Examination

CPxP

Certified Pharmacogenomics 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?

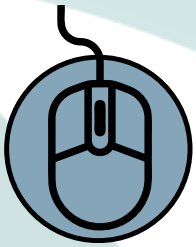
See FAQs or Contact Us from the Study Guides page.

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:

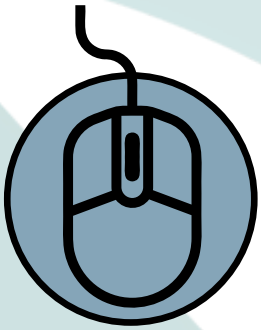
- Candidates who are not successful in achieving certification.
- No-shows or candidates who fail to test.
- Candidates who are unable to schedule within the eligibility period and do not withdraw per policy.
- Once an exam session has started.

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

CANDIDATE HANDBOOK

ADMINISTRATIVE POLICIES

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: Foundational Genomic and Genetic Principles (15%)

Task 1: Apply principles of clinical genetics and nomenclature.

Define basic genetic terms, such as gene, allele, genotype, and phenotype.

Differentiate between different types of genetic variants.

Interpret standard gene nomenclature, including star allele nomenclature.

Explain how genetic variation can arise and be maintained in a population.

Task 2: Evaluate the function of key pharmacokinetic pharmacogenes.

Describe the function and genetic variability of key CYP enzymes (e.g., CYP2D6, CYP2C19, CYP2C9).

Describe the function of Phase II metabolizing enzymes and transporters (e.g., UGTs, TPMT, SLCO1B1).

Explain how genetic variants can lead to different metabolizer phenotypes.

Recognize the importance of phenoconversion.

Task 3: Evaluate the function of key pharmacodynamic pharmacogenes.

Explain how genetic variants in drug targets can alter drug response.

Describe the role of VKORC1 in the warfarin pharmacodynamic pathway.

Describe the function of HLA genes and their association with hypersensitivity reactions.

Explain the role of drug transporters in drug disposition and toxicity.

Task 4: Evaluate the genetic basis of idiosyncratic drug reactions.

Describe the strong association between specific HLA alleles and severe cutaneous adverse reactions (SCARs).

Identify the HLA-B*57:01 allele as a risk factor for abacavir hypersensitivity.

Identify the HLA-B*15:02 allele as a risk factor for carbamazepine-induced SJS/TEN in certain populations.

Recognize the importance of pre-emptive genotyping for certain HLA-associated reactions.

Task 5: Apply principles of population genomics and ancestry.

Understand that the frequencies of pharmacogenetic variants can differ significantly among ancestral populations.

Apply knowledge of population-specific allele frequencies when interpreting test results.

Describe the ethical and social implications of using race or ethnicity in pharmacogenomics.

Recognize the importance of increasing diversity in genomic research.

Task 6: Differentiate between pharmacogenomics and other omics technologies.

Define pharmacogenomics and differentiate it from pharmacogenetics.

Describe the role of other omics technologies (e.g., proteomics, metabolomics) in personalized medicine.

Understand how multi-omics data can be integrated to provide a more complete picture of drug response.

Recognize the current and future applications of omics beyond pharmacogenomics.

CANDIDATE HANDBOOK

EXAM CONTENT OUTLINE

Domain 2: Pharmacogenomic Testing and Interpretation (20%)

Task 1: Evaluate appropriate pharmacogenomic (PGx) tests.

Determine when a PGx test is clinically indicated based on the patient and the planned drug therapy.

Differentiate between reactive (single-gene) and pre-emptive (multi-gene panel) testing strategies.

Select the most appropriate test based on the specific drug-gene interaction of concern.

Understand the difference between clinical-grade genetic tests and direct-to-consumer (DTC) tests.

Task 2: Evaluate various PGx testing platforms and laboratory operations.

Differentiate between genotyping and sequencing technologies, including next-generation sequencing (NGS).

Recognize the strengths and limitations of different testing platforms, such as whole-genome vs. panel-based tests.

Assess the CLIA certification, CAP accreditation, and other quality metrics of a testing laboratory.

Understand that a "no variant detected" result on a targeted panel does not rule out the presence of a rare variant.

Task 3: Translate genotype results into clinical phenotypes.

Use standardized tables (e.g., from CPIC) to translate a diplotype into a predicted phenotype.

Calculate a CYP2D6 activity score based on the assigned values of the patient's alleles.

Assign a metabolizer status phenotype (e.g., poor, intermediate, normal, ultrarapid).

Consider non-genetic factors (phenoconversion) that may alter the predicted phenotype.

Task 4: Interpret a pharmacogenomic test report.

Identify the key components of a PGx laboratory report.

Evaluate the drug-specific recommendations provided on the report.

Assess the quality and evidence base of the interpretations provided by the lab.

Cross-reference the lab report with primary literature and clinical guidelines.

Task 5: Apply standards for variant classification.

Understand the principles of variant classification according to ACMG/AMP standards.

Differentiate between pathogenic, likely pathogenic, uncertain significance, likely benign, and benign variants.

Utilize public databases such as ClinVar to assist in variant interpretation.

Recognize the importance of re-evaluating variants of uncertain significance over time.

Task 6: Assess the clinical validity and utility of PGx tests.

Define and differentiate between analytical validity, clinical validity, and clinical utility.

Assess the clinical validity of a test by evaluating the strength of the gene-drug association.

Critically appraise the evidence for the clinical utility of a test in improving patient outcomes.

Prioritize the implementation of PGx tests with demonstrated clinical utility.

Domain 3: Clinical Application and Therapeutic Decision-Making (30%)

Task 1: Apply guidelines for cardiovascular drugs.

Apply CPIC guidelines to guide antiplatelet therapy based on CYP2C19 genotype.

Utilize VKORC1, CYP2C9, and CYP4F2 genotypes to guide initial dosing of warfarin.

Use SLCO1B1 genotype to guide statin selection and dosing to reduce the risk of myopathy.

Recommend alternative therapies for patients with high-risk genotypes.

EXAM CONTENT OUTLINE

Task 2: Apply guidelines for psychiatric drugs.

Apply CPIC guidelines to guide the selection and dosing of SSRIs and tricyclic antidepressants based on CYP2D6 and CYP2C19 genotypes.

Utilize PGx information to manage therapy with other psychotropic medications, such as antipsychotics.

Use PGx to explain a patient's previous treatment failures or intolerances.

Integrate PGx data into a comprehensive approach to psychiatric medication management.

Task 3: Apply guidelines for pain management drugs.

Apply CPIC guidelines to avoid the use of codeine and tramadol in CYP2D6 ultrarapid and poor metabolizers.

Use CYP2D6 genotype to guide the dosing of other opioids, such as hydrocodone and oxycodone.

Utilize CYP2C9 genotype to guide the dosing of certain NSAIDs.

Make specific therapeutic recommendations to ensure both effective analgesia and patient safety.

Task 4: Apply guidelines for oncology drugs.

Apply CPIC and other guidelines to guide the dosing of thiopurines and fluoropyrimidines.

Understand the role of somatic (tumor) genetic testing in guiding targeted cancer therapies.

Differentiate between germline PGx for toxicity and somatic mutations for efficacy.

Utilize PGx to reduce the risk of severe, life-threatening toxicities with chemotherapy.

Task 5: Manage drug-drug-gene interactions in the context of polypharmacy.

Synthesize a patient's PGx results, clinical data, and full medication list to create a holistic plan.

Evaluate how a single genetic variant can impact multiple drugs in a patient's regimen.

Assess the combined impact of multiple genetic variants on a patient's overall drug therapy.

Resolve complex cases involving ambiguous results or conflicting data.

Task 6: Manage PGx considerations in special populations.

Adapt PGx recommendations for pediatric patients, considering developmental changes in gene expression.

Apply PGx principles in geriatric patients, accounting for polypharmacy and comorbidities.

Evaluate PGx data in specific therapeutic areas such as oncology and psychiatry.

Respond to new PGx-based FDA safety alerts and recalls.

Domain 4: Practice Implementation and Patient Education (15%)

Task 1: Design a clinical PGx implementation program.

Conduct a needs assessment and build a business case for a new PGx service.

Develop a strategic plan for a phased implementation of PGx testing.

Establish a governance structure, such as a PGx committee, to oversee the program.

Develop standardized workflows for ordering tests, interpreting results, and making recommendations.

Task 2: Provide patient counseling on PGx results.

Explain the purpose of pharmacogenomic testing in patient-friendly language.

Communicate the patient's specific test results and what they mean for their medication therapy.

Counsel on the specific medication changes that are recommended based on their results.

Address any questions or concerns the patient may have about their genetic information.

EXAM CONTENT OUTLINE

Task 3: Educate providers and other healthcare professionals.

Develop and deliver educational presentations on pharmacogenomics to physicians, pharmacists, and nurses.

Create concise educational materials, such as tip sheets and newsletters.

Provide one-on-one "academic detailing" or consultation for providers with specific questions.

Serve as a subject matter expert and resource for the entire healthcare organization.

Task 4: Implement interprofessional training programs.

Design and deliver training programs to nurses, physicians, and genetic counselors on their roles in the PGx process.

Develop a "super user" program to build expertise within clinical departments.

Foster a collaborative, team-based approach to the implementation of PGx.

Use a train-the-trainer model to scale educational efforts across a large organization.

Task 5: Implement telehealth delivery of PGx counseling.

Utilize telehealth platforms to provide remote PGx consultations and patient counseling.

Adapt communication and educational techniques for a virtual environment.

Ensure that the delivery of telehealth services is compliant with all legal and privacy regulations.

Use digital tools to share PGx information securely with patients and providers.

Task 6: Implement culturally competent and health-literate patient education.

Tailor all verbal and written communication to the patient's level of understanding.

Engage interpreters for patients with limited English proficiency.

Ensure that care plans are culturally sensitive and respectful of patient beliefs about genetics.

Employ universal precautions for health literacy and the teach-back method in all patient interactions.

Domain 5: Informatics, Data Science, and Technology in PGx (10%)

Task 1: Integrate PGx into Electronic Health Records (EHRs) and clinical decision support (CDS).

Collaborate with informatics teams to build PGx alerts and guidance within the EHR.

Design CDS that is interruptive for high-risk, pre-emptive scenarios.

Develop a process for entering structured PGx results into the EHR.

Troubleshoot CDS alerts, including managing alert fatigue.

Task 2: Utilize bioinformatics tools for variant interpretation.

Use online databases (e.g., PharmGKB, CPIC) to find evidence for drug-gene associations.

Utilize tools to translate genotypes into phenotypes and clinical recommendations.

Evaluate the evidence supporting the information in various PGx knowledgebases.

Use bioinformatics tools for PGx data visualization.

Task 3: Apply big data and AI/ML approaches to pharmacogenomics.

Understand how real-world data (RWD) from EHRs and claims can be used to discover and validate PGx associations.

Describe the use of artificial intelligence and machine learning in predicting drug response.

Analyze data from large-scale biobanks to understand population-level PGx.

Evaluate the potential of AI-driven tools to enhance clinical decision support.

EXAM CONTENT OUTLINE

Task 4: Manage data privacy, interoperability, and cybersecurity.

Ensure that all storage and sharing of PGx data is compliant with HIPAA and other privacy regulations.

Promote the use of interoperability standards (e.g., FHIR) for the exchange of genetic data.

Implement cybersecurity measures to protect sensitive genetic information.

Develop policies and procedures for the secure sharing of PGx data with patients and other providers.

Task 5: Evaluate the role of PGx in drug development.

Understand how PGx is used in clinical trials to stratify patients and identify responders.

Describe the process for incorporating PGx information into a new drug's FDA label.

Evaluate how PGx can be used to "rescue" a drug that failed in clinical trials.

Recognize the growing importance of PGx in the drug development pipeline.

Task 6: Manage PGx-based drug safety crises.

Develop a plan for responding to a new FDA safety warning based on pharmacogenomic data.

Implement a process for identifying and notifying patients who may be at risk.

Manage a large-scale intervention, such as a recall or revised prescribing guidelines.

Communicate effectively with patients and providers during a safety crisis.

Domain 6: Ethics, Regulatory, and Health System Integration (10%)

Task 1: Manage ethical considerations in pharmacogenomics.

Apply ethical principles of autonomy, beneficence, and justice to PGx testing.

Manage the process of informed consent, ensuring the patient understands the scope of testing.

Develop a policy for the management of incidental findings and the return of results.

Address patient concerns about genetic privacy and the potential for discrimination.

Task 2: Implement strategies to address health equity and access.

Analyze how disparities in access to PGx testing can exacerbate health inequities.

Develop strategies to ensure equitable access to testing for underserved and diverse populations.

Advocate for the inclusion of diverse populations in genomic research.

Ensure that PGx implementation programs are designed to be equitable.

Task 3: Evaluate regulatory frameworks for PGx testing.

Understand the role of the FDA in regulating PGx tests and drug labels.

Describe the role of CLIA in ensuring the analytical validity of laboratory-developed tests.

Compare the U.S. regulatory framework to international counterparts (e.g., EMA, PMDA, Health Canada).

Stay current with the evolving regulatory landscape for genetic testing.

Task 4: Implement health system-wide PGx strategies.

Contribute to the development of institutional policies and procedures for PGx.

Participate in a multidisciplinary PGx steering committee or workgroup.

Collaborate with laboratory, informatics, and clinical teams to create an integrated program.

Advocate for the adoption of PGx at the institutional level.

EXAM CONTENT OUTLINE

Task 5: Evaluate economic and reimbursement models for PGx.

Understand the current coverage policies of CMS and major commercial payers for PGx testing.

Evaluate the pharmacoeconomic evidence supporting the cost-effectiveness of PGx testing.

Develop a business case to justify investment in a PGx program.

Navigate the billing and coding process for PGx tests and associated clinical services.

Task 6: Collaborate with interprofessional care teams.

Serve as the primary PGx expert for physicians, nurses, genetic counselors, and other providers.

Communicate complex genetic information in a clear and actionable manner.

Integrate PGx recommendations into the patient's overall care plan.

Foster a team-based approach to the implementation of personalized medicine.

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