COPT Learning Guide – Domain I

Core Oncology Pharmacy Training (25% of Exam)

Overview: Domain I will assess your fundamental knowledge as an oncology pharmacy technician. You will need to understand oncology pharmaceutical calculations and be familiar with safety regulations and accreditation within the pharmacy field.

Instructions: This guide describes the concepts to know and the practice problems for each section of the exam content outline. Use the corresponding hyperlinks in each section to complete this guide.

Important Note: This guide was developed to help you prepare for the COPT examination. It should be utilized in addition to your own notes, as it is not an all-inclusive review of all exam topics.

Objective 1.1: Identify mathematical computations relevant to oncology pharmacy.

Description:	Oncology pharmacy technicians must have a baseline understanding of calculations used for dosing oral oncologic medications. Dosing calculations are specific to each patient, thereby optimizing treatment efficacy and minimizing adverse events. Although oncology pharmacy technicians are not responsible for using the calculations to dose medication, it is important to know how oral oncolytic medication doses are calculated and what factors need to be collected for the pharmacist to complete the calculation (e.g. age, gender, weight, etc.).
Calculations	Some oral oncolytic medications are dosed according to the patient's body surface area (BSA), while creatinine clearance (CrCl) is used to adjust doses based on kidney function and identify any potential medication issues. By understanding these calculations, pharmacy technicians can play a vital role in detecting errors and ensuring patients receive the correct amount of medication is dispensed for safe and effective treatment. Body Surface Area • Body Surface Area (BSA) is the total surface area of the human body. • BSA is used in calculating some oral oncolytic medication doses. • Factors: Height and body weight are needed to complete this calculation. • $BSA\ (m^2) = \sqrt{\frac{height\ (cm) \bullet weight(kg)}{3600}}$ Creatinine Clearance • Cockcroft Gault's Equation is used to calculate Creatinine Clearance (CrCl) • Factors: Age, weight, creatinine serum, and gender and needed to complete the calculation. • Creatinine Clearance is used to check a patient's kidney function and is used to adjust doses for renally excreted medications. • $CrCl\ \left(\frac{ml}{min}\right) = \frac{[140-age\ ]\bullet[body\ weight\ (kg)]}{Serum\ creatinine\ \left(\frac{mg}{dl}\right) \bullet 72} \rightarrow Multiply\ answer\ by\ 0.85\ if\ Female$
Conversions	When calculating medication doses, weight is used in grams or kilograms (not pounds), and height is used in centimeters (not inches and feet). Fill in the missing conversations below. Pounds to Kilograms • 2.2 lbs. ≈ Choose an item. kg Grams to Milligrams

	• 1g = Choose an item. mg Kilograms to Grams • 1kg = Choose an item.g Inches to Centimeters • 1in = Choose an item.cm
Practice Problems	1. Convert 78 kilograms to grams. Answer: 2. What factors are NOT needed to calculate Body Surface Area? (Select all that apply) a. Height in inches b. Height in centimeters c. Weight in kilograms d. Age 3. Which of the following statements are true about Cockcroft Gault's Equation? (Select all that apply) a. The equation includes age, weight, gender, and serum creatinine. b. It is used to adjust doses or renally excreted medication. c. It is used to estimate lung capacity. d. Calculates Creatinine Clearance (CrCl).

Objective 1.2: Define common medical terminology related to oncology care and oral oncolytics.

Description	A foundational understanding of medical terminology equips oncology pharmacy technicians to perform their duties safely and effectively. It will help with clear communication, reduce medication errors, and ultimately improve patient care. While you will not be asked to simply define terms on the exam, you must be familiar with the basic definitions to fully understand all exam questions.
National Cancer Institute Dictionary of Cancer Terms	Use the National Cancer Institute Dictionary of Cancer Terms to define the following terms. Absolute neutrophil count (ANC): Acute: Adenocarcinoma: Adjuvant therapy: Adverse event (AE): Alopecia: Anemia: Anorexia: Antiemetic: Antineoplastic: Apoptosis: Aromatase Inhibitor (AI): Asymptomatic: Bilirubin: Biomarker testing: Biosimilar: Cachexia: Cardiotoxicity:

	Carcinoembryonic antigen (CEA): Comorbidity: Copay: Deductible: Disease progression: Deep Vein Thrombosis (DVT): Epidermal Growth Factor Receptor **(**EGFR): Emetogenic: Hand-foot syndrome: Hemorrhage: Hormonal therapy: Hormone receptor: Hyperglycemia: Hypertension: Immunotherapy: KRAS Gene: Low-income subsidy: Lymphedema: Medicare: Medicaid: Metastatic: Monotherapy: Neurotoxicity: Neutropenia: Palliative care: Precision medicine: Prophylaxis: Proteinuria: Radiation therapy: Refractory: Regimen: Sarcoma: Second-line treatment: Staging: Symptomatic: Targeted therapy: Thrombocytopenia: Tumor lysis syndrome (TLS): Tumor profiling:
Additional Terms	The following terms are not defined in the National Cancer Institute Dictionary of Cancer Terms. Use an internet search engine to identify their basic definitions. Blood glucose: Chromosomal abnormalities: Chronic: Chronic kidney disease: Cytotoxic: DIR Fees: Dispense as Written (DAW): Federal Employee Program (FEP): Hazardous drugs: Neo-adjuvant therapy: Personal Protected Equipment (PPE): Pneumocystis Jirovecii Pneumonia (PJP): QT prolongation:

Practice Problems	Use the pull-down to complete sentences with the correct term. 1. The patient is exhibiting Choose an item. side effects, such as nausea and vomiting, following chemotherapy, indicated by the sudden and severe onset of symptoms. 2. The oncologist recommended Choose an item. after the patient's surgery to prevent cancer reoccurrence. 3. Choose an item. presents as a distinct side effect characterized by swelling due to lymphatic system damage. 4. Patients on oral chemotherapy medication develop Choose an item., a condition characterized by abnormally low levels of white blood cells (neutrophils) in the blood. 5. Choose an item. harnesses the body's immune system to fight cancer. 6. Choose an item. offer a more precise approach to cancer treatment aiming to specifically inhibit cancer cell growth while minimizing damage to healthy tissue. 7. Choose an item. are retroactive charges that reduce the reimbursement pharmacies receive from pharmacy benefit managers (PBMs). 8. The tumor marker Choose an item. is found in the blood and can help track how well cancer treatments work. 9. The patient received a prescription for a Choose an item. to alleviate their nausea. 10. As part of the patient's treatment plan, Choose an item. measures were implemented to manage the potential side effects of the oral chemotherapy drugs.

Objective 1.3: Identify the roles and functions of common pharmacy organizations and accrediting bodies.

Description	It is essential for oncology pharmacy technicians to know about accrediting pharmacy bodies because these organizations set the standards for safe, high-quality patient care, particularly in specialized areas like oncology. Understanding accrediting bodies helps pharmacy technicians stay informed on best practices, compliance requirements, and industry changes, ensuring they meet high standards for handling and dispensing complex cancer therapies.
Pharmacy Resources	Oncology pharmacy technicians should be familiar with available pharmacy recourse programs that assist in managing patients undergoing treatment with oral oncolytic medications. Click on each hyperlink to review the resources and take notes on the information and functions they provide. ● MedWatch ○ Function: ○ Information you should report to MedWatch: ● National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) ○ Function: ○ Information you should report to NCCMERP:

	• National Institute for Occupational Safety and Health (NIOSH)
	  ○ Function:
	• ChemoCare
	  ○ Function:

Accrediting Bodies	Pharmacy accreditation bodies play a vital role in maintaining high standards of quality care and safety. By being knowledgeable about accreditation bodies, pharmacy technicians can ensure that their practices align with established guidelines and standards.
	
	Review the article Independent Pharmacy Accreditation to take notes on the three bodies responsible for accrediting specialty pharmacies.
	
	• Accreditation Commission for Health Care (ACHC)
	  ○
	• Center for Pharmacy Practice Accreditation (CPPA)
	  ○
	• Utilization Review Accreditation Commission (URAC)
	  ○

Practice Problems	1. A patient was administered the wrong medication as the bottles of different medicines manufactured by the company looked identical. Which organization should this error be reported to?
	  a. MedWatch
	  b. NCC MERP
	  c. NIOSH
	  d. ChemoCare
	
	2. A patient's family has requested additional information about cancer wellness. What resource could you provide them?
	  a. MedWatch
	  b. NCC MERP
	  c. NIOSH
	  d. ChemoCare
	
	3. What does URAC (Utilization Review Accreditation Commission) primarily focus on in the healthcare industry?
	  a. Pharmaceutical Research and Development
	  b. Hospital Facility Accreditation
	  c. Quality and Accountability in Healthcare Management
	  d. Medical Device Regulation

Objective 1.4: Describe the USP 800 and NIOSH safety standards for handling and storage of oral oncolytic medications.

Description	USP 800 and NIOSH safety standards focus on protecting healthcare workers and the environment from hazardous medications. NIOSH identifies these medications based on potential harm, while USP 800 sets comprehensive guidelines for their handling. Pharmacy technicians must be familiar with these standards to minimize exposure risks throughout the entire medication lifecycle, from receiving to disposal.
USP 800	The USP General Chapter 800 provides safety standards for handling hazardous medications such as oral oncolytics to help prevent the risk of exposure. USP 800 standards are the pharmacy's fundamental guide to ensure minimum risk to patients and pharmacy staff who come in contact with hazardous medications.

	Oncology pharmacy technicians should be familiar with USP 800 requirements for containment, storage, personal protective equipment (PPE), and final dosage form as they relate to oral oncolytic medications. Review the USP 800 – Hazardous Drugs. Take notes on the following sections: • Containment Requirements (Box 1) ○ • Receipts (5.1) ○ • Storage (Section 5.2) ○ • Personal Protective Equipment (all of section 7) ○ • Final Dosage Form (all of section 12) ○
NIOSH	The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that oversees workplace hazards. NIOSH informs healthcare workers, including pharmacy technicians, about workplace hazards and ways to improve safety. The NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings documents provides a full list of hazardous medications, a definition of hazardous medications, classifications, and supplemental information to be used as standard precautions. Review NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings and take notes on the following: Drugs Considered Hazardous • 1. General Approach to Handling Hazardous Drugs ○ Group 1: ○ Group 2: ○ Group 3: • 2. Defining Hazardous Drugs ○ Drugs considered hazardous include those that exhibit one or more of the following five characteristics in humans or animals: ▪ 1: ▪ 2: ▪ 3: ▪ 4: ▪ 5: • 3. How to Generate Your Own List of Hazardous Drugs ○ NIOSH List of Hazardous Drugs: NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 (Define each table. What information is on each table, and how are the tables different? You do not need to memorize the medications and information within each table) • Table 1: • Table 2: • Table 3:
Practice Problems	1. What PPE is needed when dispensing in final dosage forms? (Select all that apply) a. Shoe covers

	b. Face shield c. Gown d. One pair of chemo gloves e. Hair net 2. The pharmacy technician has been assigned to do an oral HD inventory of stock on hand. Several bottles of HD medication are open. What should be used to count the HD medications? a. Automatic counting machine b. Using one pair of chemo gloves and face protection c. No designated area is needed d. Separate counting tray and spatula 3. According to Section B of the NIOSH List of Hazardous, which criteria are used to classify a drug as hazardous? a. Therapeutic efficacy b. Patient age group c. Reproductive toxicity, carcinogenicity, and other toxicities d. Cost-effectiveness 4. Which of the following are characteristic of Hazardous Drugs as defined by NIOSH? (Select all that apply) a. Carcinogenicity b. Development Toxicity c. Reproductive Toxicity d. Cytotoxicity e. Genotoxicity

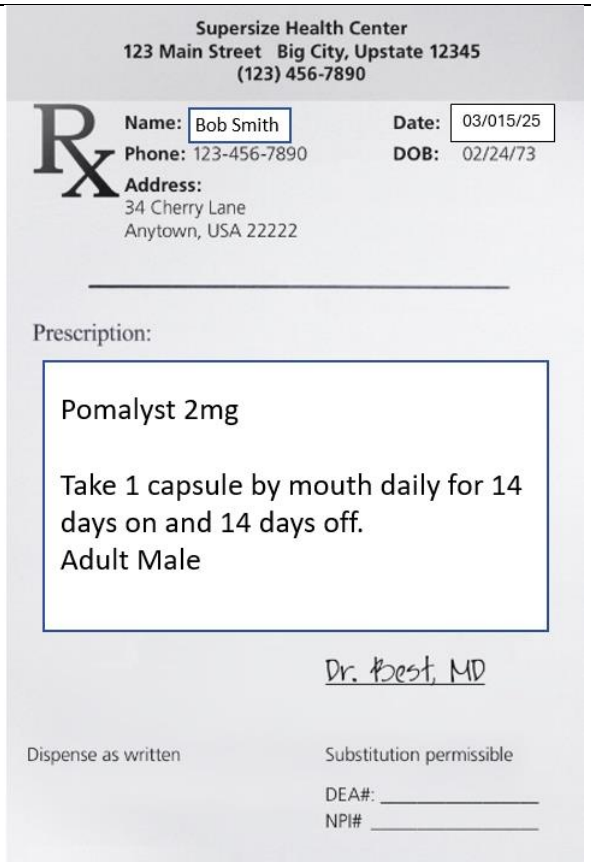
Objective 1.5: Identify the purpose of the Risk Evaluation and Mitigation Strategies (REMS) Program and dispensing requirements.

Description	The Risk Evaluation and Mitigation Strategy (REMS) is a medication safety program designed by the U.S. Food and Drug Administration (FDA) that helps ensure medications are used safely and the risks of severe side effects are minimized. The REMS program helps to ensure that the patient, caregiver, and prescriber have all been properly educated on medication risk factors.
Risk Evaluation and Mitigation Strategies (REMS)	While all oral oncolytics require safe handling and pose risks, it is important to note that not all medications require a REMS program. There are three factors the FDA has identified to distinguish a REMS medication: • The medication is highly effective but can cause serious side effects. • It contains a new chemical structure that has not been used in the past. • The medication can treat serious and rare diseases, but the risk of taking the medication is very high. Dispensing Requirements of all REMS Products: • Prescribing MD, DO, NP, or PA must be enrolled as a provider in the REMS Program for each product they wish to prescribe. • Patients must complete REMS enrollment and sign consent to be on the medication. • An authorization number must be obtained by the provider from the REMS program to be written on the prescription.

	• Prescriptions must include both the authorization number as well as the corresponding Patient Risk Factor (for lenalidomide, pomalidomide and thalidomide:
	  ○ Adult male
	  ○ Adult female non-reproductive
	  ○ Adult female of reproductive age
	• Prescriptions cannot be written for more than 28-day supply
	• No refills are allowed on the prescription
	• A new prescription must be written for each medication refill
	• Patient surveys are required for each patient risk factor schedule
	
	Review the general information and take additional notes on Risk Evaluation and Mitigation Strategies (REMS). Be sure to include the program's purpose.
	• Notes:

Immunomodulator Drug Class	While several oral oncolytic medications require the REMS program, the immunomodulator drug class has very specific dispensing requirements.
	
	Click on each of the medications below and navigate to the summary tab. Review the "Healthcare providers who prescribe" section and take notes on the following medications in the Immunomodulator Drug Class.
	• Lenalidomide
	  ○ Healthcare providers who prescribe lenalidomide must:
	• Pomalidomide
	  ○ Healthcare providers who prescribe pomalidomide must:
	• Thalidomide
	  ○ Healthcare providers who prescribe thalidomide must:

Practice Problems	1. Which REMS requirement(s) are missing from the prescription? (Select all that apply)



Supersize Health Center
123 Main Street Big City, Upstate 12345
(123) 456-7890

Rx

Name: Bob Smith
Phone: 123-456-7890
Address:
34 Cherry Lane
Anytown, USA 22222

Date: 03/015/25
DOB: 02/24/73

Prescription:

Pomalyst 2mg

Take 1 capsule by mouth daily for 14 days on and 14 days off.
Adult Male

Dr. Best, MD

Dispense as written

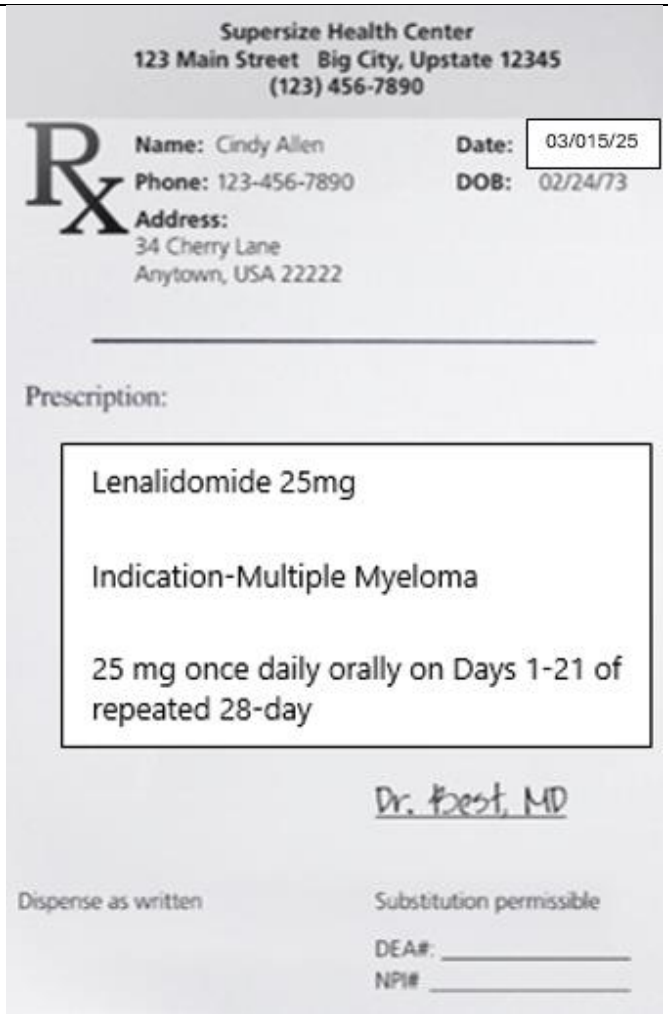
Substitution permissible

DEA#: _____
NPI# _____

a. Patient Risk Factor
b. Day Supply
c. Authorization Number
d. Number of Refills

2. Which statement is NOT true about the REMS program?
    a. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.
    b. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.
    c. REMS are designed to mitigate all the adverse events of a medication.
    d. REMS focuses on preventing, monitoring, and/or managing a specific risk.
    e. REMS is run by the U.S. Food and Drug Administration (FDA).

3. What is the Patient Risk Factor for the following patient?



Supersize Health Center
123 Main Street Big City, Upstate 12345
(123) 456-7890

Rx

Name: Cindy Allen
Phone: 123-456-7890
Address:
34 Cherry Lane
Anytown, USA 22222

Date: 03/015/25
DOB: 02/24/73

Prescription:

Lenalidomide 25mg

Indication-Multiple Myeloma

25 mg once daily orally on Days 1-21 of repeated 28-day

Dr. Best, MD

Dispense as written

Substitution permissible

DEA#: _____
NPI# _____

a. Adult female
b. Female child of reproductive age
c. Adult female non-reproductive
d. Female child non-reproductive
e. Adult female reproductive

Practice Problem Answers

Objective 1.1

1. 78,000
2. a. Height in inches and d. Age
3. a. b. and d.

Objective 1.2

1. Acute
2. Adjuvant Therapy
3. Lymphedema
4. Neutropenia
5. Immunotherapy
6. Targeted Therapy
7. DIR Fees
8. CEA
9. Antiemetic
10. Prophylactic

Objective 1.3

1. NCCMERP
2. ChemoCare
3. Quality and Accountability in Healthcare Management

Objective 1.4

1. a. Covered shoes and c. Gown
2. d. Separate counting tray and spatula
3. c. Reproductive toxicity, carcinogenicity, and other toxicities
4. a. Carcinogenicity, b. Development Toxicity, c. Reproductive Toxicity, and e. Genotoxicity

Objective 1.5

1. b. Day supply and c. Authorization number
2. b. REMS is designed to mitigate all the adverse events of a medication
3. c. Adult Female non-reproductive