URAC Specialty Pharmacy & Mail Service Pharmacy v5.0 Workshop

Accreditation Standards

Disclosure

The faculty for this activity, including Heather Bonome, Jennifer Richards, and Heather Valiton, have no relevant financial relationships with ineligible companies to disclose.

Learning Objectives

1. Discuss the changes in accreditation requirements resulting from the revision process.
2. Explain the intent of each accreditation standard.
3. Identify the documentation required to demonstrate compliance with the accreditation standards.
4. Describe examples of best practices in Specialty Pharmacy and Mail Service Pharmacy patient care.
5. Define strategies for maintaining ongoing compliance with accreditation standards.

Foundational Focus Areas

- Risk Management (RM)
- Operations and Infrastructure (OPIN)
- Performance Monitoring and Improvement (PMI)
- Consumer Protection and Empowerment (CPE)
- Reporting Performance Measures to URAC (RPT)

Program Specific Focus Areas

Specialty Pharmacy

- Pharmacy Operations (P-OPS)
- Medication Distribution (P-MD)
- Patient Services and Communications (P-PSC)
- Patient Management (PM)

Mail Service Pharmacy

- Pharmacy Operations (P-OPS)
- Medication Distribution (P-MD)
- Patient Services and Communications (P-PSC)

Specialty Pharmacy Services

- Patient Services and Communications (P-PSC)
- Patient Management (PM)

Foundational Focus Areas

Risk Management (RM)

RM 1: Regulatory Compliance and Internal Controls
RM 2: Regulatory Compliance
RM 3: Information Systems
RM 4: Business Continuity

RM 1: Regulatory Compliance and Internal Controls

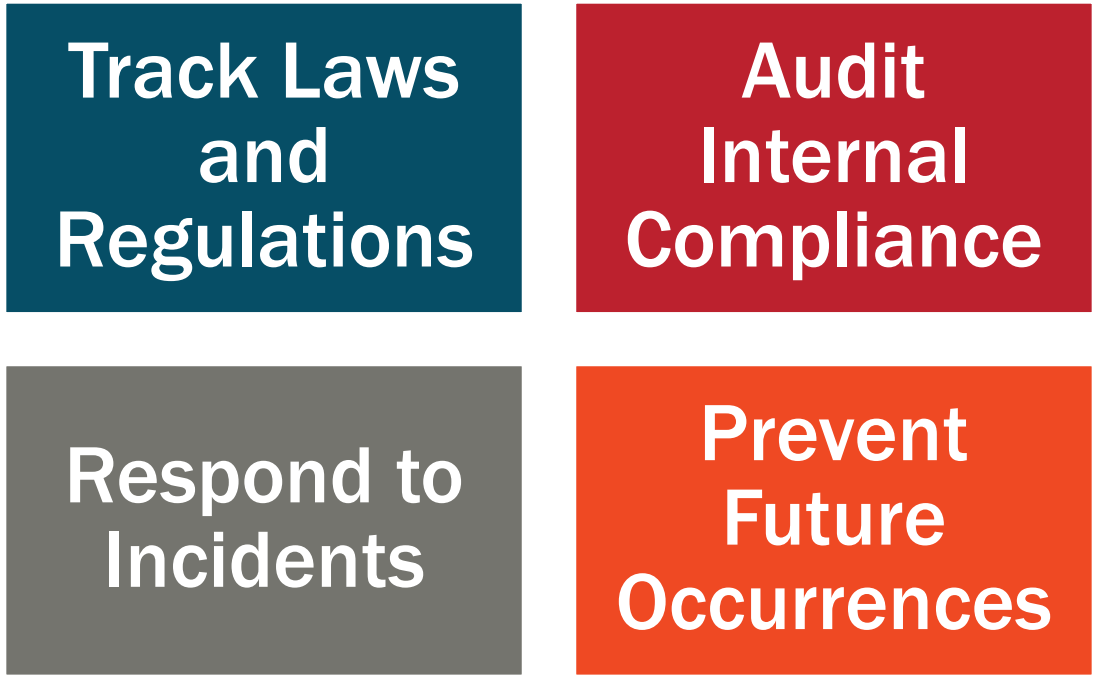
Standard

The organization promotes compliance with applicable jurisdictional laws and regulations. [M]

EPGs

RM 1-1: Regulatory Compliance Management

RM 1-1: Regulatory Compliance Management



The organization:

a. Tracks applicable jurisdictional laws and regulations

b. Audits compliance with applicable jurisdictional laws and regulations

c. Responds to detected risks, problems and incidents related to regulatory compliance and takes appropriate action to prevent future occurrences

d. Identifies a Compliance Officer responsible for overseeing the Compliance Program

RM 1-1: Demonstrating Compliance

- Describe the **process** for:
  - Tracking laws and regulations
  - Auditing
  - Responding to risks
  - Taking appropriate action to prevent future occurrence
- **Evidence**
  - Tracking mechanism
  - Auditing
- Compliance Officer **Job Description**

RM 2: Regulatory Compliance

Standard

The organization maintains compliance with applicable jurisdictional laws and regulations.

EPGs

RM 2-1: Maintaining Compliance

RM 2-1: Maintaining Compliance

Remain in Good Standing and Comply with Laws and Regulations

The organization:

a. Maintains compliance with all applicable jurisdictional laws, regulations and requirements not otherwise addressed by the program standards [8]

RM 2-1: Demonstrating Compliance

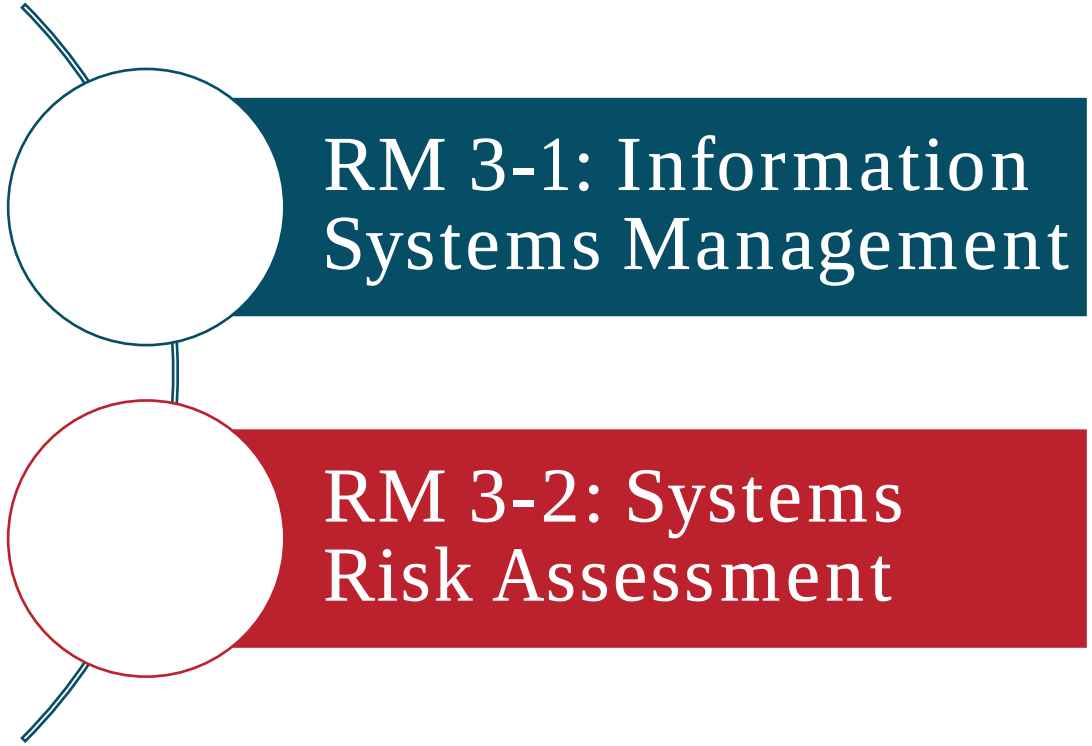
- **Attestation** confirming the organization maintains compliance with law/regulations

RM 3: Information Systems

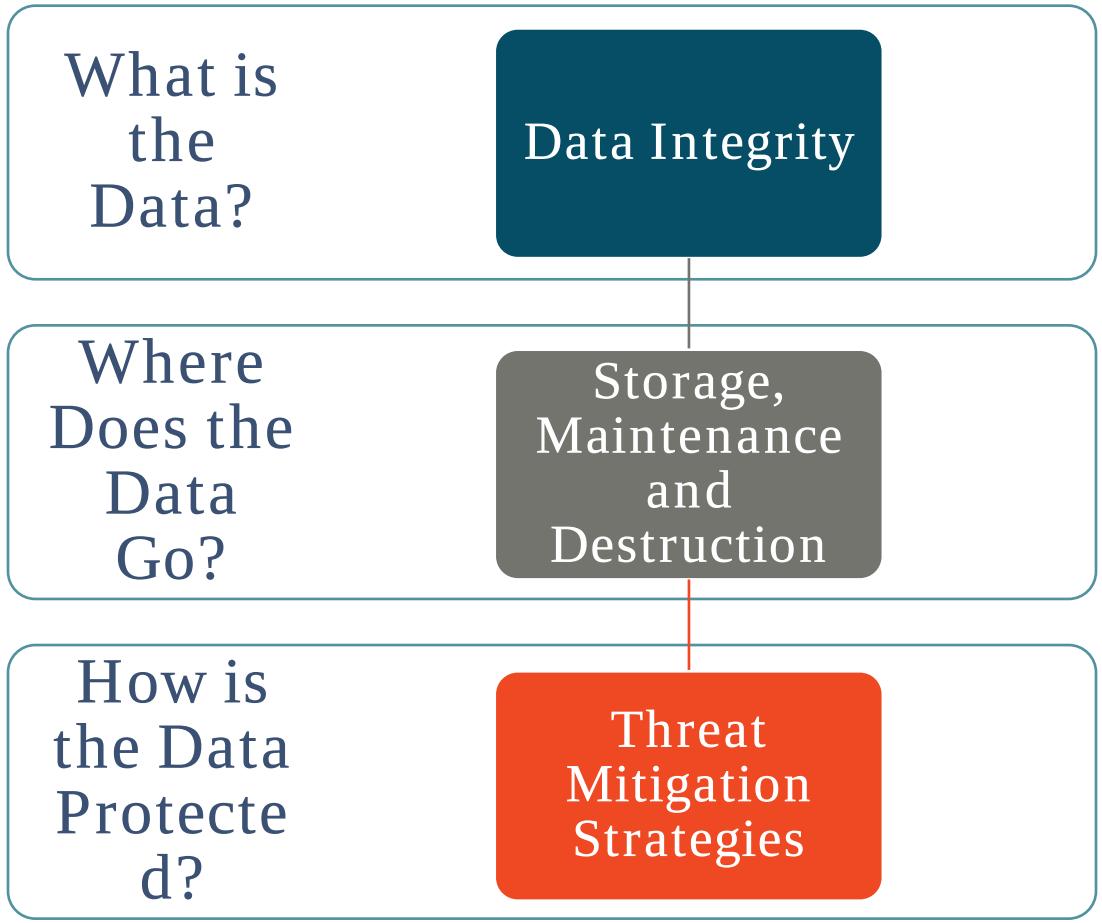
Standard

The organization promotes information system maintenance and security through prevention and risk assessments.

EPGs



RM 3-1: Information Systems Management



The organization:

a. Provides for data integrity of information systems [8]

b. Implements a plan for storage, maintenance and destruction of information [8]

c. Implements strategies to mitigate threats to privacy of information systems data in transit and at rest, including encryption, at a minimum [8]

RM 3-1: Demonstrating Compliance

- Outline **how** the organization
  - Provides for data integrity
  - Information is stored maintained and destroyed
- Outline **strategies** to mitigate threats

RM 3-2: Systems Risk Assessment

The organization:

a. Maintains a risk assessment process, which includes: [4]
   i. Periodic risk assessments of information systems
   ii. Corrective action(s), if applicable, based on findings from the risk assessment

RM 3-2: Demonstrating Compliance

- Describe the risk assessment **process**
- **Evidence** of
  - Periodic risk assessment conducted
  - Applicable corrective actions based on findings

RM 4: Business Continuity

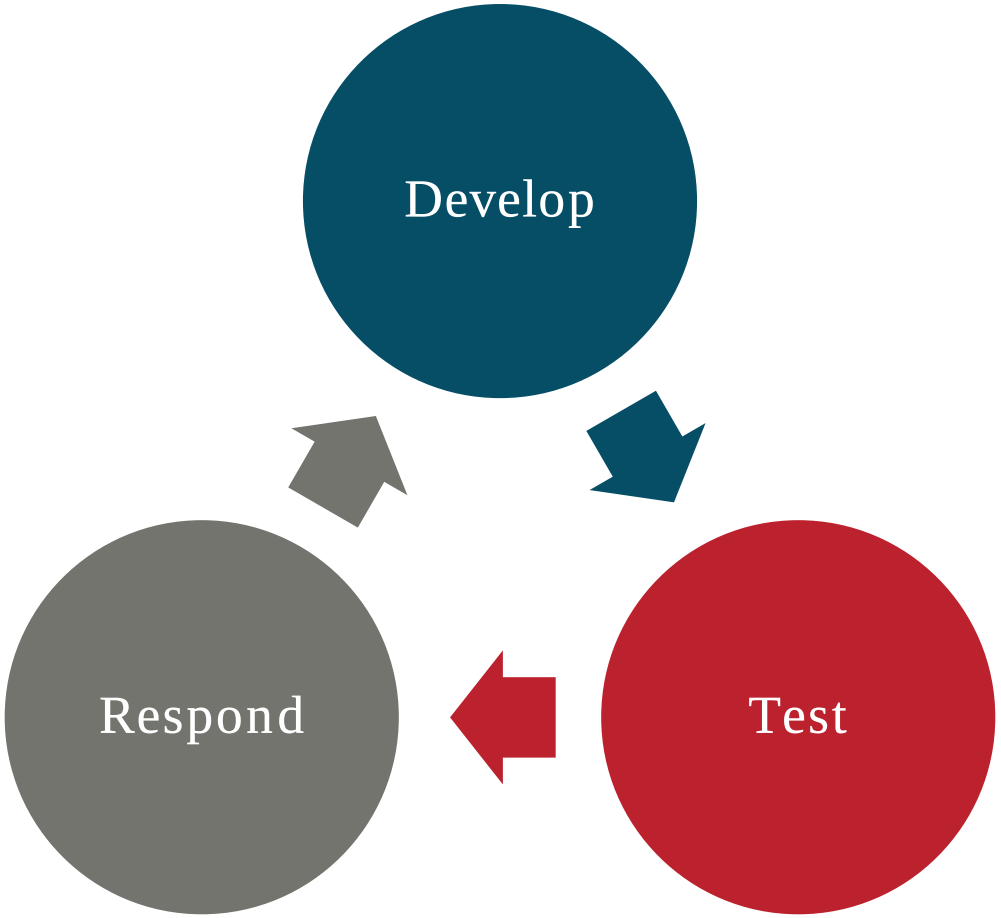
Standard

The organization maintains a business continuity plan designed to promote continuity of care during unplanned events.

EPGs

RM 4-1: Business Continuity Plan

RM 4-1: Business Continuity Plan



The organization:

a. Maintains a business continuity plan, which: [4]
   i. Is developed by an inter-departmental team and approved by leadership
   ii. Outlines the systems and processes that must be maintained
   iii. Describes how business continuity is maintained given various scenarios

b. Requires the business continuity plan to be used or tested at least every 2 years and incorporates corrective actions and updates in response to any findings [4]

RM 4-1: Demonstrating Compliance

- Describe the business continuity **process**
- **Evidence** of
  - Business continuity plan used or tested
  - Corrective actions based on findings

RM Assessment Question

Which of the following does not qualify as a comprehensive Business Continuity Plan use or test?

a) Tabletop exercise
b) Call roll over test
c) Implementation of plan due to natural disaster
d) Planned downtime to test all systems

RM Assessment Answer

Which of the following does not qualify as a comprehensive Business Continuity Plan use or test?

a) Tabletop exercise
b) Call roll over test
c) Implementation of plan due to natural disaster
d) Planned downtime to test all systems

Reference: RM 4-1: Business Continuity Plan

Operations and Infrastructure (OPIN)

OPIN 1: Business Management

OPIN 2: Staff Management

OPIN 3: Clinical Leadership

OPIN 1: Business Management

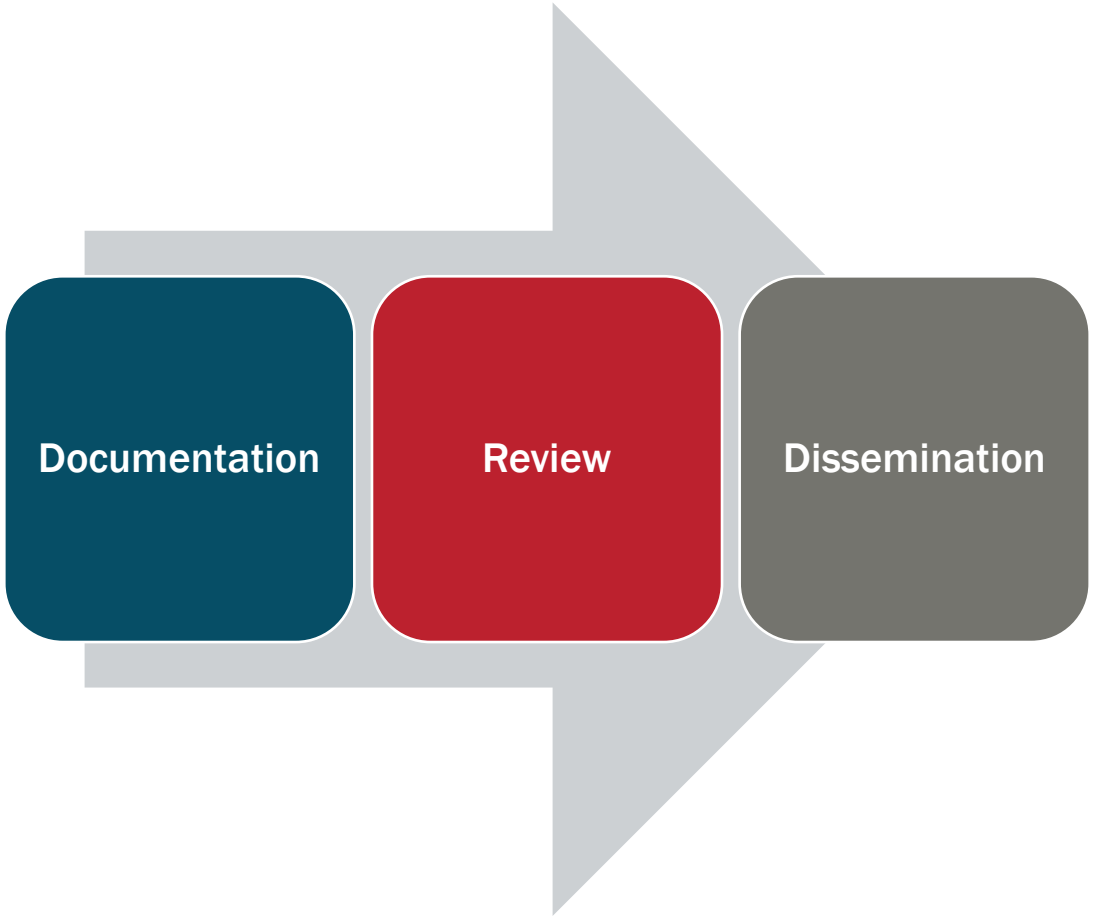
Standard

The organization reviews and disseminates policies and processes in a timely manner. Delegation arrangements are maintained.

EPGs

- OPIN 1-1: Policy and Process Maintenance
- OPIN 1-2: Delegation Management

OPIN 1-1: Policy and Procedure Maintenance



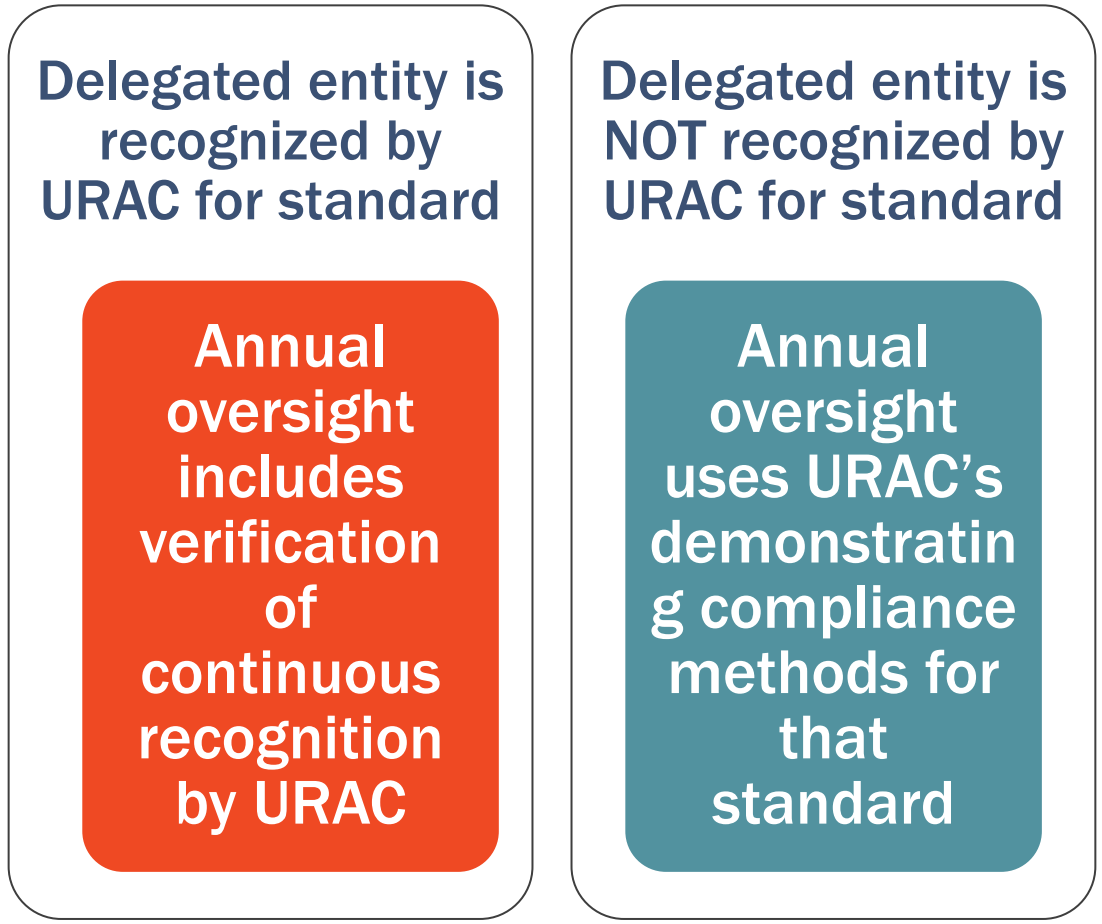
The organization:

a. Maintains policies and processes that include: [4]
   i. A record of effective dates, review dates, revision dates and identification of approval authority
   ii. Review of policies and processes at least every 36 months
   iii. Dissemination of new, changed and/or updated policies and processes to staff in a timely manner

OPIN 1-1: Demonstrating Compliance

- Outline **how** the organization maintains, reviews and disseminates policies and processes
- **Evidence** of
  - Recorded dates and approval authority
  - Review at least every 36 months

OPIN 1-2: Delegation Management



The organization retains accountability for delegated functions under the scope of the accreditation by:

a. Maintaining executed agreements with delegated entities [8]

b. Conducting annual oversight of the quality of performance and ongoing compliance with pertinent standards [4]

OPIN 1-2: Demonstrating Compliance

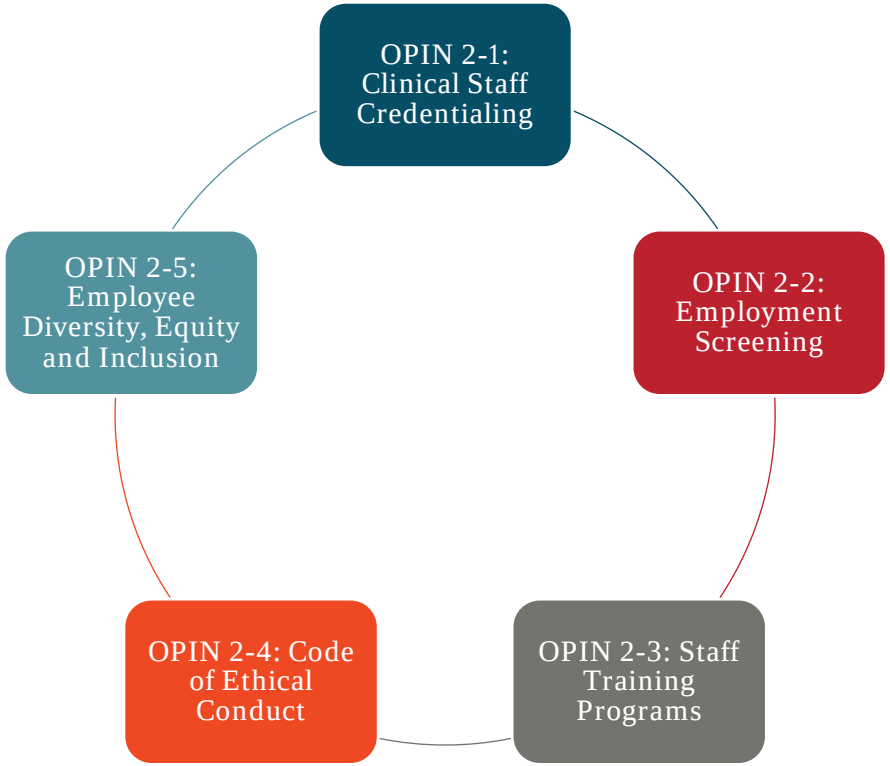
- **Describe** oversight
  - For URAC recognized, verify continuous accreditation or certification
  - For non-URAC recognized, use the demonstrating compliance methods for that standard
- **List** of delegated functions and applicable standards

OPIN 2: Staff Management

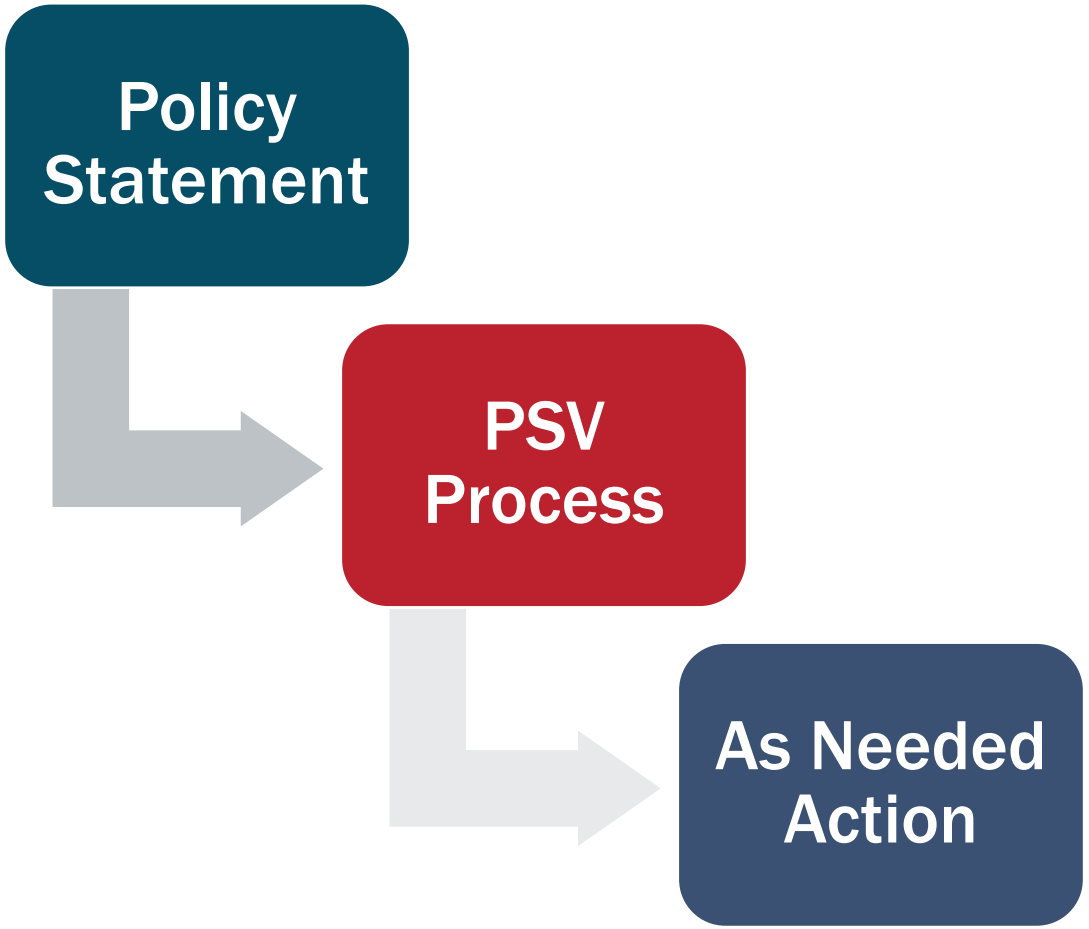
Standard

Staff are appropriately licensed and screened prior to hire. Licensure and/or certifications are verified no less than every three years. Staff members are trained initially and on an ongoing basis.

EPGs



OPIN 2-1: Clinical Staff Credentialing



The organization:

a. Primary source verifies the current licensure and/or certification of staff whose job description requires licensure and/or certification: [8]
   i. Prior to hire
   ii. No less than every three (3) years

b. Requires staff to notify the organization in a timely manner of an adverse change in licensure and/or certification status and implements corrective action in response to adverse change(s) [8]

OPIN 2-1: Demonstrating Compliance

- Outline **how** the organization
  - Conducts primary source verification
- Outline the organization's **requirement** for
  - Staff reporting adverse changes in licensure/ certification
  - Taking corrective action in response to licensure/ certification changes

OPIN 2-2: Employment Screening

Prior to Hire

- Drug Screen
- Background Check

Optional

- Drug Screen for all staff (Leading Indicator)

The organization's Employee Screening Program receives results prior to hire and responds appropriately to:

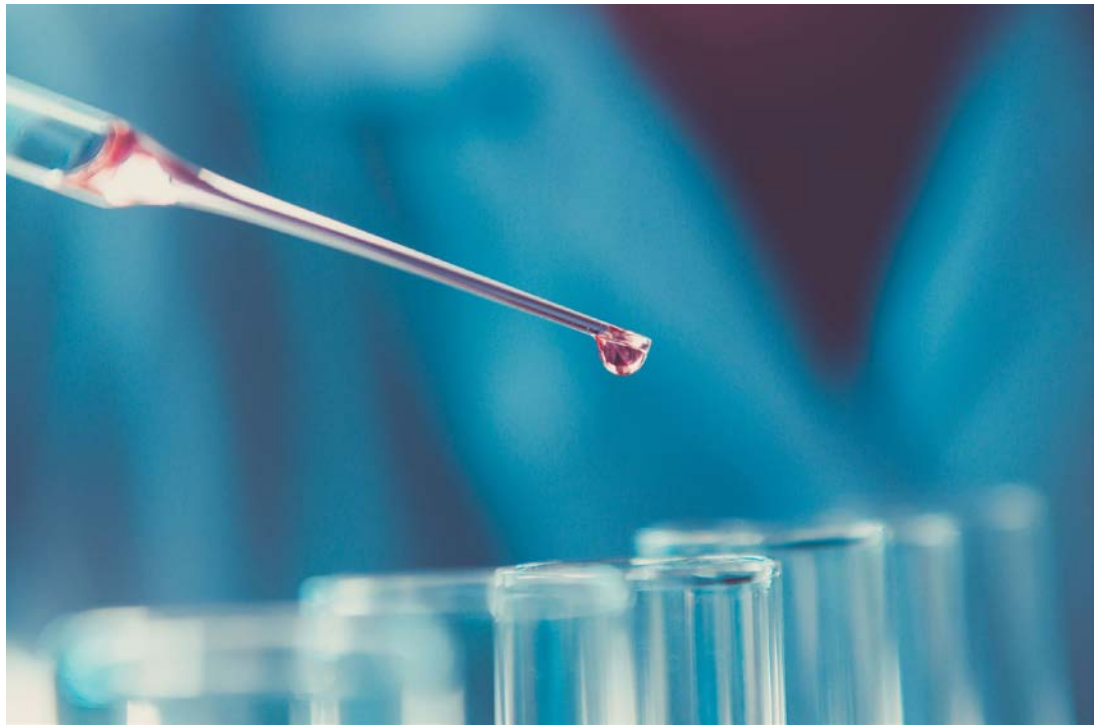
a. A background check on employees who handle personal information [8]

b. A drug test/screen for employees who have access to pharmaceuticals [8]

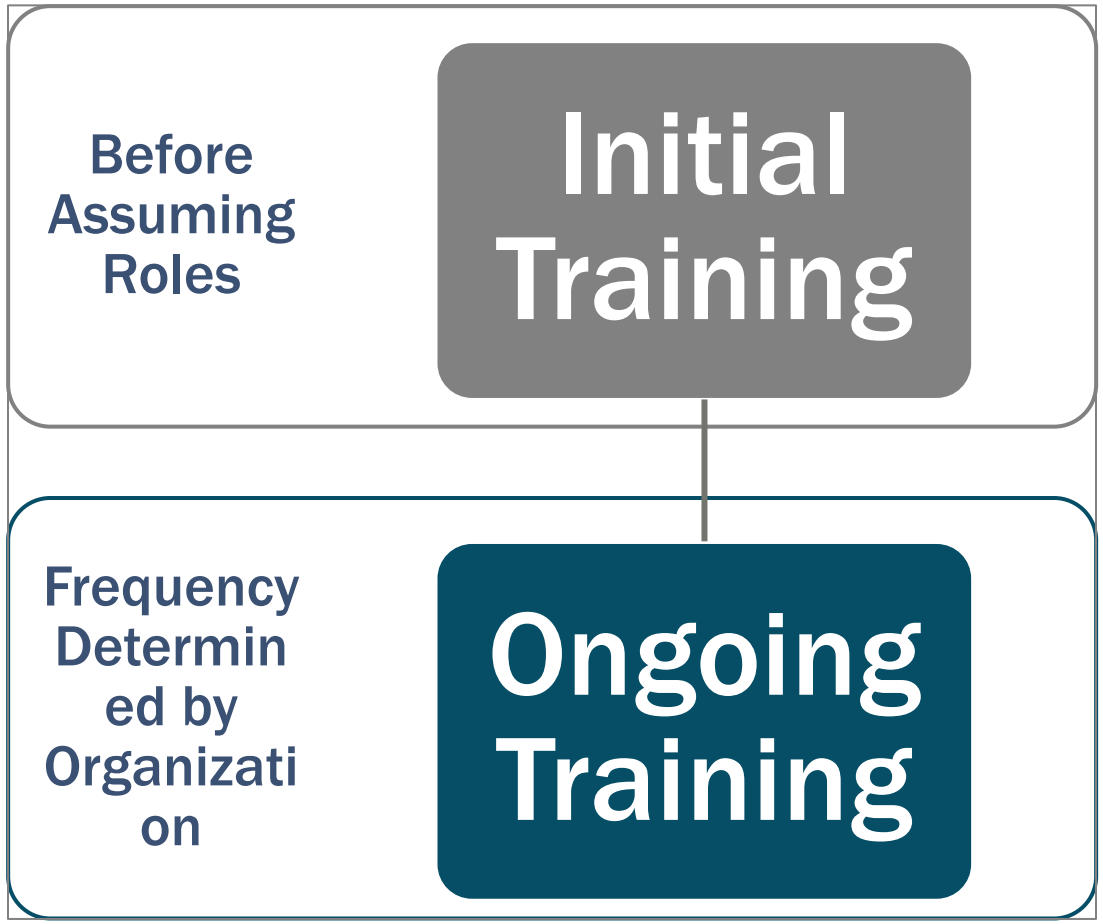
c. A drug test/screen for all employees [L]

OPIN 2-2: Demonstrating Compliance

- Describe the **process** for
  - Conducting background checks prior to hire
  - Conducting drug screens prior to hire



OPIN 2-3: Staff Training Programs



The organization:

a. Educates staff on their responsibilities regarding privacy and security of patient information [8]

b. Provides training to staff, to include: [4]

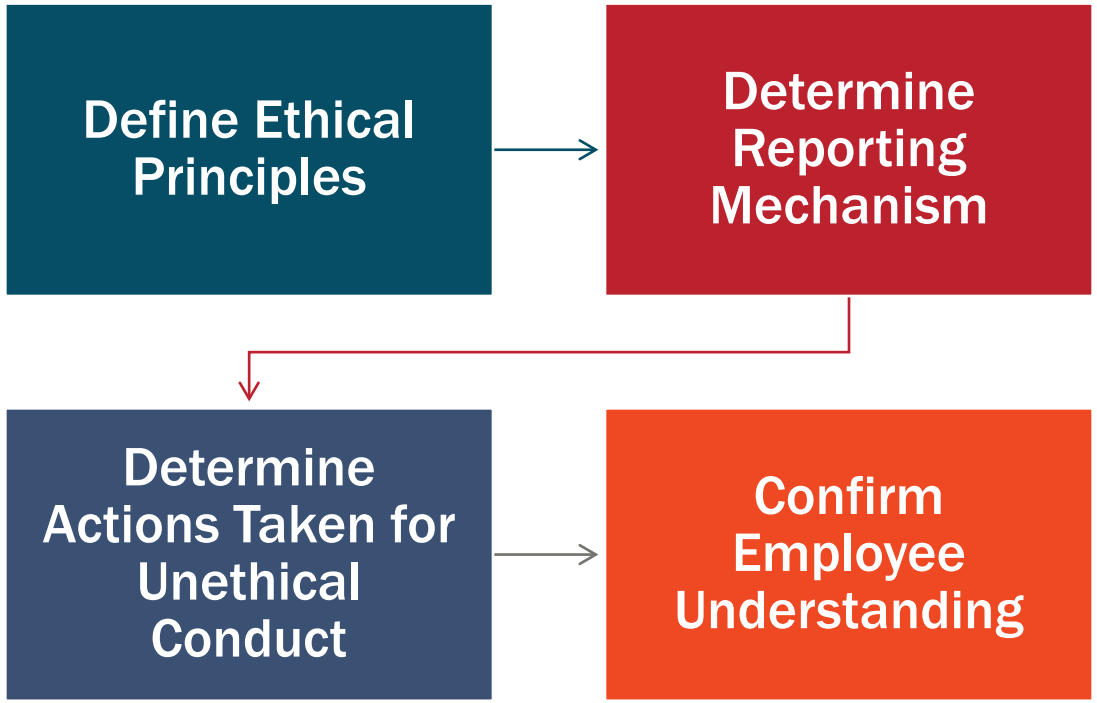
   i. Initial orientation and/or job-related training for all staff before assuming assigned roles and responsibilities

   ii. Ongoing training to maintain current job knowledge

OPIN 2-3: Demonstrating Compliance

- **Outline**
  - Training topics
  - Frequency of training
  - Methods for tracking participation
- **Example** training materials

OPIN 2-4: Code of Ethical Conduct



The organization:

a. Maintains a code of ethical conduct, which includes: [4]
   i. Ethical principles
   ii. Reporting mechanisms for unethical conduct
   iii. Actions taken when unethical conduct is identified

b. Implements mechanism(s) for confirming employee understanding [4]

OPIN 2-4: Demonstrating Compliance

- Code of ethical conduct, including
  - Ethical principals
  - Reporting mechanisms
  - Actions taken
  - Mechanism for confirming employee understanding

OPIN 2-5: Employee Diversity, Equity and Inclusion

The organization:

a. Promotes employee: [4]
   i. Diversity
   ii. Equity
   iii. Inclusion

OPIN 2-5: Demonstrating Compliance

- **Examples** demonstrating promotion
  - Policies
  - Procedures
  - EEO statements

OPIN 3: Clinical Leadership

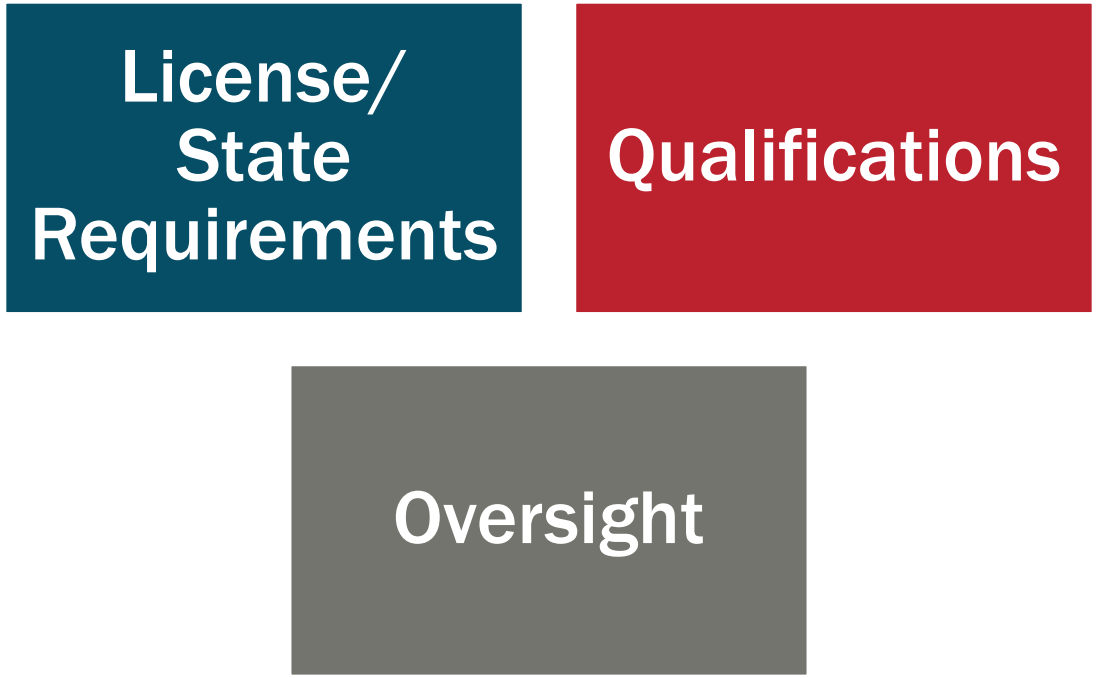
Standard

A senior clinical staff person oversees the services provided.

EPGs

OPIN 3-1: Clinical Staff Leadership

OPIN 3-1: Clinical Staff Leadership

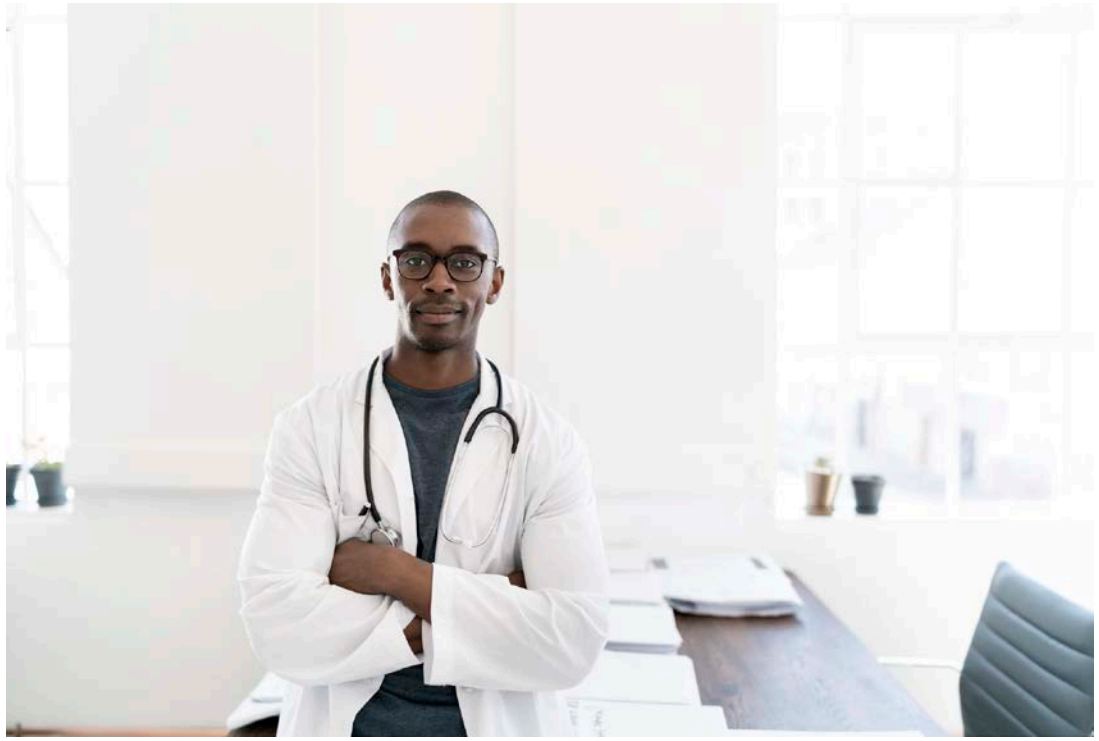


The organization:

a. Designates at least one senior clinical staff person who is: [8]
   i. Currently licensed or otherwise permitted to practice a health profession in the relevant jurisdiction(s)
   ii. Qualified to perform clinical oversight for the services provided
   iii. Responsible for oversight of clinical decision-making aspects of the program and provides clinical guidance

OPIN 3-1: Demonstrating Compliance

- **Job Description**
- **Evidence** of meeting the requirements in the job description



OPIN Assessment Question

Which of the following mechanisms does not demonstrate compliance with promoting diversity, equity, and inclusion?

a) Policies & Procedures
b) EEO Statements
c) Employee Handbook
d) Patient Welcome Packet

OPIN Assessment Answer

Which of the following mechanisms does not demonstrate compliance with promoting diversity, equity, and inclusion?

a) Policies & Procedures
b) EEO Statements
c) Employee Handbook
d) Patient Welcome Packet

Reference: OPIN 2-5: Diversity, Equity, and Inclusion

Performance Monitoring and Improvement (PMI)

PMI 1: Quality Management Scope

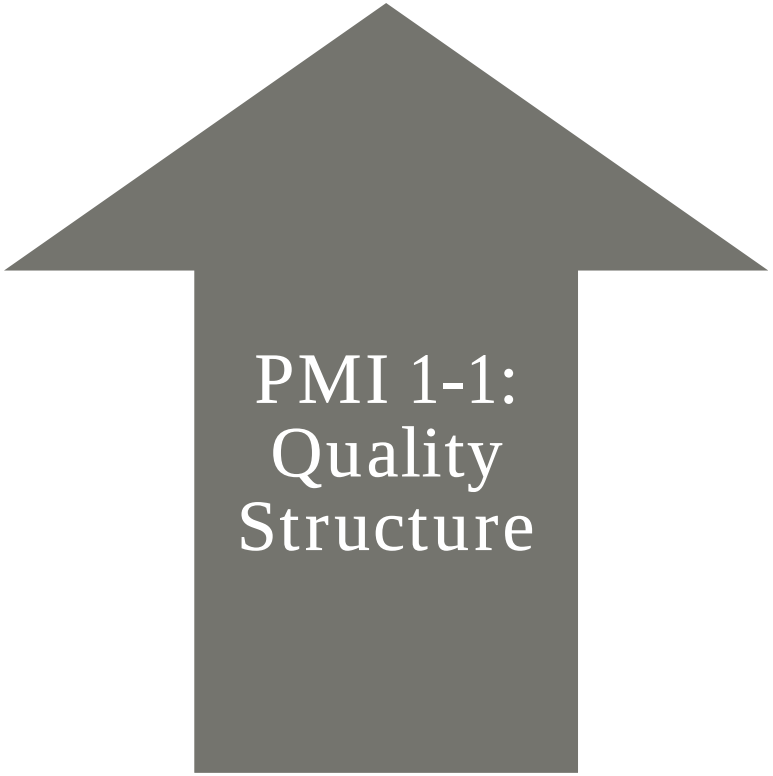
PMI 2: Quality Data Collection and Evaluation

PMI 1: Quality Management Scope

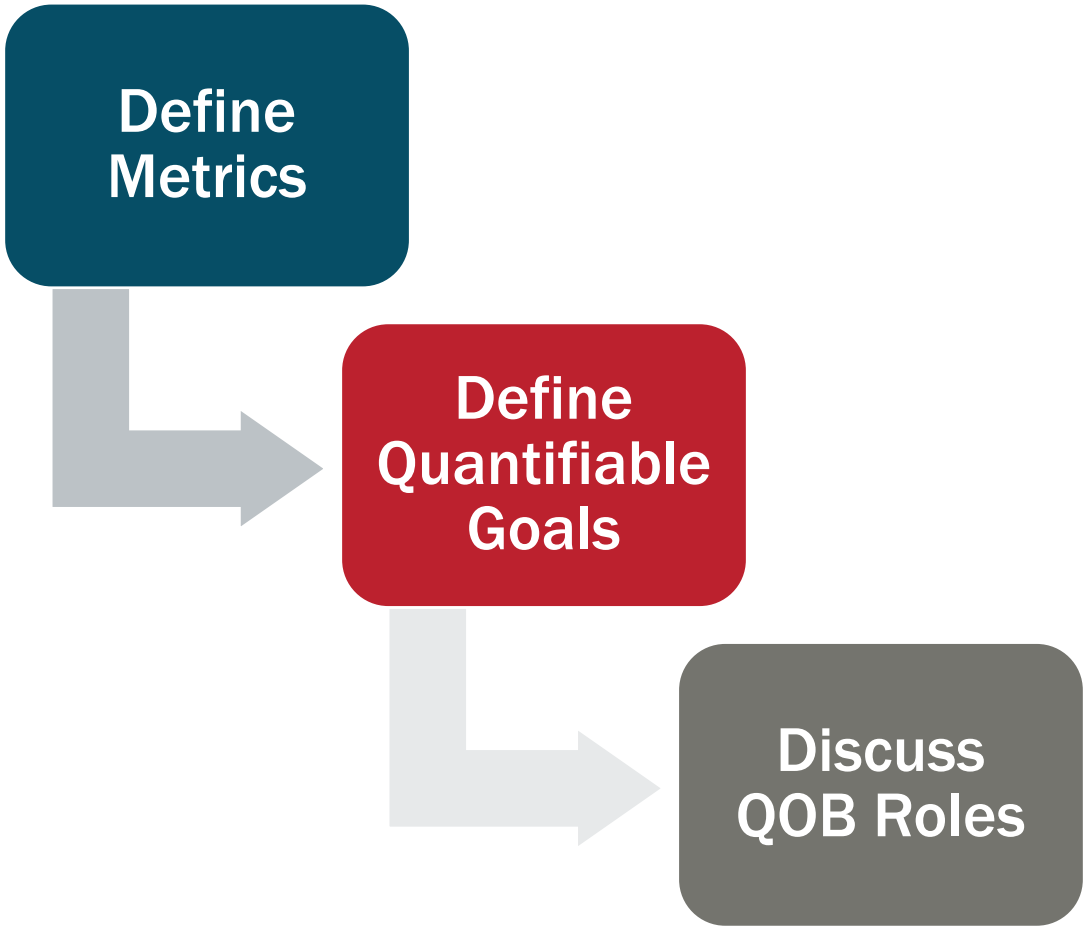
Standard

The organization maintains a quality management program that promotes measurement and implementation of quality improvement activities based on the performance results. The quality management program is overseen by a quality oversight body. [M]

EPGs



PMI 1-1: Quality Structure



The organization's quality management program:

a. Identifies metrics and the quantifiable goals relevant to the program

b. Maintains a quality oversight body responsible for monitoring metrics and progress in meeting quantifiable goals and overseeing improvement activities

PMI 1-1: Demonstrating Compliance

- Describe the quality management **process**
  - Identifying metrics and goals
  - QOB responsibilities
- **Evidence** of
  - Metrics
  - Quantifiable goals

PMI 2: Quality Data Collection and Evaluation

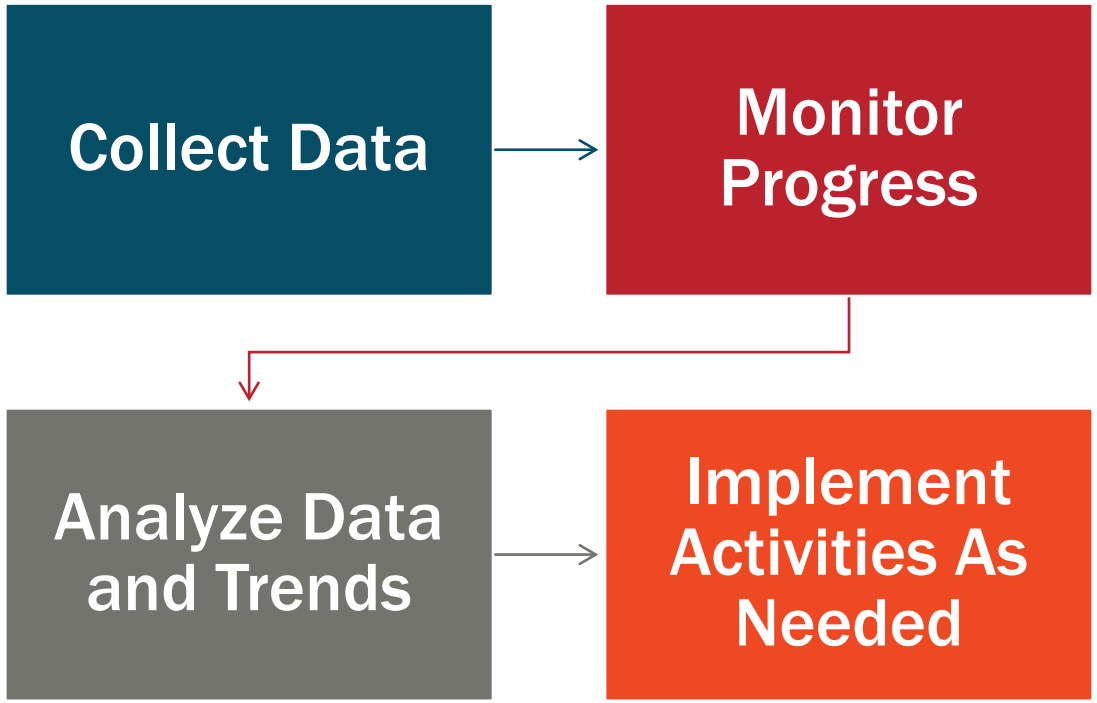
Standard

The organization maintains a quality management program that promotes accurate collection, analysis and evaluation of data.

EPGs

PMI 2-1: Data Collection and Evaluation

PMI 2-1: Data Collection and Evaluation



The organization's quality management program:

a. Collects accurate data for each metric [8]

b. Monitors progress in meeting each quantifiable goal [8]

c. Analyzes data and identifies performance trends for each metric at a minimum annually [8]

d. Designs and implements activities to improve performance levels when the need is indicated through monitoring and analysis [8]

PMI 2-1: Demonstrating Compliance

- Describe the quality management **process**
  - Collection process
  - Monitoring process in meeting goals
  - Analysis and trending
  - Designing activities to improve performance
- **Evidence** of activities implemented

PMI Assessment Question

Which of the following is a required responsibility of the Quality Oversight Body?

a) Monitors metrics and progress in meeting quantifiable goals
b) Provides guidance to staff on quality management priorities and projects
c) Periodically evaluates the effectiveness of the quality management program
d) Meets quarterly

PMI Assessment Answer

Which of the following is a required responsibility of the Quality Oversight Body?

a) Monitors metrics and progress in meeting quantifiable goals
b) Provides guidance to staff on quality management priorities and projects
c) Periodically evaluates the effectiveness of the quality management program
d) Meets quarterly

Reference: PMI 1-1: Quality Structure

Consumer Protection and Empowerment (CPE)

CPE 1: Protection of Consumer Information

CPE 2: Consumer Safeguards and Communication

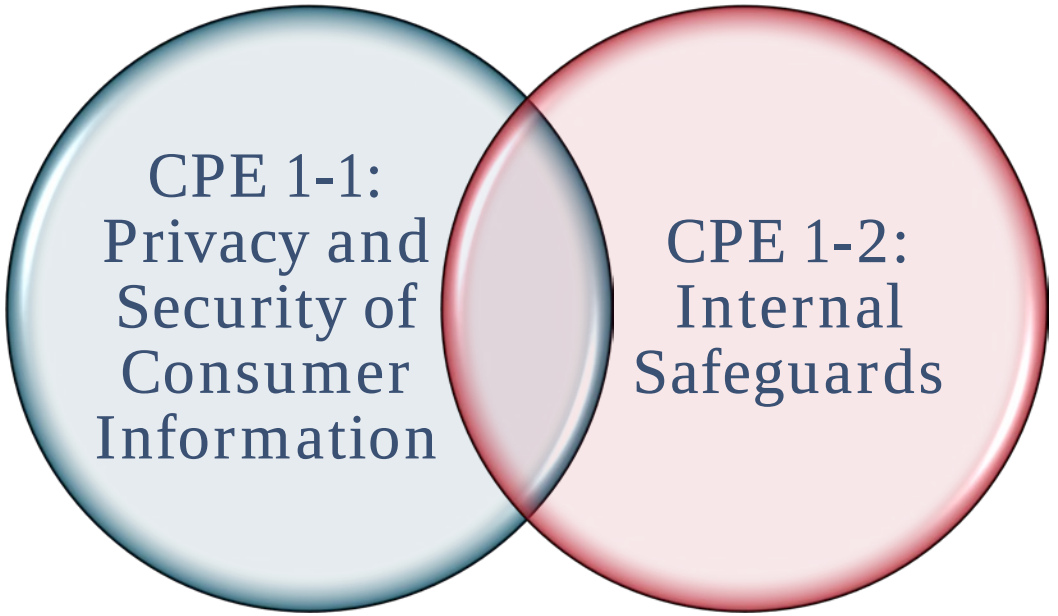
CPE 3: Privacy and Security Safeguards

CPE 1: Protection of Consumer Information

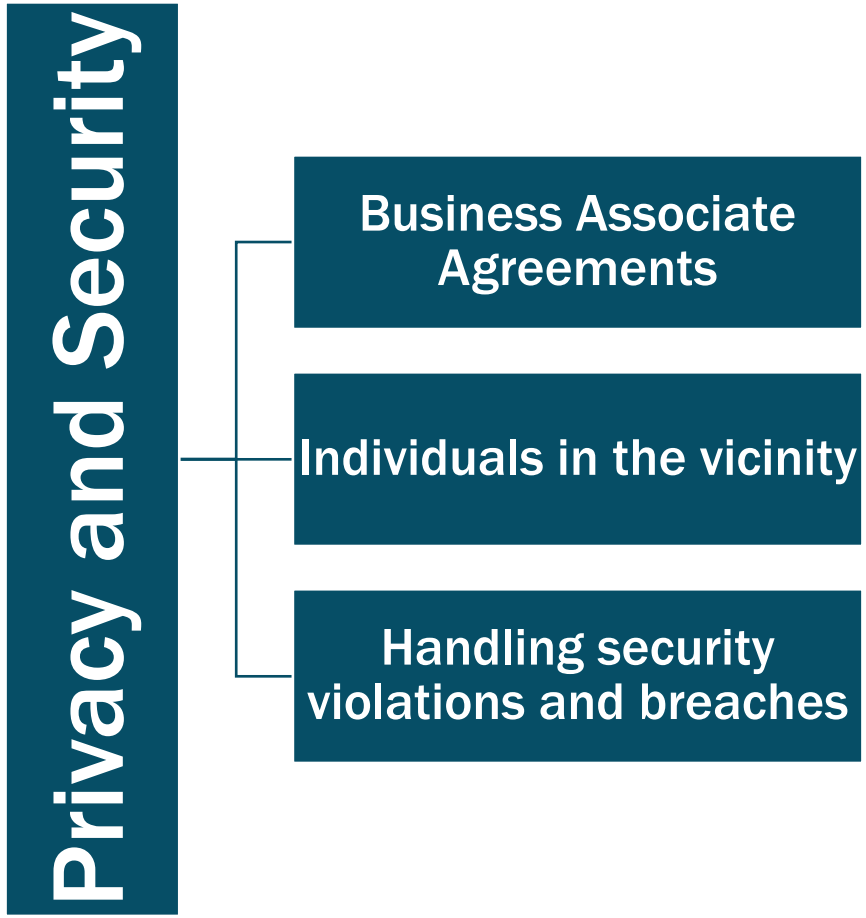
Standard

The organization ensures the privacy and security of consumer information.

EPGs



CPE 1-1: Privacy and Security of Consumer Information



The organization:

a. Executes business associate agreements with business associates as required by applicable jurisdictional laws and regulations [8]

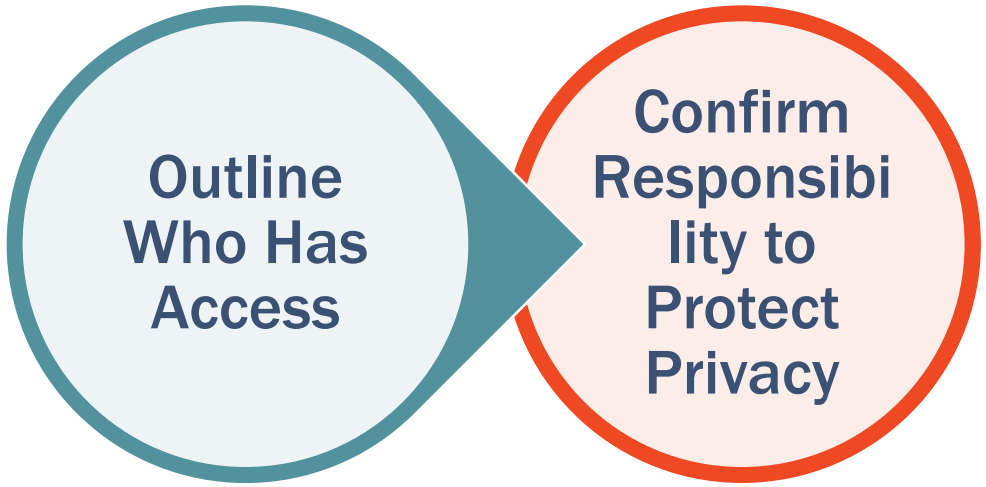
b. Addresses situations where an individual or entity's functions or services do not involve the use or disclosure of confidential/protected health information or individually identifiable health information, but their work puts them in the vicinity of this type of information [8]

c. Detects, contains and corrects privacy and security violations and data breaches [8]

CPE 1-1: Demonstrating Compliance

- **Sample** Business Associate Agreement (BAA)
- **Define** the
  - Types of individuals in the vicinity
  - Methods to protect confidentiality
- Outline **how** the organization
  - Detects violations and breaches
  - Contains violations and breaches
  - Corrects violations and breaches

CPE 1-2: Internal Safeguards

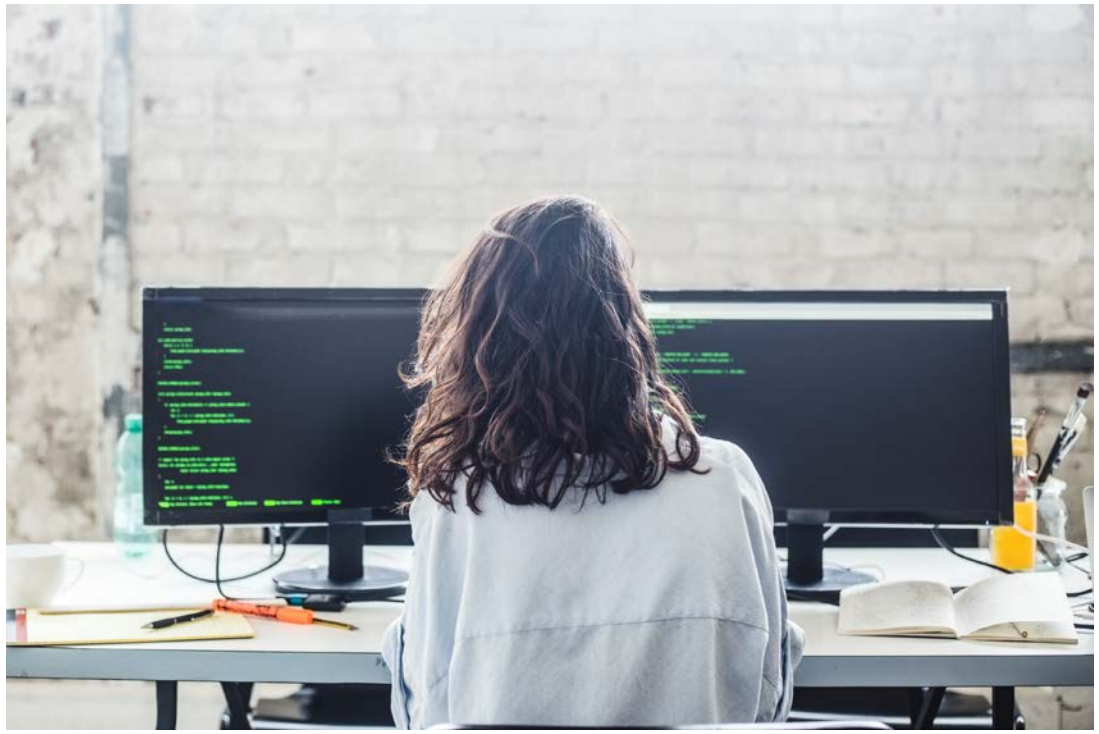


The organization:

a. Promotes internal privacy and security safeguards to include: [8]
   i. Who within the organization has access to confidential/protected health information or individually identifiable health information
   ii. Confirmation of responsibility for individuals within the organization who have access to confidential/protected health information or individually identifiable health information to maintain confidentiality

CPE 1-2: Demonstrating Compliance

- **Outline** safeguards, including:
  - Who has access to confidential information
  - Confirmation of responsibility



CPE 2: Consumer Safeguards and Communication

Standard

The organization has mechanisms to keep consumers safe and informed. There are mechanisms for consumers to communicate their issues and concerns with services to the organization.

EPGs

- CPE 2-1: Consumer Diversity, Equity and Inclusion
- CPE 2-2: Consumer Safety Protocols
- CPE 2-3: Consumer Complaint Process
- CPE 2-4: Health Literacy Promotion
- CPE 2-5: Consumer Marketing and Communication Safeguards

CPE 2-1: Consumer Diversity, Equity and Inclusion

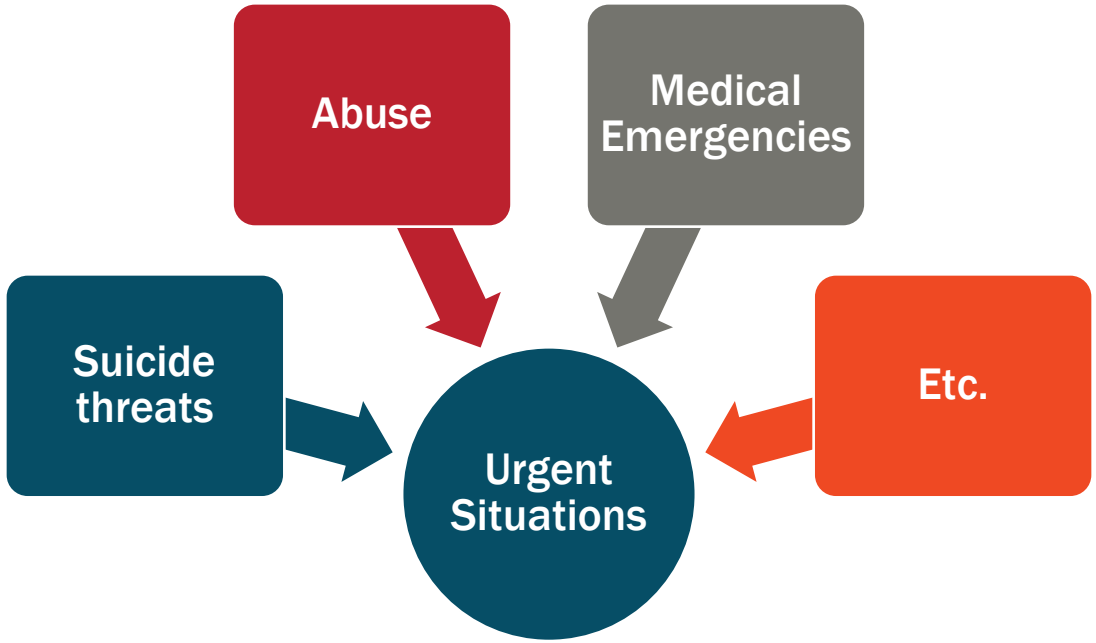
The organization:

a. Promotes consumer: [4]
   i. Diversity
   ii. Equity
   iii. Inclusion

CPE 2-1: Demonstrating Compliance

- Outline **how** the organization educates regarding
  - Diversity
  - Equity
  - Inclusion

CPE 2-2: Consumer Safety Protocols

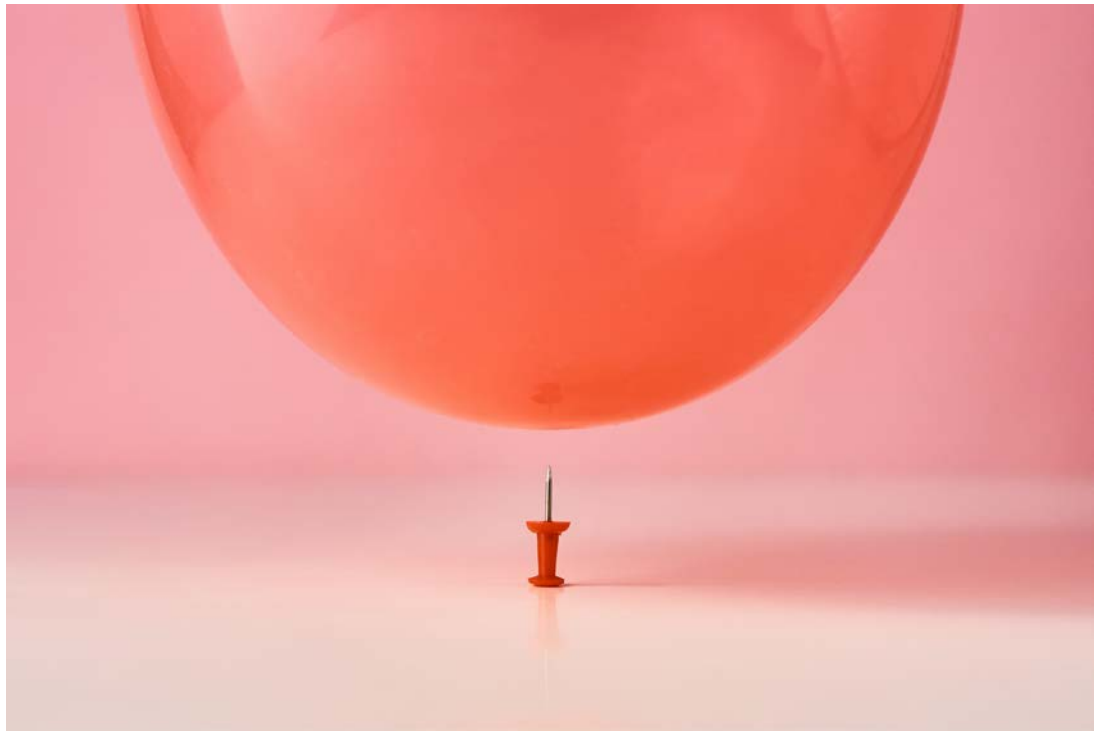


The organization maintains consumer safety protocols to:

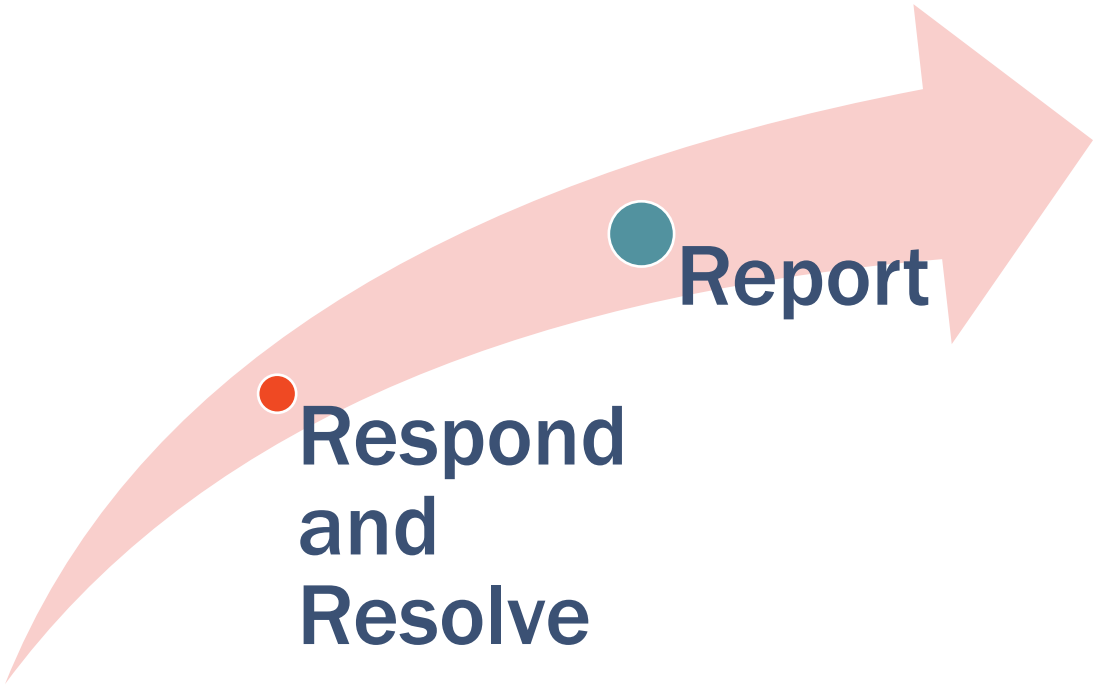
a. Respond, on an urgent basis, to situations that pose an immediate threat to the health and safety of consumers [8]

CPE 2-2: Demonstrating Compliance

- **Address** immediate consumer threats



CPE 2-3: Consumer Complaint Process



The organization's consumer complaints process includes:

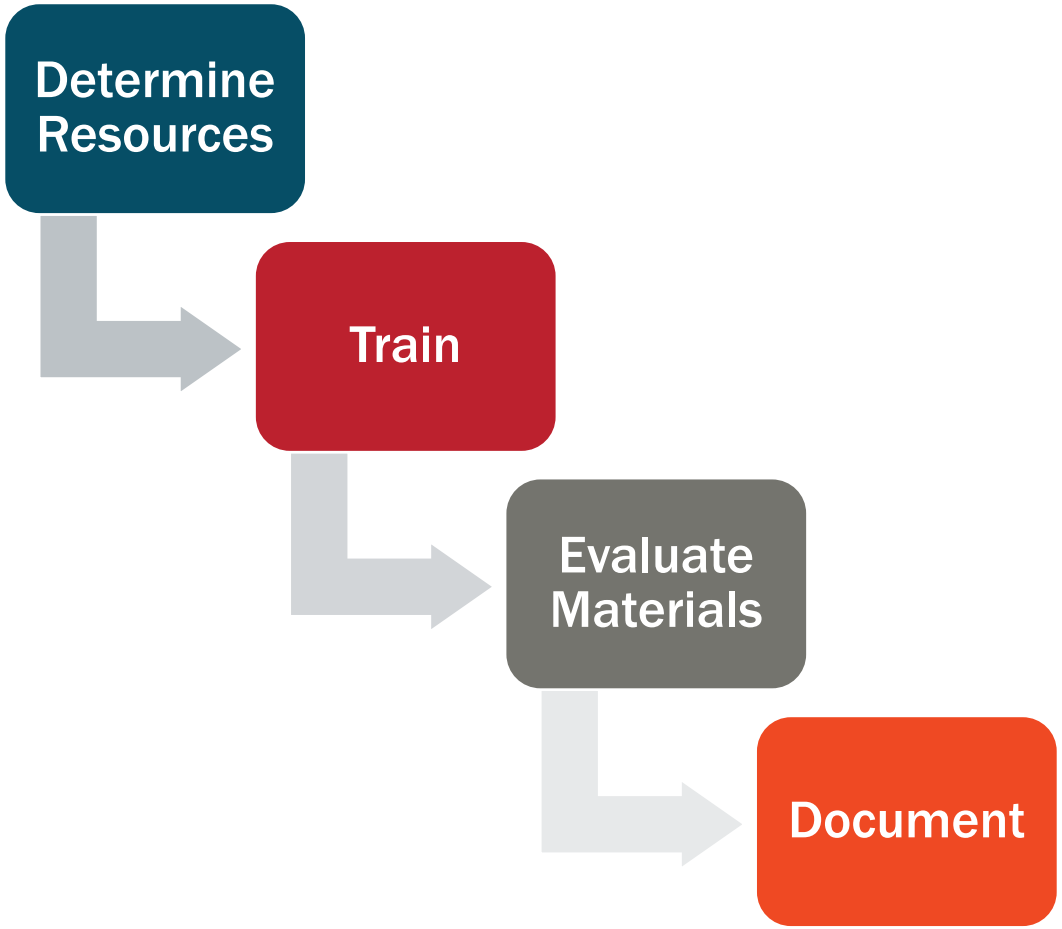
a. A process to respond to and resolve complaints for the consumer in a timely manner [8]

b. Reporting analysis of consumer complaints to the quality oversight body [4]

CPE 2-3: Demonstrating Compliance

- Describe the **process**
  - Responding to and resolving complaints in a timely manner
  - Reporting complaint analysis to quality oversight body

CPE 2-4: Health Literacy Promotion



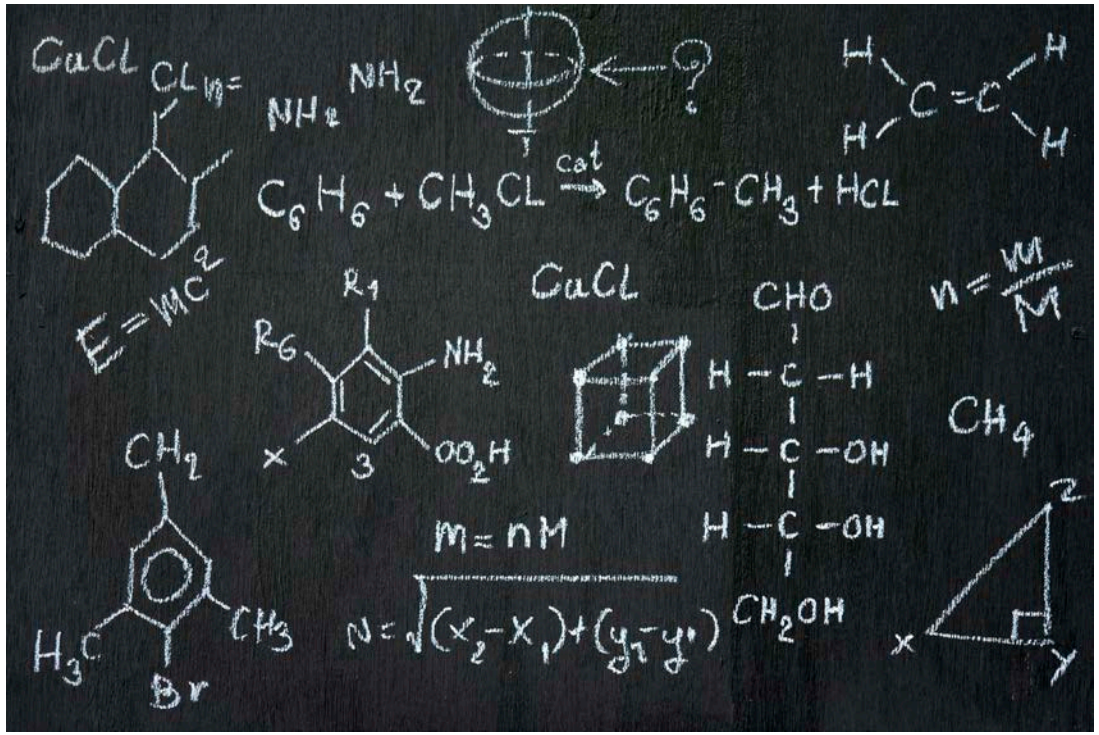
The organization's health communication practices:

a. Require consumer materials to be in plain language [8]

b. Provide information and guidance on health literacy to staff who write or review content for consumers [4]

CPE 2-4: Demonstrating Compliance

- **Outline** Plain language resources
- Outline **how**
  - The use of resources is documented
  - Information and guidance is provided to staff
- **Evidence**
  - Mechanism used to document use of plain language
  - Information and guidance provided to staff



CPE 2-5: Consumer Marketing and Communication Safeguards

Prevent Misrepresentation

Respond to Issues

The organization:

a. Implements consumer marketing and communication practices, which include: [4]
   i. Mechanisms that safeguard against misrepresentations about the organization's services
   ii. Prompt response to detected problems and corrective action as needed

CPE 2-5: Demonstrating Compliance

- Describe the **process**
  - Mechanisms for safeguarding against misrepresentation
  - Prompt response to detected problems
- **Evidence**
  - Development and review process for a material

CPE Assessment Question

What of the following is not an appropriate resource on plain language?

- plainlanguagenetwork.org
- plainlanguage.gov
- Medlineplus.gov
- Flesch-Kinkead readability score

CPE Assessment Answer

What of the following is not an appropriate resource on plain language?

- plainlanguagenetwork.org
- plainlanguage.gov
- Medlineplus.gov
- Flesch-Kinkead readability score

Reference: CPE 2-4: Health Literacy Promotion

Program Specific Focus Areas

Pharmacy Operations (P-OPS)

P-OPS 1: Scope of Services

P-OPS 2: Prescription Processing and Dispensing

P-OPS 3: Dispensing Accuracy Monitoring and Promotion

P-OPS 4: Adherence Monitoring

P-OPS 5: Product Management

P-OPS 1: Scope of Services

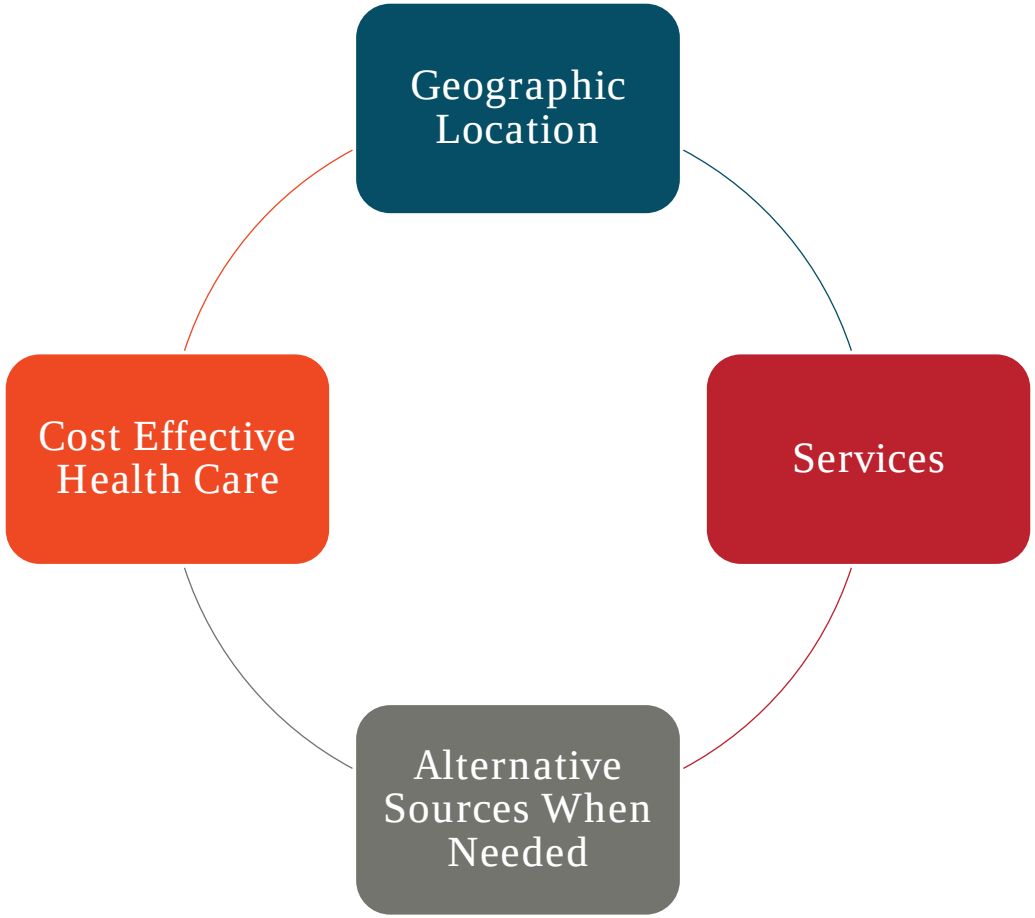
Standard

The pharmacy's scope of services is clearly outlined.

EPGs

P-OPS 1-1: Services

P-OPS 1-1: Services



The pharmacy:

a. Defines the following: [2]
    i. Geographic location(s) served
    ii. Services provided
b. Facilitates an alternative source of medication(s) for patients when the pharmacy has limited access and/or availability [4]
c. Promotes cost effective health care practices [4]

P-OPS 1-1: Demonstrating Compliance

- **Define** the:
  - States the organization services
  - Scope of services
- Outline **how** the pharmacy:
  - Facilitates alternative sources of medications
  - Promotes cost-effective health care practices

P-OPS 2: Prescription Processing and Dispensing

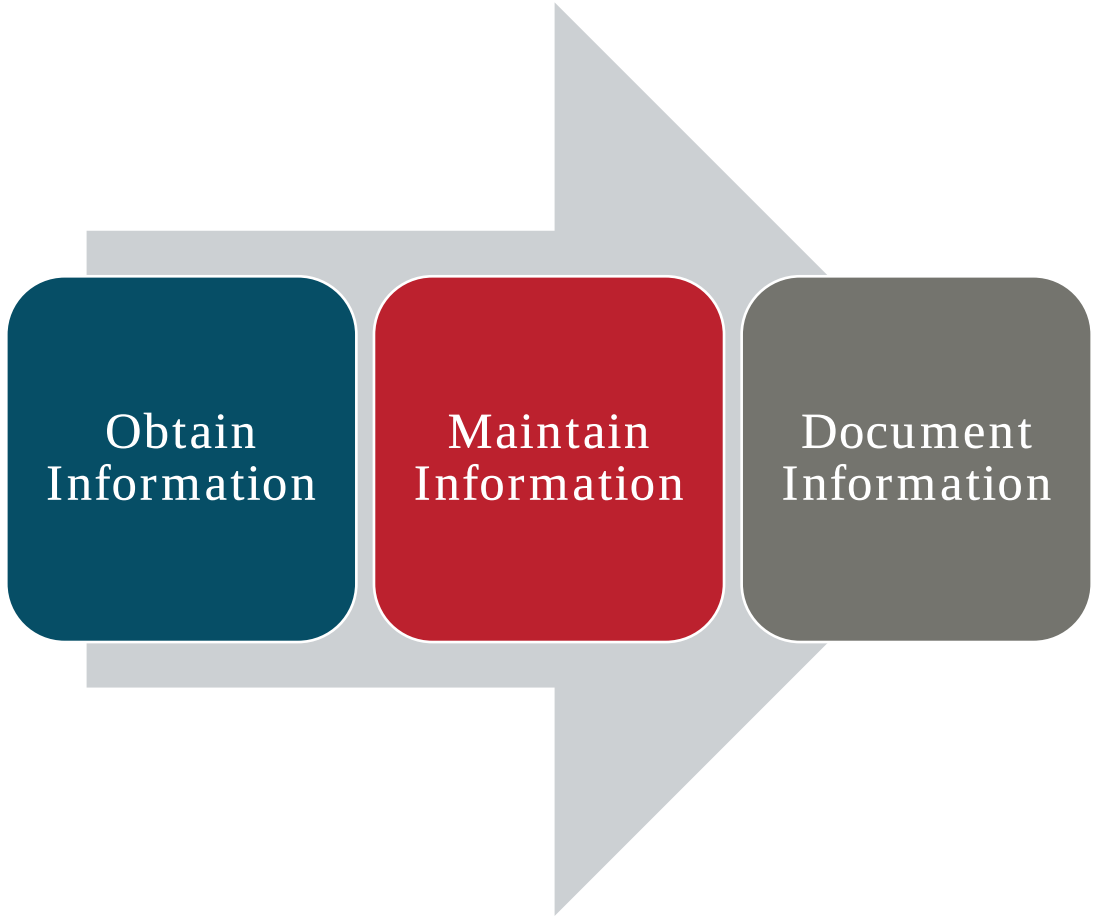
Standard

Prescription processing and dispensing promotes patient safety.

EPGs

- P-OPS 2-1: Reviewing Patient Information
- P-OPS 2-2: Verifying Eligibility
- P-OPS 2-3: Resolving Issues
- P-OPS 2-4: Dispensing Practices
- P-OPS 2-5: Machine and Equipment Maintenance

P-OPS 2-1: Reviewing Patient Information

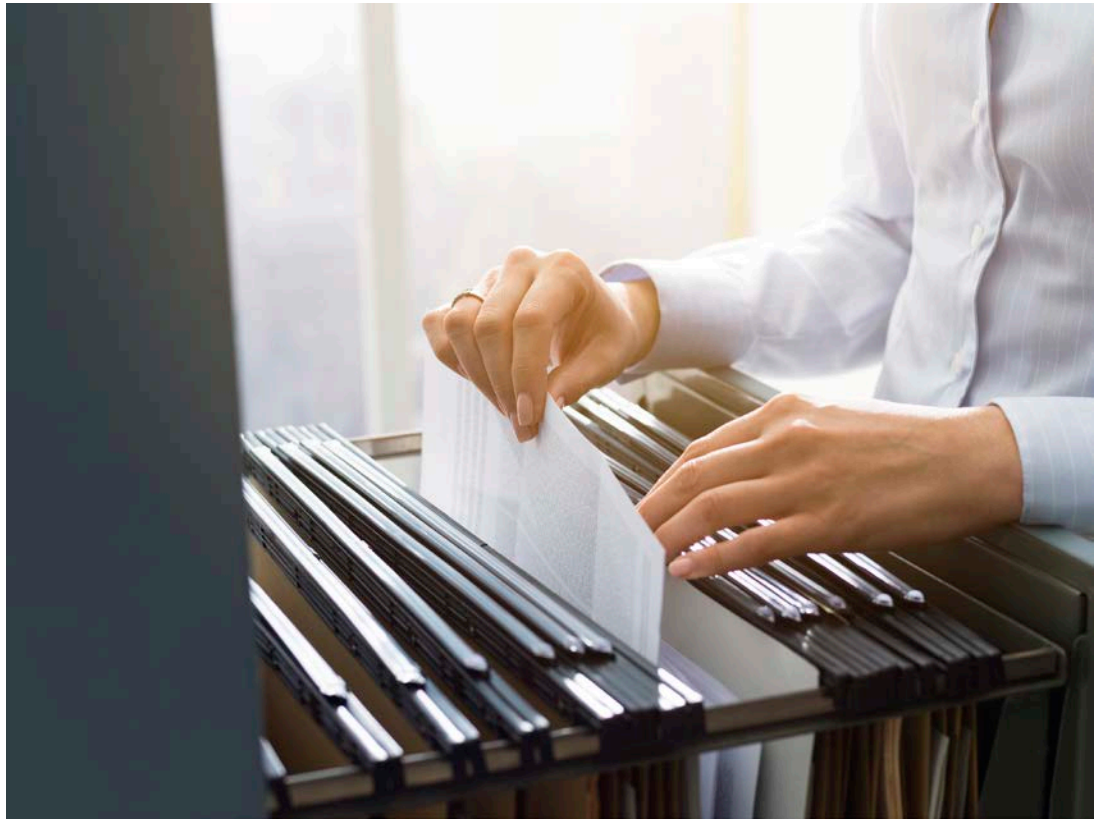


The pharmacy:

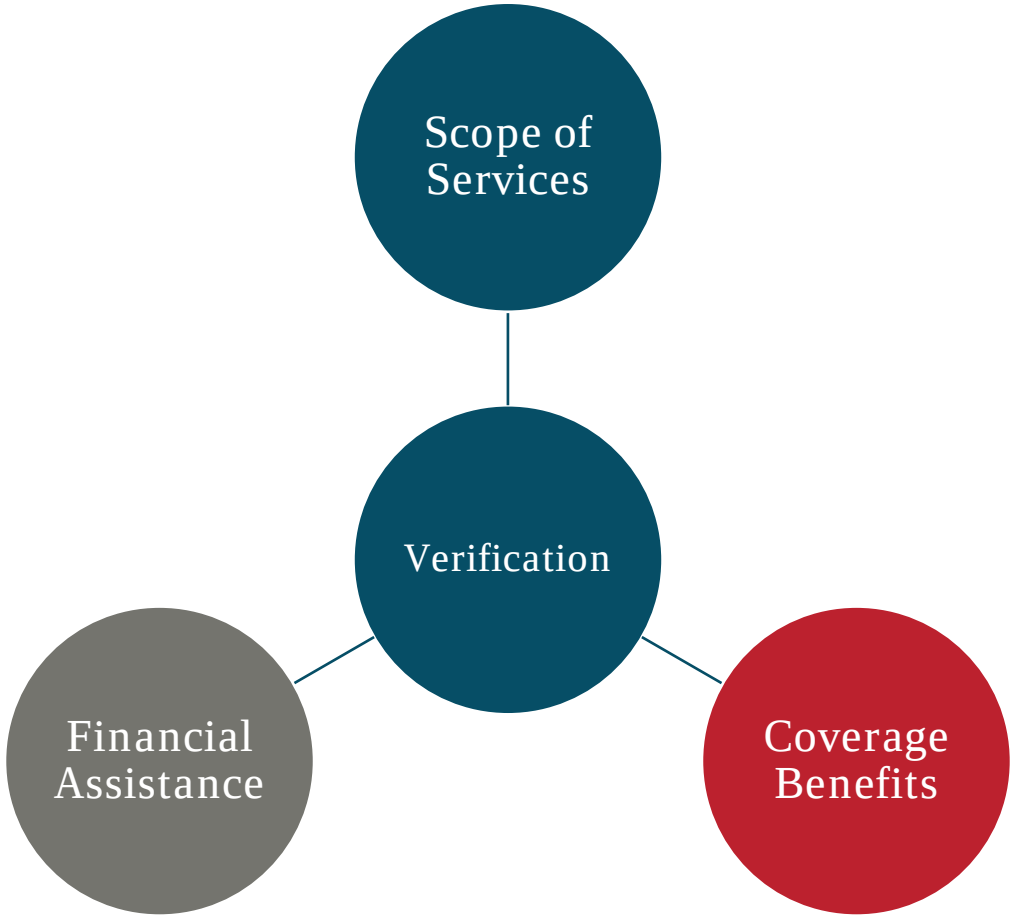
a. Obtains, maintains and documents: [4]
   i. Patient health history
   ii. Medication history
   iii. Allergies and past sensitivities
   iv. Information necessary to consult with the prescriber and counsel the patient and caregivers

P-OPS 2-1: Demonstrating Compliance

- Outline **how** the pharmacy:
  - Obtains information
  - Maintains information, and
  - Documents information



P-OPS 2-2: Verifying Eligibility



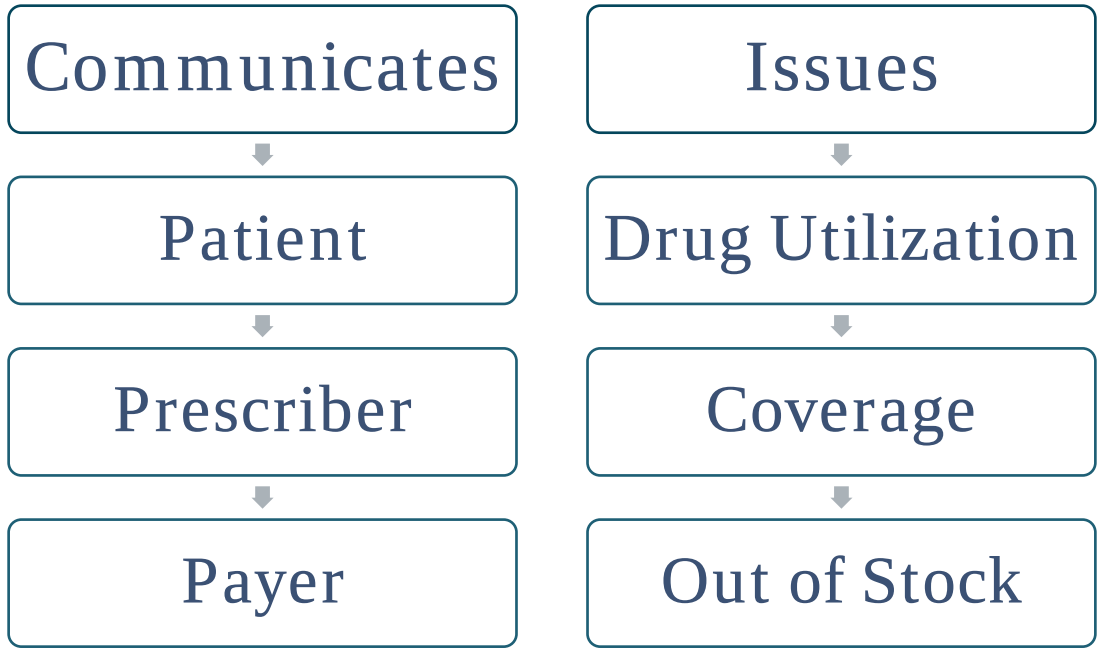
The pharmacy:

a. Verifies: [2]
   i. That a patient is within the scope of pharmacy services
   ii. Patient coverage benefits
   iii. Eligibility for financial assistance, if needed

P-OPS 2-2: Demonstrating Compliance

- Describe the **process** for verifying patient eligibility, including:
  - Scope of services
  - Coverage benefits
  - Financial assistance eligibility

P-OPS 2-3: Resolving Issues



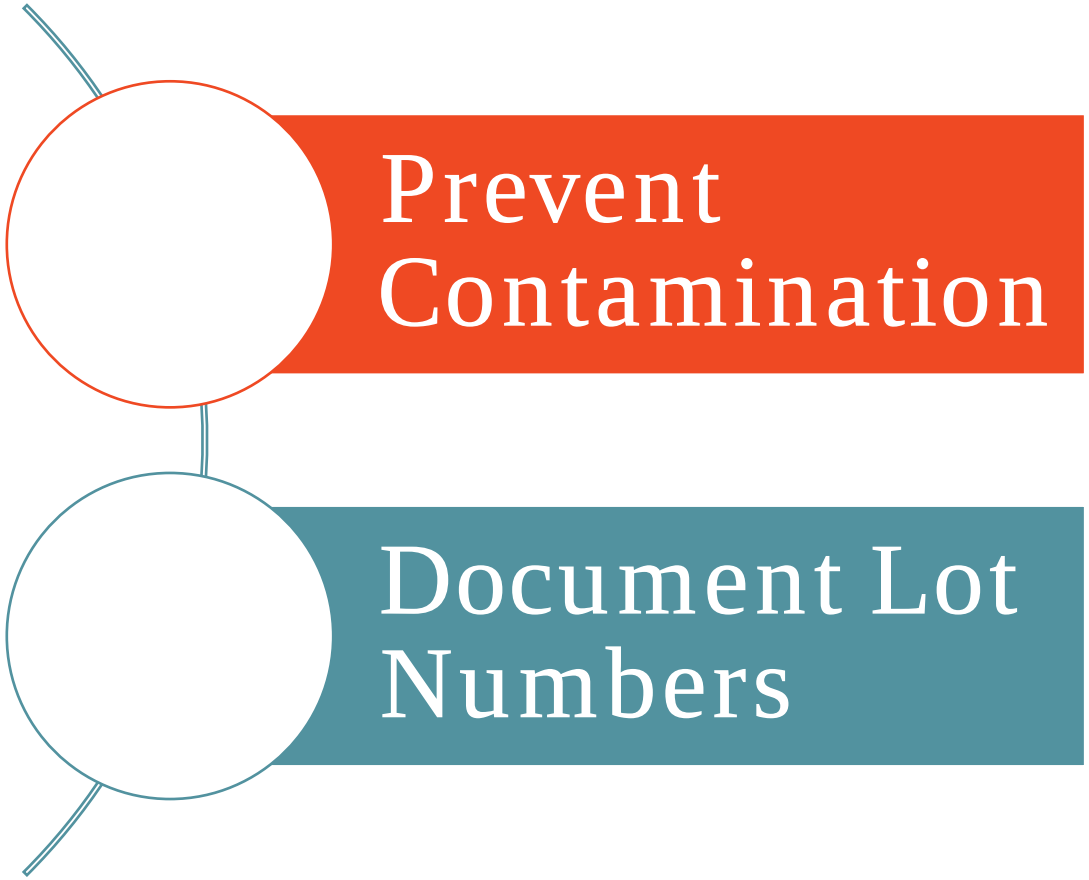
The pharmacy:

a. Communicates in a timely manner with the patient, prescriber and/or payer to resolve issues related to: [4]
   i. Drug utilization review
   ii. Coverage or benefits
   iii. Out of stock and backorder products

P-OPS 2-3: Demonstrating Compliance

- Describe the **process** for communicating with patients, providers, and/or payers regarding the following issues:
  - Drug utilization review
  - Coverage or benefits
  - Out of stock and backorder products

P-OPS 2-4: Dispensing Practices



The pharmacy:

a. Prevents contamination in the dispensing process [4]

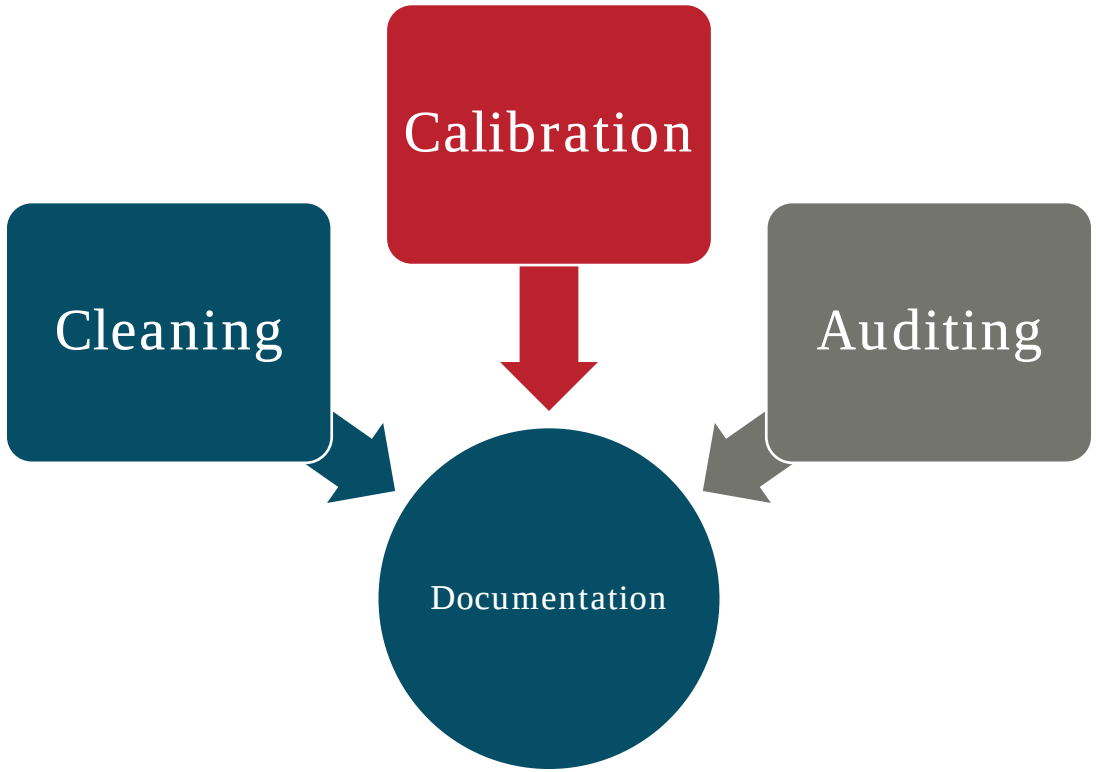
b. Documents lot numbers of products dispensed for tracking purposes [L]

P-OPS 2-4: Demonstrating Compliance

- Outline **how** the pharmacy:
  - Prevents contamination
  - Documents lot numbers

If the organization chooses not to meet the leading indicator – submit a statement

P-OPS 2-5: Machine and Equipment Maintenance



The pharmacy:

a. Maintains machines and equipment used for dispensing in accordance with manufacturer guidelines and state and federal regulations including documented cleaning, calibration, and auditing [4]

P-OPS 2-5: Demonstrating Compliance

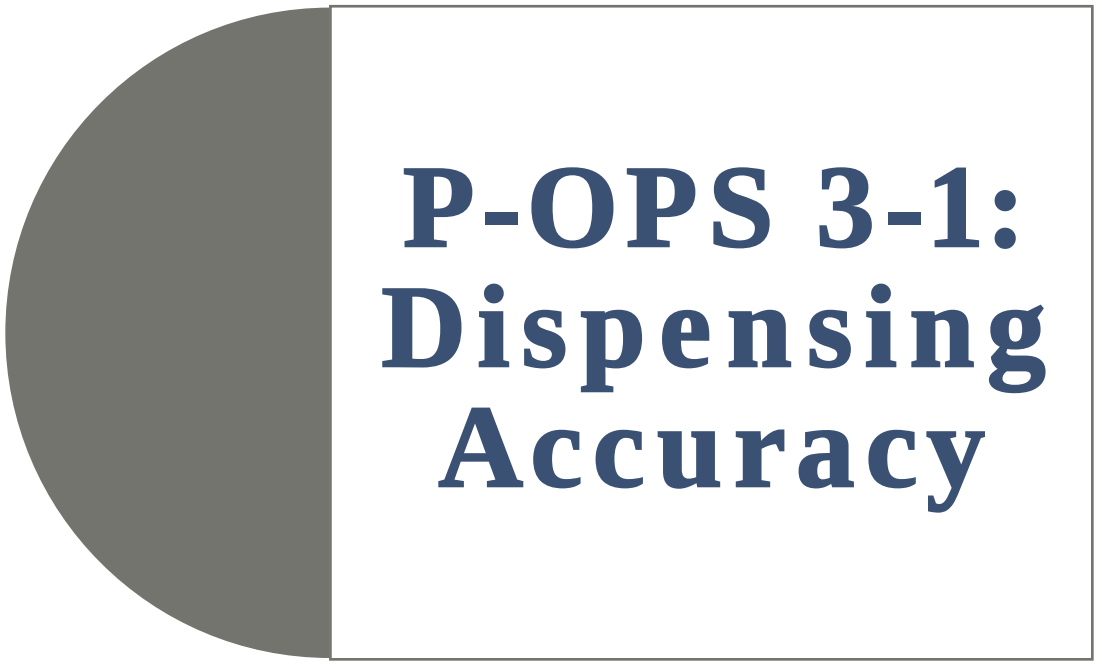
- **List** of Machines and Equipment used in the dispensing process
- Describe the **process** for maintaining machines and equipment
- **Sample documentation or template** demonstrating documentation of cleaning, calibration, and auditing

P-OPS 3: Dispensing Accuracy Monitoring and Promotion

Standard

The pharmacy monitors and promotes dispensing accuracy.

EPGs

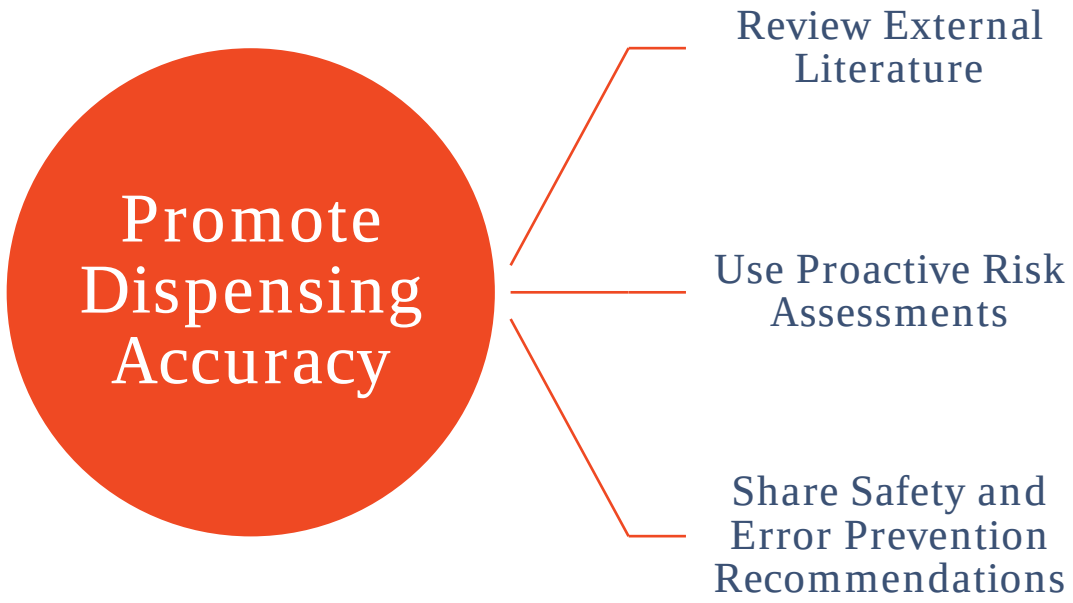


P-OPS 3-1: Dispensing Accuracy

The pharmacy:

a. Monitors dispensing accuracy through: [8]
   i. Tracking both errors and near misses
   ii. Reporting errors to appropriate internal and external entities
   iii. Analyzing data and identifying performance trends on dispensing accuracy for review by the quality oversight body at least quarterly
   iv. Implementing action plans designed to improve or correct identified problems as needed

P-OPS 3-1: Dispensing Accuracy, CONT.



The pharmacy:

b. Reviews relevant external literature at least annually, to incorporate safety and error prevention recommendations into pharmacy practice as appropriate [4]

c. Utilizes proactive risk assessments [4]

d. Shares safety and error prevention recommendations and updates with staff [4]

P-OPS 3-1: Demonstrating Compliance

- Outline **how** the pharmacy:
  - Monitors dispensing accuracy, including tracking, reporting, analyzing, trending, and implementing corrective actions
  - Reviews and incorporates relevant literature recommendations
  - Utilizes proactive risk assessments
  - Shares safety and error prevention recommendations and updates with staff

P-OPS 3-1: Demonstrating Compliance, CONT.

- **Sample documentation or template** demonstrating:
  - Quality oversight body review of dispensing accuracy analysis and trending
  - A literature review, including any recommendations
  - A completed proactive risk assessment
  - A safety or error prevention recommendation shared with staff

P-OPS 4: Adherence Monitoring

Standard

The pharmacy monitors and promotes medication adherence.

EPGs

P-OPS 4-1: Adherence

P-OPS 4-1: Adherence

The pharmacy:

a. Monitors medication adherence to identify when a patient is non-adherent [4]

b. Promotes medication adherence when a patient is identified as non-adherent [4]

c. Analyzes data and identifies performance trends on adherence for review by the quality oversight body at least once in a calendar year [4]

P-OPS 4-1: Demonstrating Compliance

- Outline **how** the pharmacy:
  - Monitors medication adherence
  - Promotes medication adherence
  - Analyzes and trends adherence for review by the QOB
- **Sample documentation or template** demonstrating QOB review of adherence analysis and trends

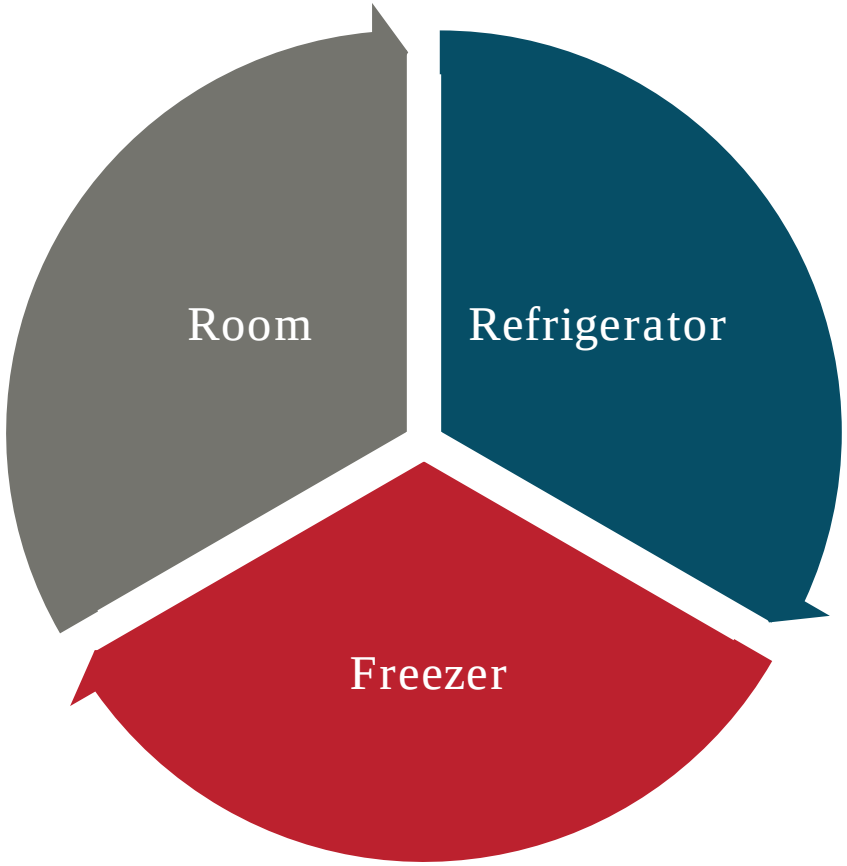
P-OPS 5: Product Management

Standard

Inventory is managed to promote employee and patient safety.

EPGs

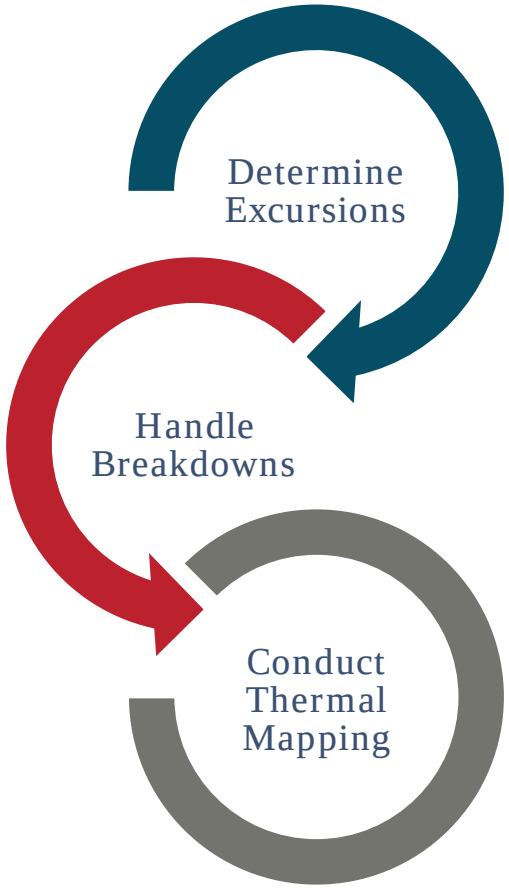
P-OPS 5-1: Inventory Temperature Management



The pharmacy:

a. Continuously monitors all drug storage areas for: [4]
   i. Refrigerator temperature
   ii. Freezer temperature
   iii. Ambient room air temperature
   iv. Humidity

P-OPS 5-1: Inventory Temperature Management, CONT.



The pharmacy:

b. Determines acceptable excursions in temperature and humidity for drug storage areas in accordance with manufacturer guidelines or other published literature [2]

c. Handles breakdowns resulting in excursions that exceed guidelines from the manufacturer or published literature [4]

d. Conducts inventory storage thermal mapping [L]

P-OPS 5-1: Demonstrating Compliance

- Describe **process** for continuous monitoring
- Outline **how** the pharmacy
  - Determines acceptable excursions
  - Handles breakdowns
  - Conducting inventory thermal mapping [optional]
- If the organization chooses not to do thermal mapping – submit a statement
- If the organization chooses to conduct thermal mapping – submit an example demonstrating a completed map

P-OPS 5-2: Hazardous Material Management

The pharmacy:

a. Identifies the hazardous materials and medications kept in the pharmacy [4]

b. Handles, stores and disposes of hazardous materials and medications in accordance with USP 800 guidelines [8]

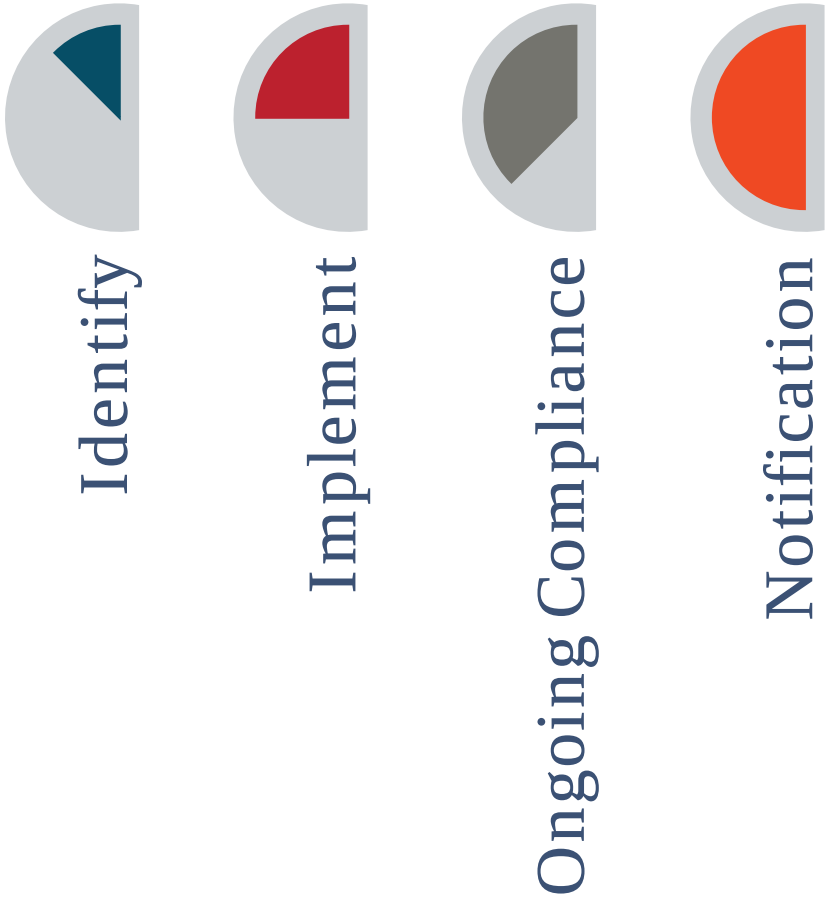
c. Makes readily available and educates on the use of [8]
   i. Safety Data Sheets (SDS)
   ii. Employee spill kits
   iii. Eye wash stations

P-OPS 5-2: Demonstrating Compliance

- Outline **how** the pharmacy
  - Identifies hazardous materials and medications
  - Handles, stores, and disposes of hazardous materials and medications in compliance with USP 800 requirements
  - Educates on how to use these items
- **Require** SDS, employee spill kits and eye wash stations within the pharmacy
- **List** of hazardous medications;

  completed risk assessments
- **Example** of a completed risk assessment

P-OPS 5-3: Manufacturer and FDA Requirements



The pharmacy:

a. Identifies and implements FDA guidance and self-imposed manufacturer requirements, and promotes ongoing compliance [4]

b. Notifies patients and prescribers of a new FDA guidance or self-imposed manufacturer restriction that could cause a potential safety event [4]

P-OPS 5-3: Demonstrating Compliance

- Outline **how** the pharmacy identifies and implements guidance and restrictions, and how ongoing compliance is promoted
- Describe the **process** for notifying patients and prescribers of new guidance and restrictions, including when notification occurs

P-OPS Assessment Question

Compliance with which USP General Chapter is required for URAC's Hazardous Materials standard?

a) USP 659
b) USP 795
c) USP 797
d) USP 800

P-OPS Assessment Answer

Compliance with which USP General Chapter is required for URAC's Hazardous Materials standard?

a) USP 659
b) USP 795
c) USP 797
d) USP 800

Reference: P-OPS 5-2 Hazardous Materials

Medication Distribution (P-MD)

P-MD 1: Distribution Management

P-MD 2: Shipping Logistics

P-MD 3: Distribution Accuracy Monitoring

P-MD 1: Distribution Management

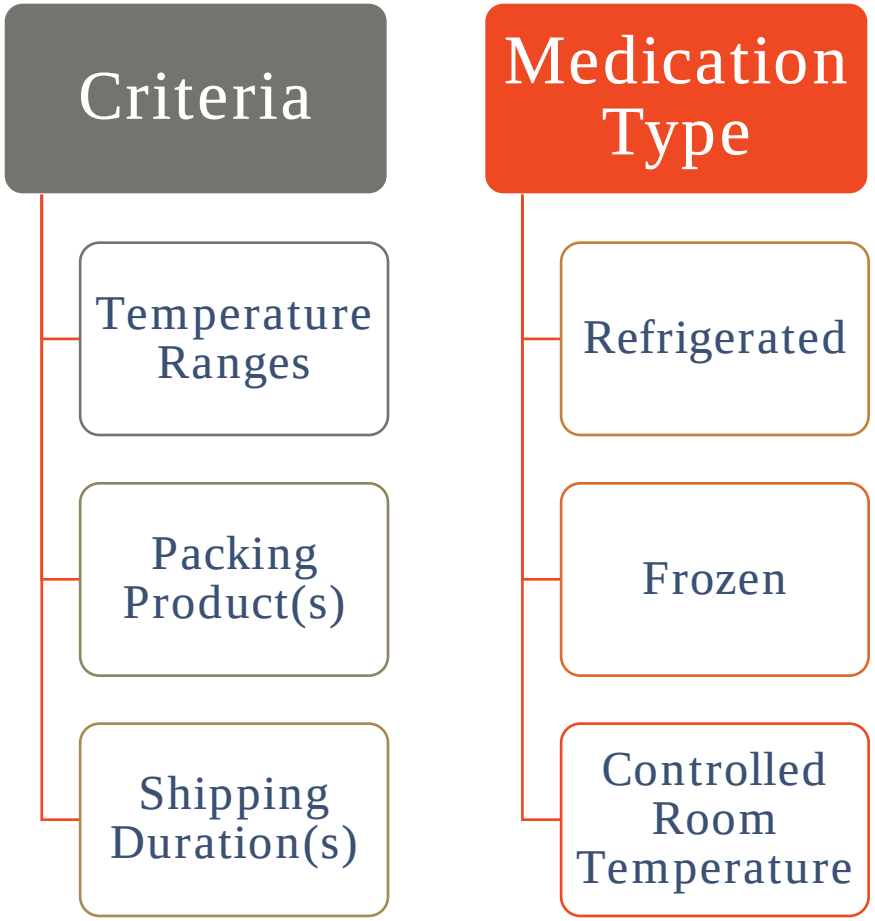
Standard

Distribution criteria are established and tested prior to shipping medications. Packing and shipping processes are audited to monitor for compliance.

EPGs

- P-MD 1-1: Defining Distribution Criteria
- P-MD 1-2: Qualification Testing
- P-MD 1-3: Packing and Shipping Procedures
- P-MD 1-4: Distribution Auditing

P-MD 1-1: Defining Distribution Criteria



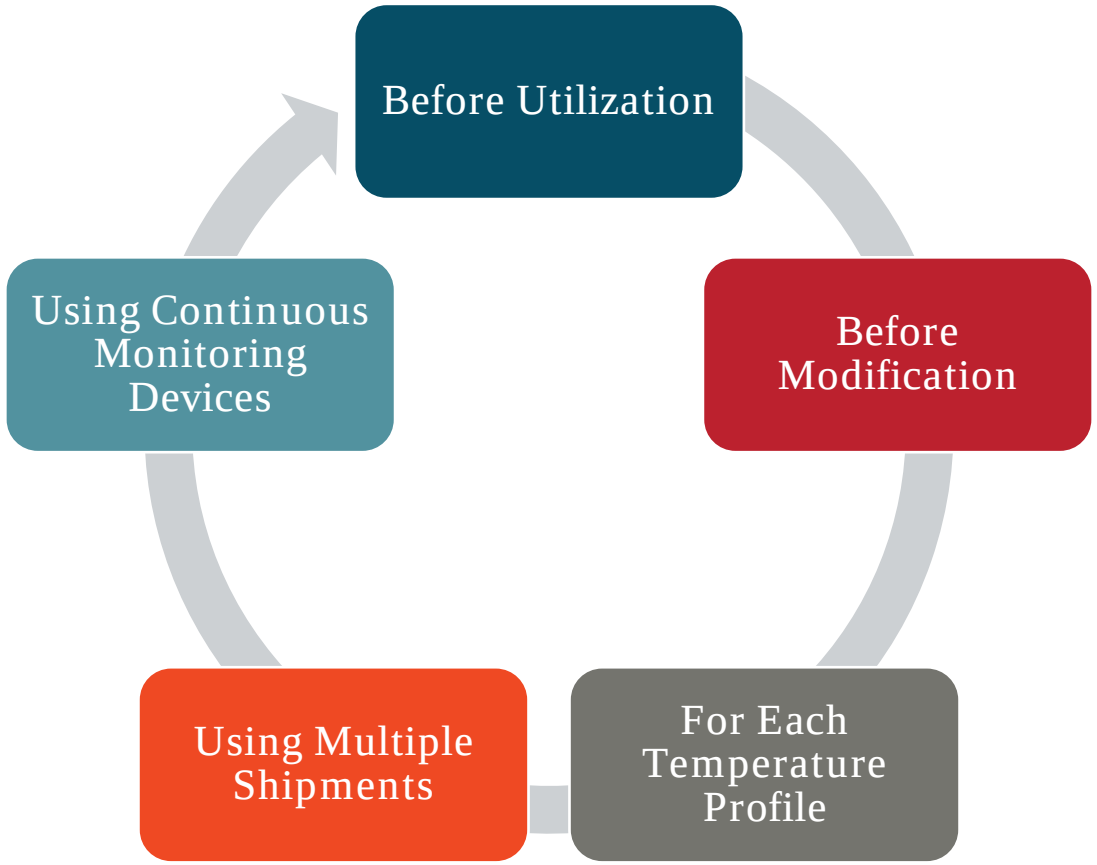
The pharmacy:

a. Defines evidence-based distribution criteria, including temperature range(s), packing product(s) and shipping duration(s), for the following types of medications: [4]
   i. Refrigerated
   ii. Frozen
   iii. Controlled room temperature

P-MD 1-1: Demonstrating Compliance

- **Define** distribution criteria for each medication type, including:
  - Temperature ranges
  - Packing products
  - Duration in transit
  - References used to determine criteria

P-MD 1-2: Qualification Testing



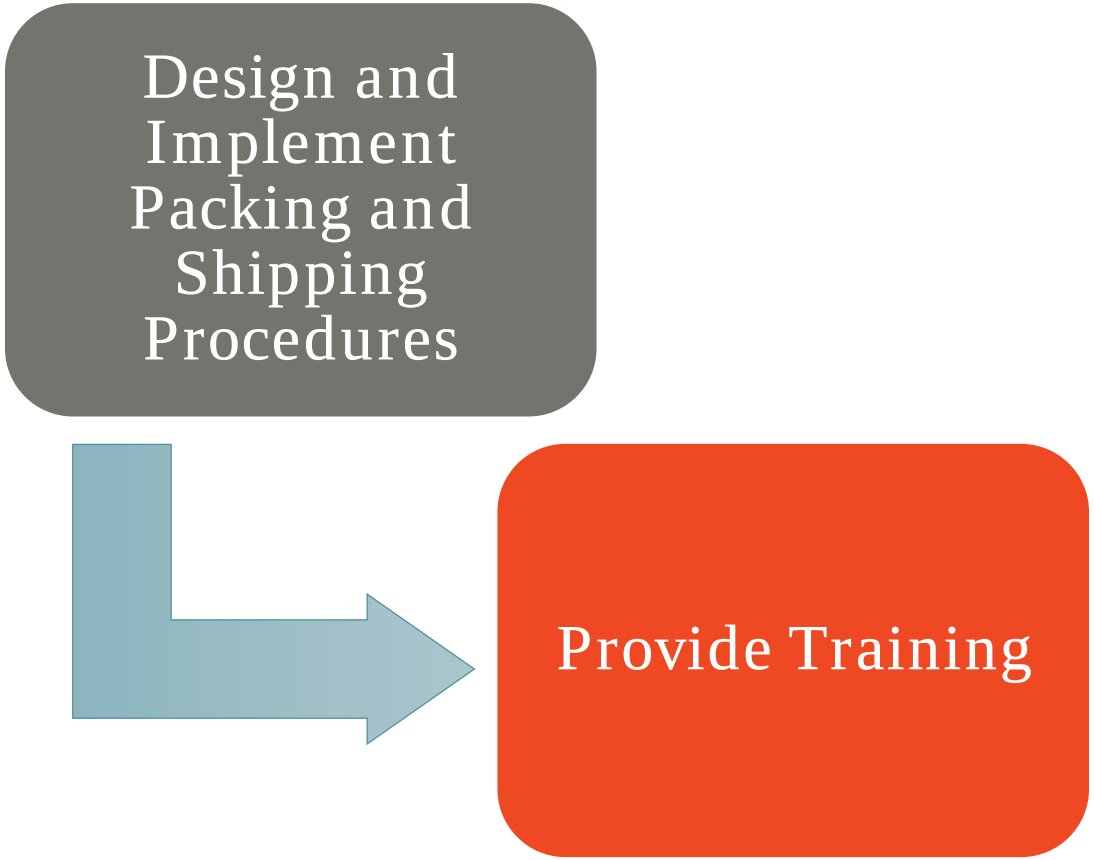
The pharmacy:

a. Develops and initiates a qualification testing plan to validate the distribution criteria is met: [8]
   i. Before utilization or modification of each packing and shipping procedure
   ii. For each temperature profile where medications are shipped
   iii. Using multiple shipments for each packing and shipping procedure
   iv. Using continuous monitoring devices

P-MD 1-2: Demonstrating Compliance

- **Qualification testing plan**
- Outline **how** the pharmacy plans to validate the distribution criteria, including:
  - Before utilization and modification
  - For each temperature profile
  - Using multiple shipments and continuous monitoring devices
- **Sample documentation** demonstrating completed qualification testing

P-MD 1-3: Packing and Shipping Procedures



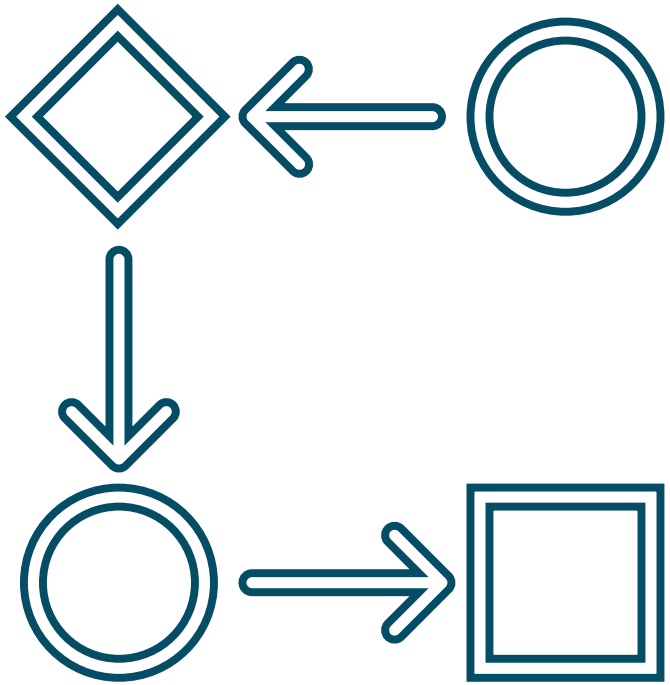
The pharmacy:

a. Designs and implements packing and shipping procedures based on the distribution criteria and qualification testing results for each medication type [4]

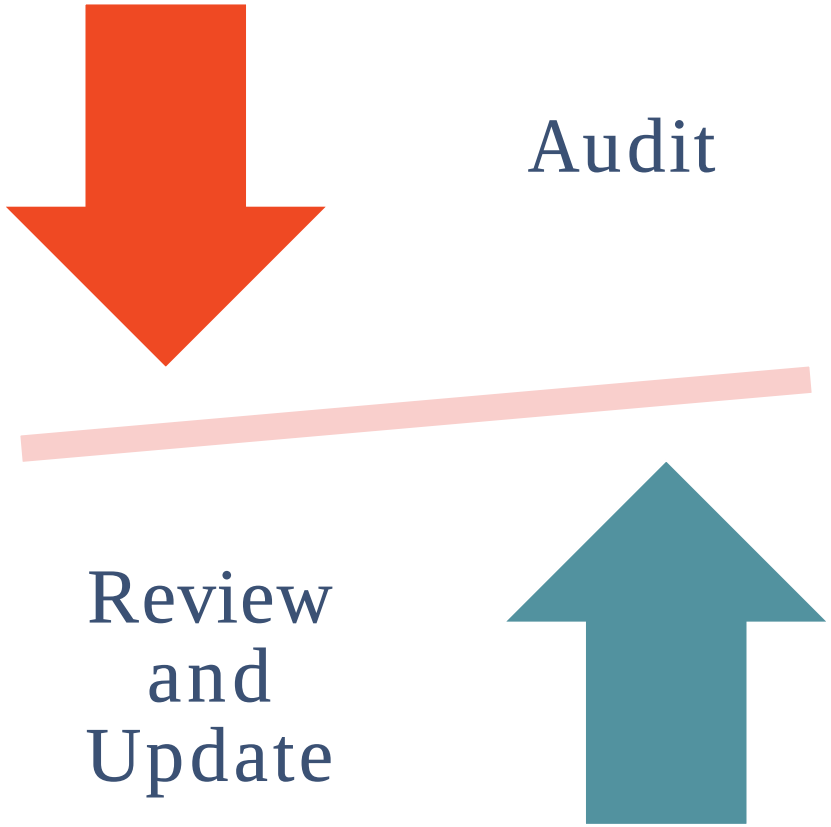
b. Provides training to appropriate staff on packing and shipping procedures [4]

P-MD 1-3: Demonstrating Compliance

- Outline **how** the pharmacy designs and implements packing and shipping procedures
- Describe the **process** for training staff
- **Sample documentation** demonstrating a training material used



P-MD 1-4: Distribution Auditing



At least annually, the pharmacy:

a. Audits each packing and shipping procedure [8]

b. Reviews, and updates as needed, packing and shipping procedures based on: [4]
   i. Distribution auditing results
   ii. Shipping complaints

P-MD 1-4: Demonstrating Compliance

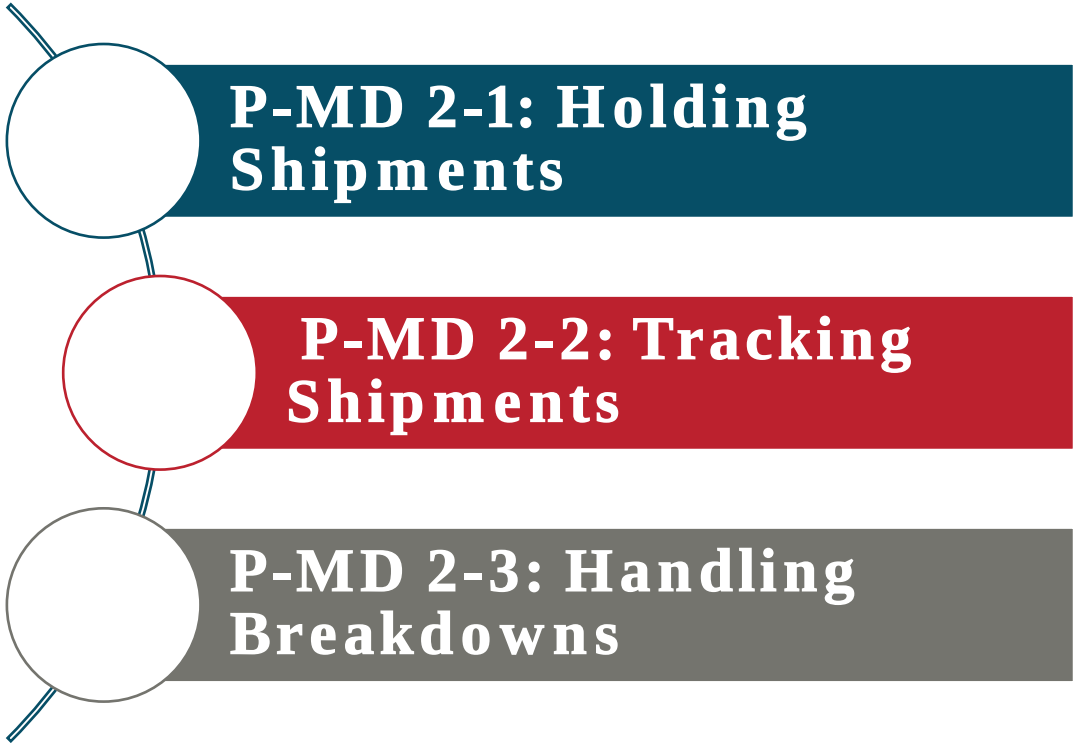
- Outline **how** the pharmacy audits
- Describe the **process** for reviewing and updating packing and shipping procedures
- **Sample documentation** demonstrating completed audits.
- **Sample documentation or template** demonstrating review of packing and shipping procedures

P-MD 2: Shipping Logistics

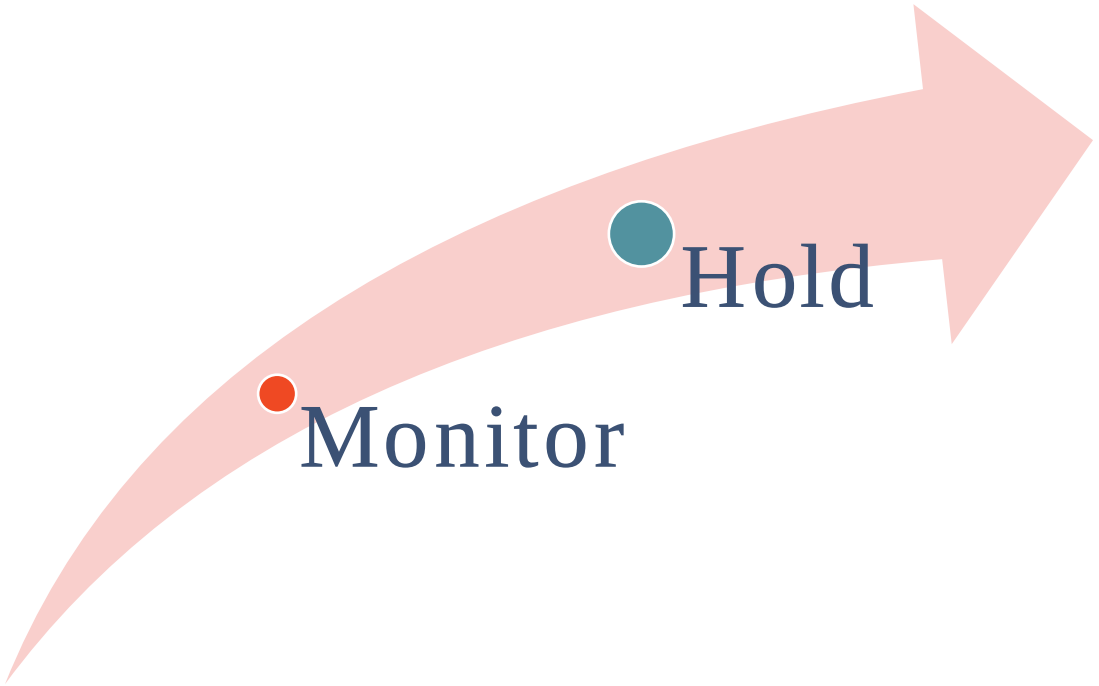
Standard

The pharmacy holds shipments when needed, tracks packages after they leave the pharmacy, and handles breakdowns in the shipping process.

EPGs



P-MD 2-1: Holding Shipments



The pharmacy:

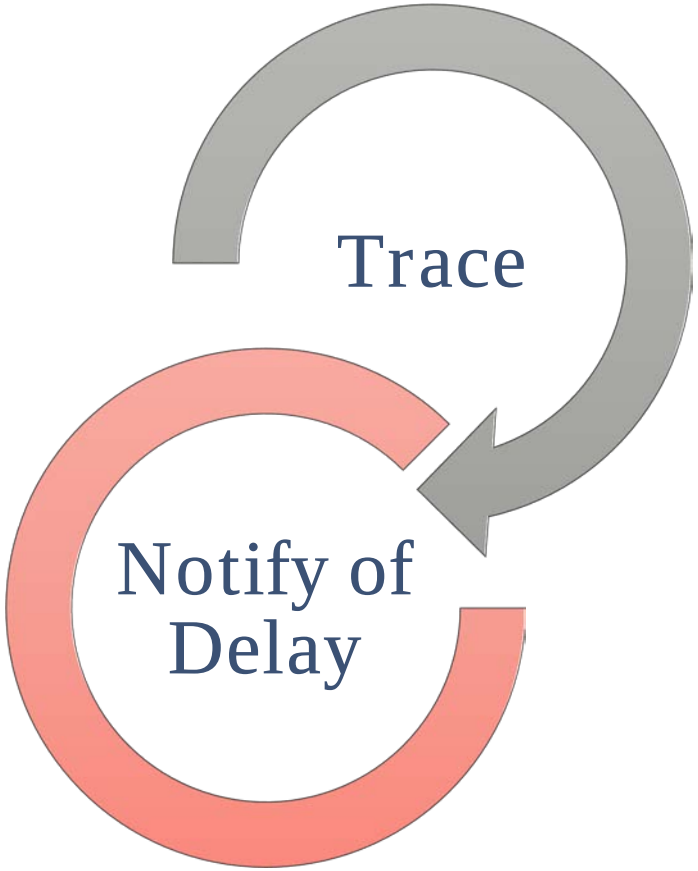
a. Monitors for weather and other expected delays [2]

b. Develops criteria to determine when a shipment should be held [2]

P-MD 2-1: Demonstrating Compliance

- Outline **how** the pharmacy monitors for weather and other delays
- **Define** the criteria for holding a shipment

P-MD 2-2: Tracking Shipments



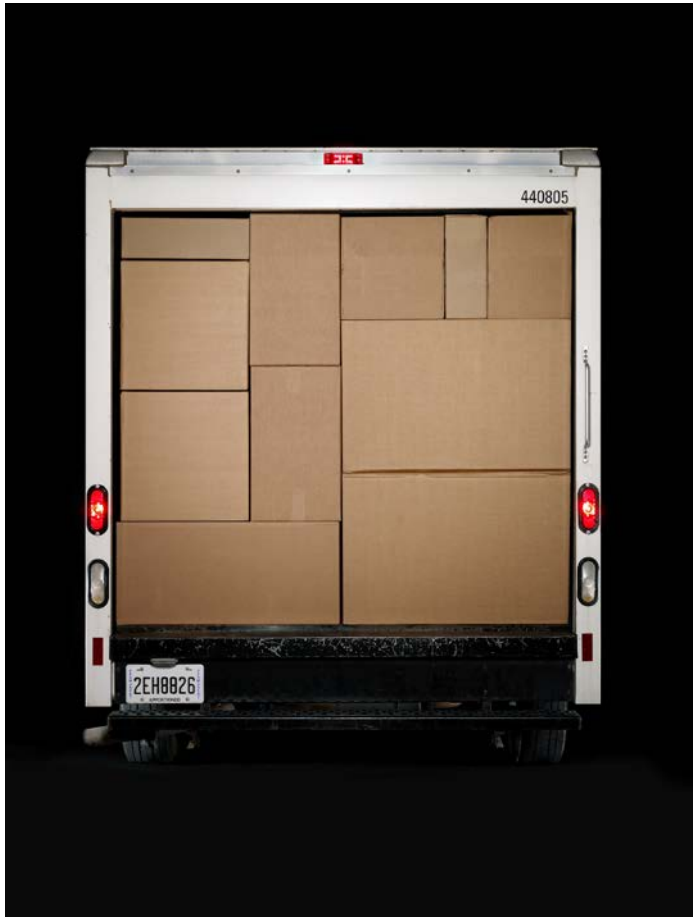
The pharmacy:

a. Traces a package after it leaves the facility [2]

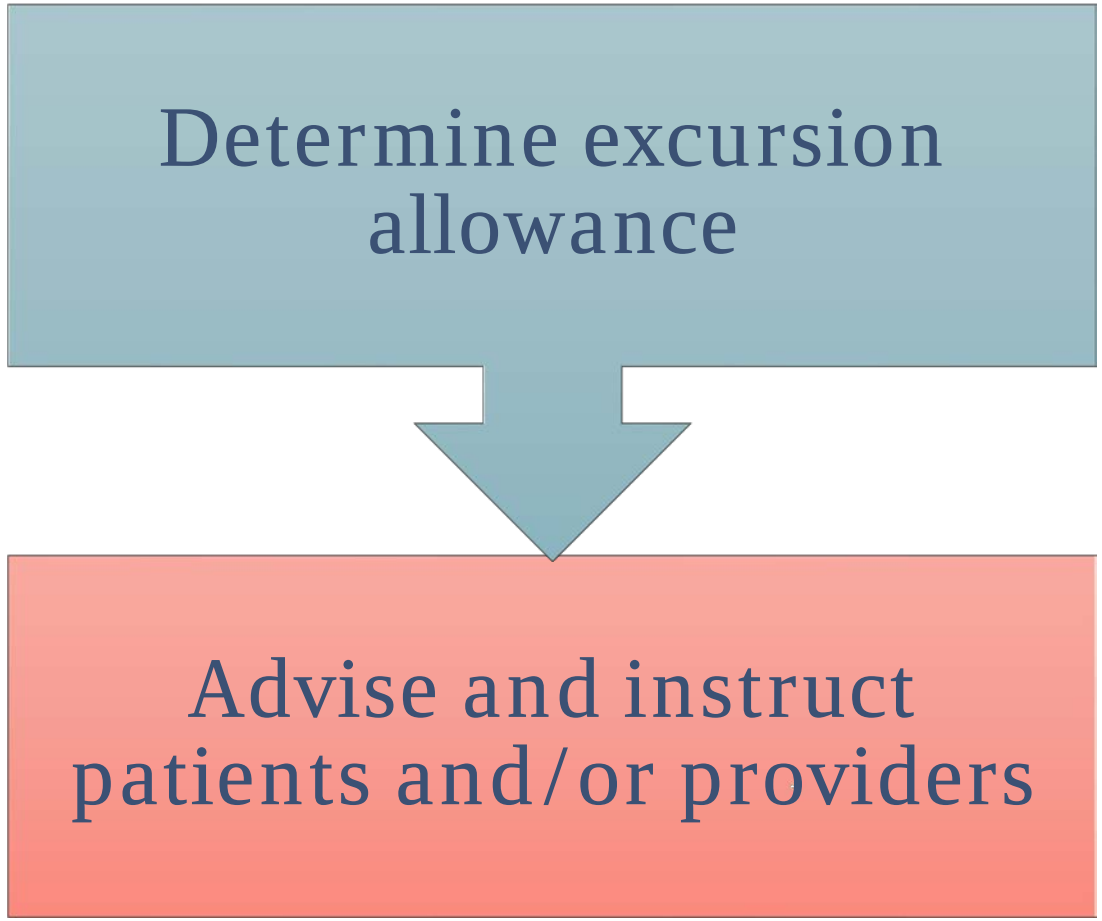
b. Notifies the patient and/or prescriber if shipments will be delayed [4]

P-MD 2-2: Demonstrating Compliance

- Outline **how** the pharmacy traces a package after it's left
- Describe the **process** for notifying of delays



P-MD 2-3: Handling Breakdowns



The pharmacy:

a. Determines the excursion allowances of a product in accordance with manufacturer guidelines or published literature [4]

b. Advises and instructs the patient and/or prescriber regarding the stability of a product when there is a breakdown in the shipping process [4]

P-MD 2-3: Demonstrating Compliance

- Outline **how** the pharmacy determines excursion allowances
- Describe the **process** for advising and instructing patients and/or providers

P-MD 3: Distribution Accuracy Monitoring

Standard

The pharmacy monitors distribution accuracy, analyzes aggregate data, identifies performance trends, and implements corrective actions when needed.

EPGs

P-MD 3-1: Distribution Accuracy

P-MD 3-1: Distribution Accuracy

The pharmacy:

a. Monitors distribution accuracy through: [8]
   i. Tracking distribution errors
   ii. Reporting distribution errors to appropriate internal and external entities
   iii. Analyzing data and identifying performance trends on distribution accuracy for review by the quality oversight body at least quarterly
   iv. Implementing action plans designed to improve or correct identified problems as needed

P-MD 3-1: Demonstrating Compliance

- Outline **how** the pharmacy monitors distribution accuracy, including tracking, reporting, analyzing, trending, and implementing corrective actions
- **Sample documentation or template** demonstrating quality oversight body review of distribution accuracy analysis and trending

P-DM Assessment Question

Which of the following would not qualify as distribution process auditing?

a) Periodic ongoing testing
b) Audits of staff-completed packouts
c) Reviewing and updating packing and shipping procedures
d) Audits on packout weights for consistency

P-DM Assessment Answer

Which of the following would not qualify as distribution process auditing?

a) Periodic ongoing testing
b) Audits of staff-completed packouts
c) Reviewing and updating packing and shipping procedures
d) Audits on packout weights for consistency

Reference: P-DM 1-4: Distribution Auditing

Patient Service and Communication (P-PSC)

P-PSC 1: Patient Information and Support

P-PSC 2: Measuring Complaints and Satisfaction

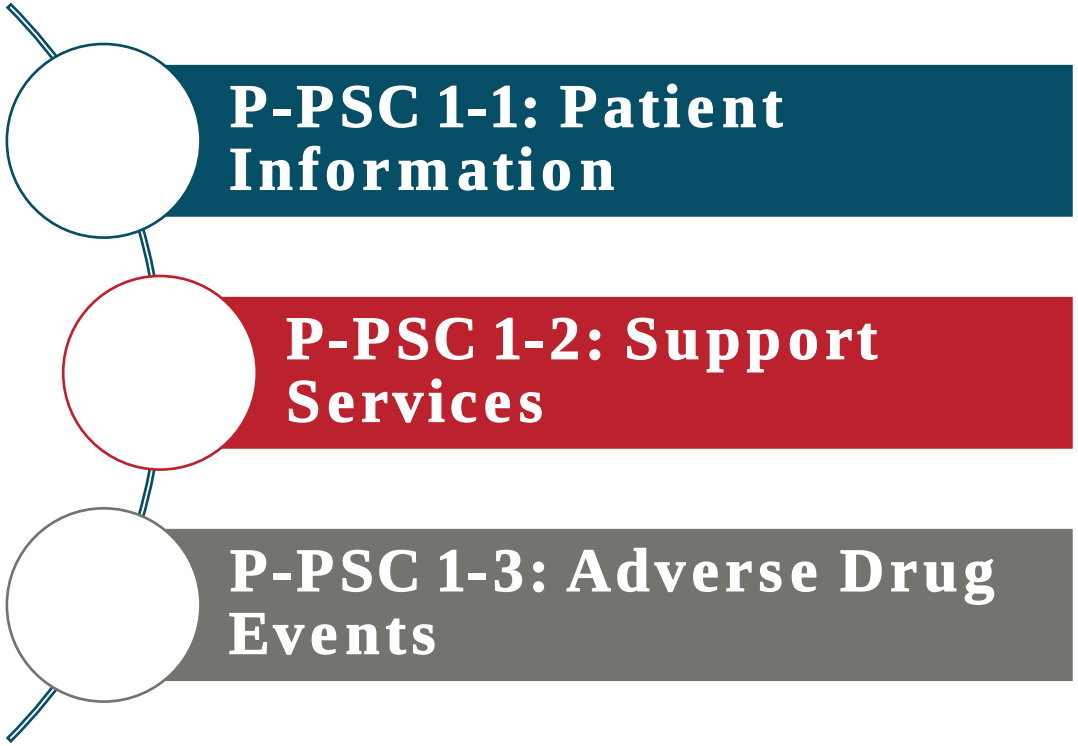
P-PSC 3: Communication Process and Monitoring

P-PSC 1: Patient Information and Support

Standard

Patients and prescribers receive support and drug-related information when needed. Adverse drug events are communicated appropriately.

EPGs



P-PSC 1-1: Patient Information

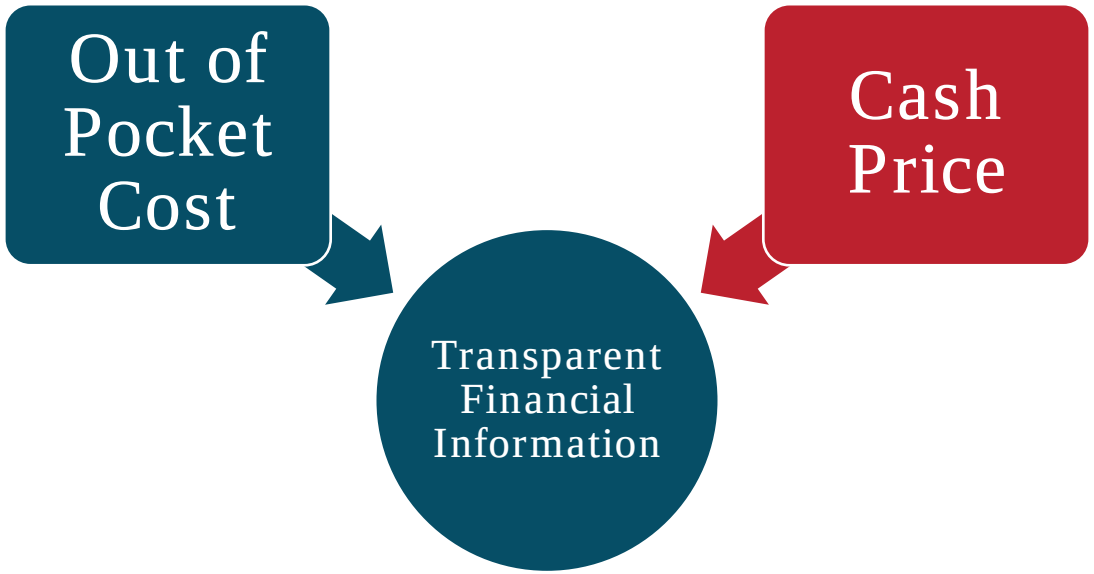
Information Provided

- Access the pharmacy
- Fill and refill prescriptions
- Obtain order status and delays
- Transfer a prescription
- Report an issue

Upon initial fill of a prescription, the pharmacy:

a. Provides information regarding how to: [2]
   i. Access pharmacy representatives
   ii. Fill a prescription, including refills
   iii. Obtain order status and delays
   iv. Have a prescription transferred
   v. Report a suspected medication issue

P-PSC 1-1: Patient Information, CONT.



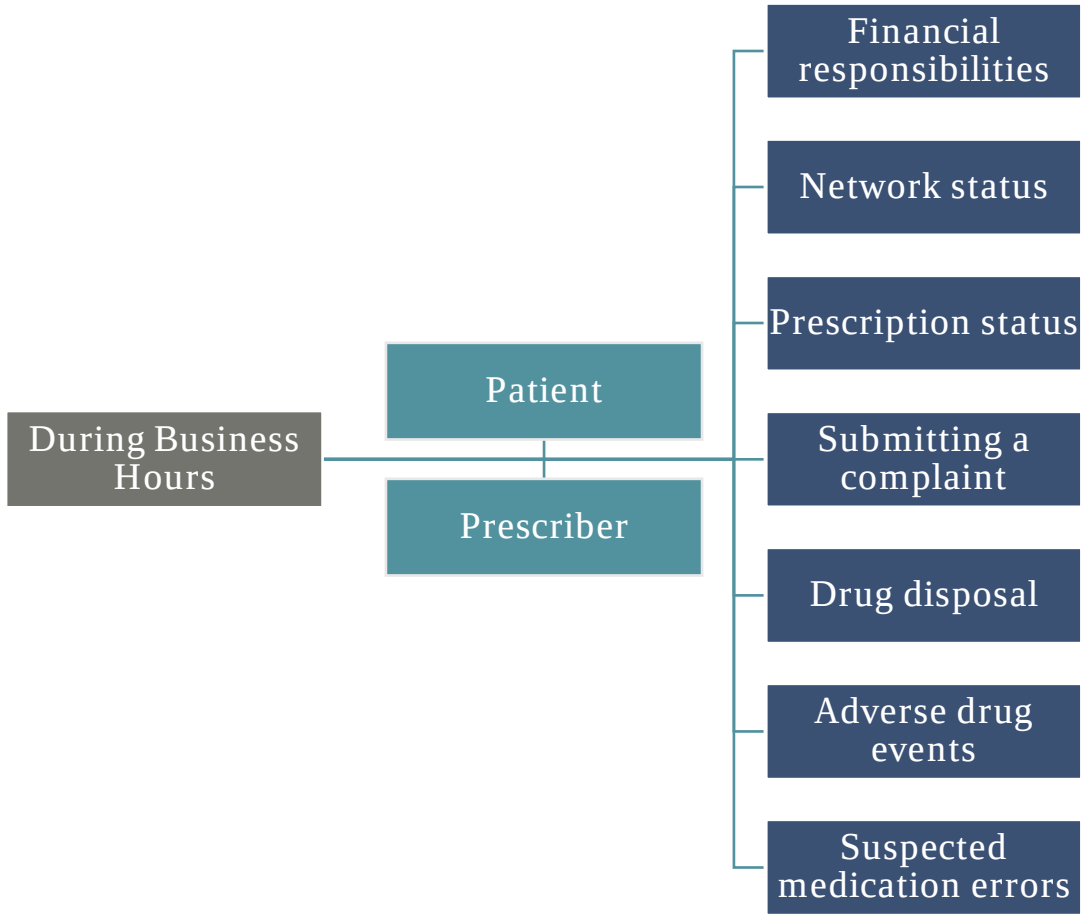
Upon initial fill of a prescription, the pharmacy:

b. Provides transparent financial information on: [2]
   i. The patient's out-of-pocket costs such as deductibles, co-pays, and co-insurance, as available
   ii. The cash price of the medication, upon request

P-PSC 1-1: Demonstrating Compliance

- Describe the **process** for
  - Providing information to patients upon initial fill
  - Providing transparent financial information to patients
- **Example evidence** demonstrating information shared with patient

P-PSC 1-2: Support Services



During business hours, the pharmacy:

a. **Responds to the following types of inquiries from patients and/or prescribers: [4]**
   i. **Patient financial responsibilities**
   ii. **Whether the pharmacy is in or out of network**
   iii. **Prescription order status**
   iv. **How to submit a complaint**
   v. **Safe drug disposal**
   vi. **How to address adverse drug events**
   vii. **How to report suspected medication errors**

P-PSC 1-2: Demonstrating Compliance

- Describe the **process** for responding to inquiries
  - During normal business hours
  - From patients and/or providers

P-PSC 1-3: Adverse Drug Events

After identifying adverse drug events, the pharmacy:

a. Reports serious and unexpected adverse drug events to appropriate external entities [4]

P-PSC 1-3: Demonstrating Compliance

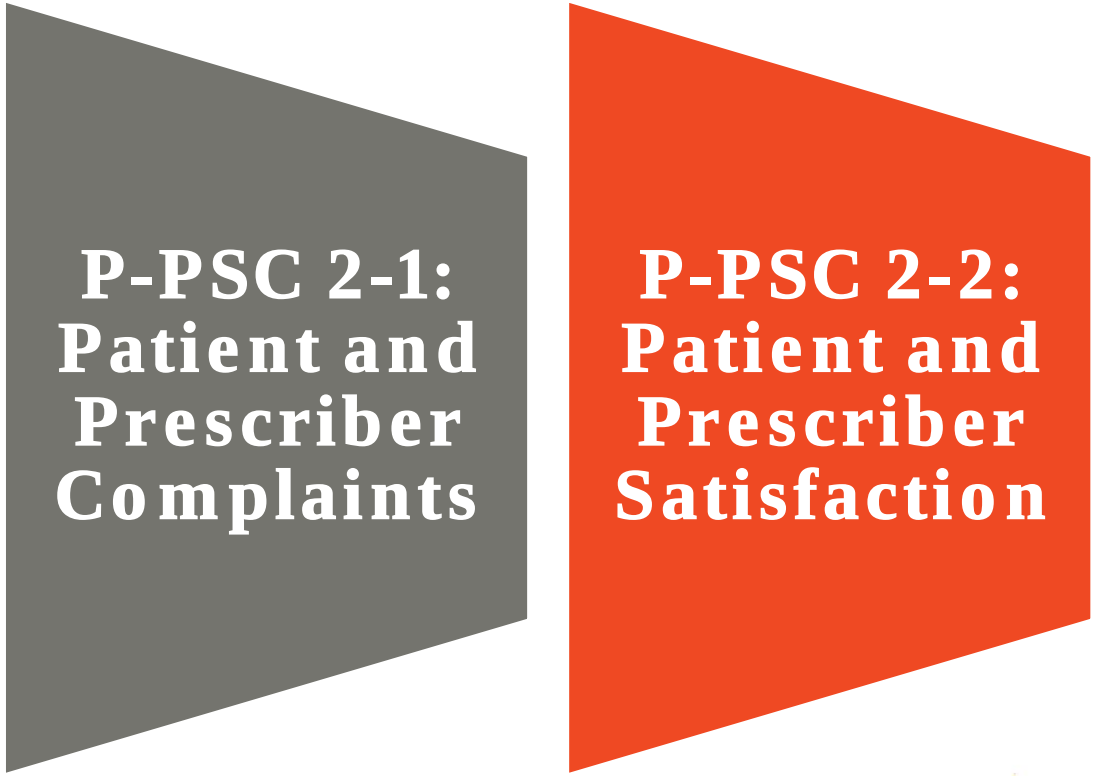
- Describe the **process** for reporting adverse drug events

P-PSC 2: Measuring Complaints and Satisfaction

Standard

Information on patient and prescriber complaints and satisfaction is used to improve the quality of pharmacy services.

EPGs



P-PSC 2-1: Patient and Prescriber Complaints

The pharmacy:

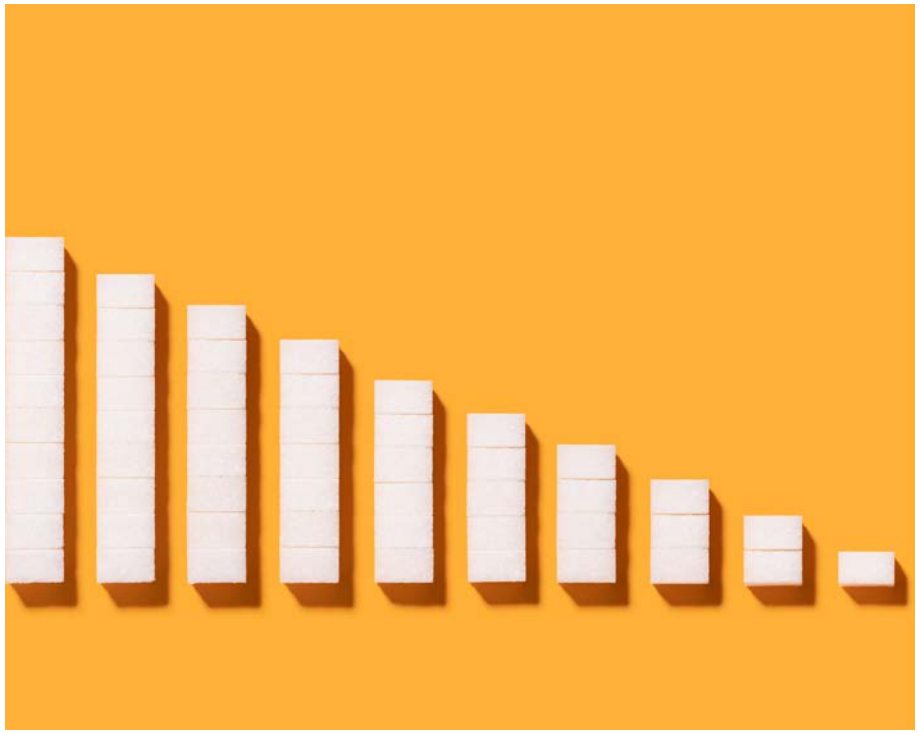
a. Measures patient and prescriber complaints [4]

b. Analyzes data and identifies performance trends for review by the quality oversight body at least quarterly on the following: [4]
   i. Patient complaints
   ii. Prescriber complaints

c. Implements action plans designed to improve or correct identified problems as needed [2]

P-PSC 2-1: Demonstrating Compliance

- Outline **how** the pharmacy :
  - Measures complaints
  - Analyzes and trends complaint data at least quarterly
  - Implements corrective actions when needed
- **Sample documentation or template** demonstrating quality oversight body review of patient and prescriber complaint analysis and trending



P-PSC 2-2: Patient and Prescriber Satisfaction

The pharmacy:

a. Measures patient and prescriber satisfaction [4]

b. Analyzes data and identifies performance trends on patient satisfaction for review by the quality oversight body at least once per calendar year [4]

c. Implements action plans designed to improve or correct identified problems as needed [2]

P-PSC 2-2: Demonstrating Compliance

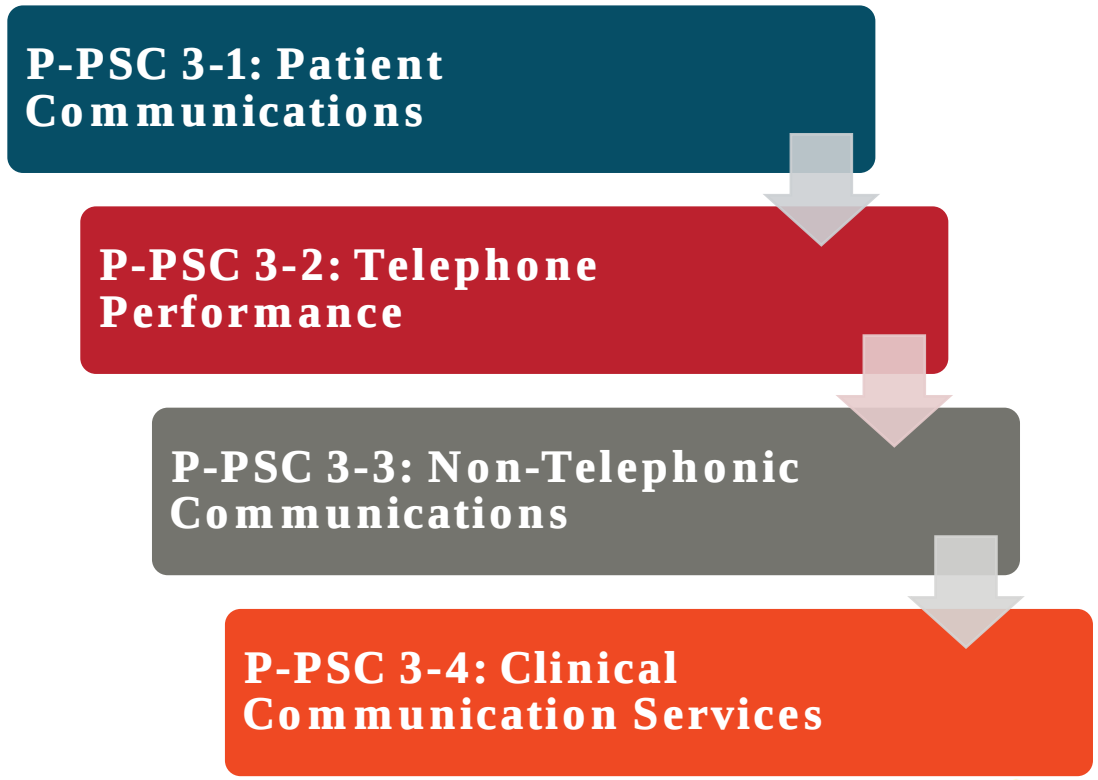
- Outline **how** the pharmacy :
  - Measures satisfaction
  - Analyzes and trends satisfaction data at least once per calendar year
  - Implements corrective actions when needed
- **Sample documentation or template** demonstrating quality oversight body review of patient satisfaction analysis and trending

P-PSC 3: Communication Process and Monitoring

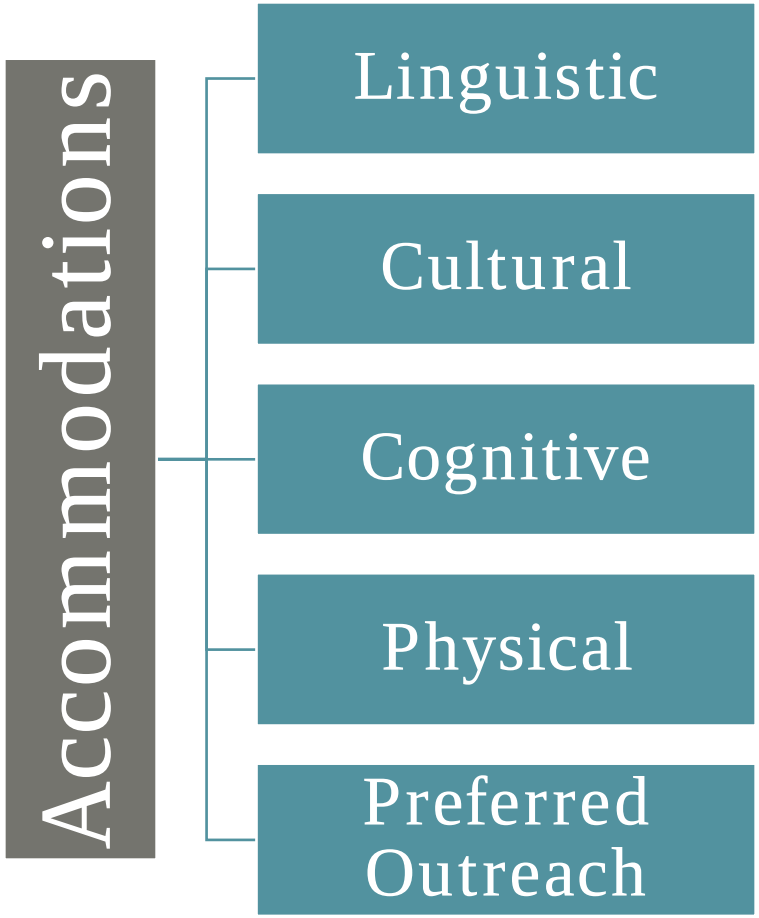
Standard

Patient communications accommodate the diversity of the population. All communications are handled in a timely manner. Clinical communications are handled by a clinician.

EPGs



P-PSC 3-1: Patient Communications



The pharmacy:

a. Accommodates the diversity of the patient population during communications, including persons with: [8]
   i. Linguistic differences
   ii. Cultural differences
   iii. Cognitive impairments
   iv. Physical impairments

b. Accommodates the patient's preferred outreach method [L]

P-PSC 3-1: Demonstrating Compliance

- Outline **how** the pharmacy
  - Accommodates the diversity of patients during communication
  - Accommodates the patient's preferred outreach method

P-PSC 3-2: Telephone Performance

The pharmacy:

a. Sustains a quarterly telephone performance metric of average abandonment rate of 5% or less [4]

b. Sustains a quarterly telephone performance metric of at least 80% of calls answered by a live person within 30 seconds [4]

c. Analyzes data and identifies performance trends on telephone performance metrics for review by the quality oversight body at least quarterly [4]

d. Implements action plans designed to improve or correct identified problems as needed [2]

P-PSC 3-2: Demonstrating Compliance

- **Require** sustained telephone performance metrics for
  - Average abandonment rate
  - Percent of calls answered by a live person within 30 seconds
- Outline **how** the pharmacy
  - Analyzes and trends telephone performance data at least quarterly
  - Implements corrective actions when needed

P-PSC 3-2: Demonstrating Compliance, CONT.

- **Sample documentation or template** demonstrating quality oversight body review of telephone performance analysis and trending

P-PSC 3-3: Non-Telephonic Communications

The pharmacy:

a. Addresses timely response of non-telephonic communications from a patient or prescriber [4]
b. Supports bi-directional electronic communication between the patient and the pharmacy [L]

P-PSC 3-3: Demonstrating Compliance

- Outline **how** the pharmacy
  - Addresses timely response of non-telephonic communication, including which communication methods are used and the response time for each
  - Supports bi-directional electronic communications

P-PSC 3-4: Clinical Communication Services

The pharmacy:

a. Provides clinical communications such that: [8]
   i. Clinical calls are handled 24 hours a day 7 days a week
   ii. All clinical communications are answered in a timely manner
   iii. Counseling is provided to patients as needed and upon request
   iv. Communications are escalated as needed to a clinician

P-PSC 3-4: Demonstrating Compliance

- Outline **how** the pharmacy handles clinical communications including:
  - 24/7 clinical calls
  - Answering all clinical communications in a timely manner
  - Counseling provided as needed and upon request
  - When communications are escalated to a clinician

P-PSC Assessment Question

True or False: It is an accreditation requirement to accommodate the patient's preferred communication outreach method.

P-PSC Assessment Answer

True or False: It is an accreditation requirement to accommodates the patient's preferred communication outreach method.

False: this is a Leading Indicator, but not an accreditation requirement.

Reference: P-PSC 3-1: Patient Communications

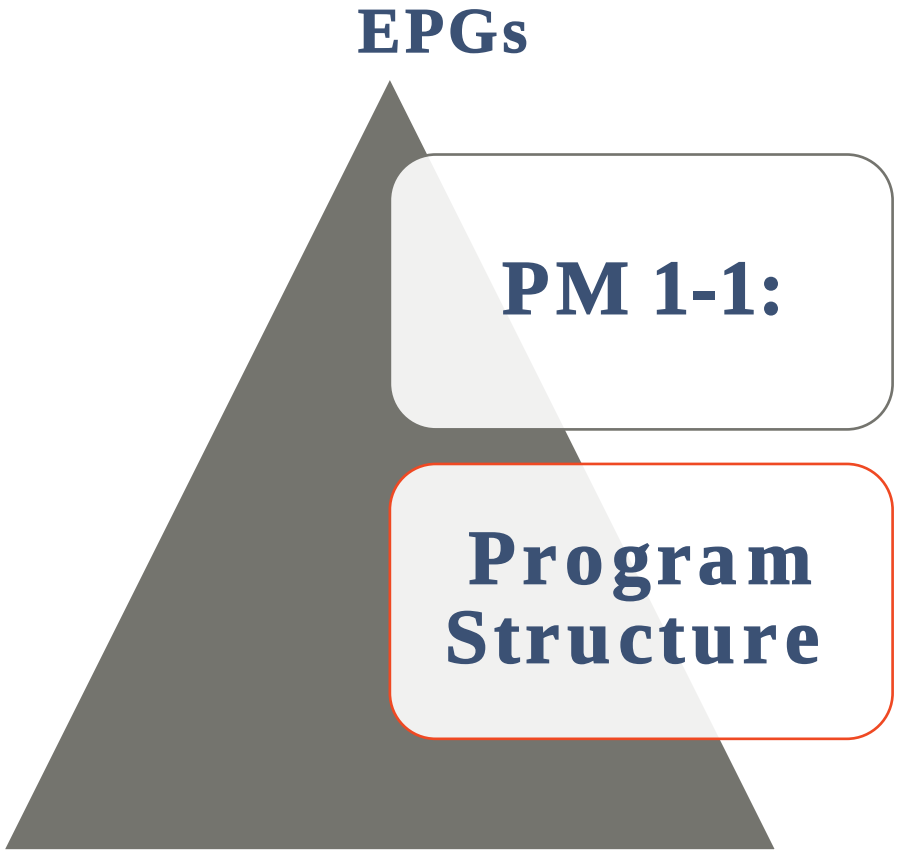
Patient Management (PM)

PM 1: Patient Management Program Structure
PM 2: Patient Management Program Overview
PM 3: Program Disclosures
PM 4: Assessments
PM 5: Education and Support
PM 6: Care Team Collaboration
PM 7: Program Evaluation and Review

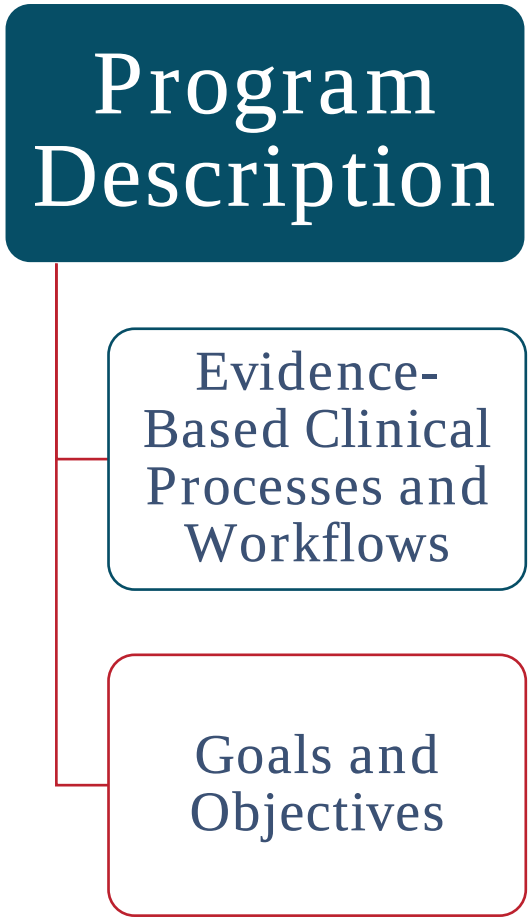
PM 1: Patient Management Program Structure

Standard

The organization maintains a patient management program description. **[M]**



PM 1-1: Program Structure

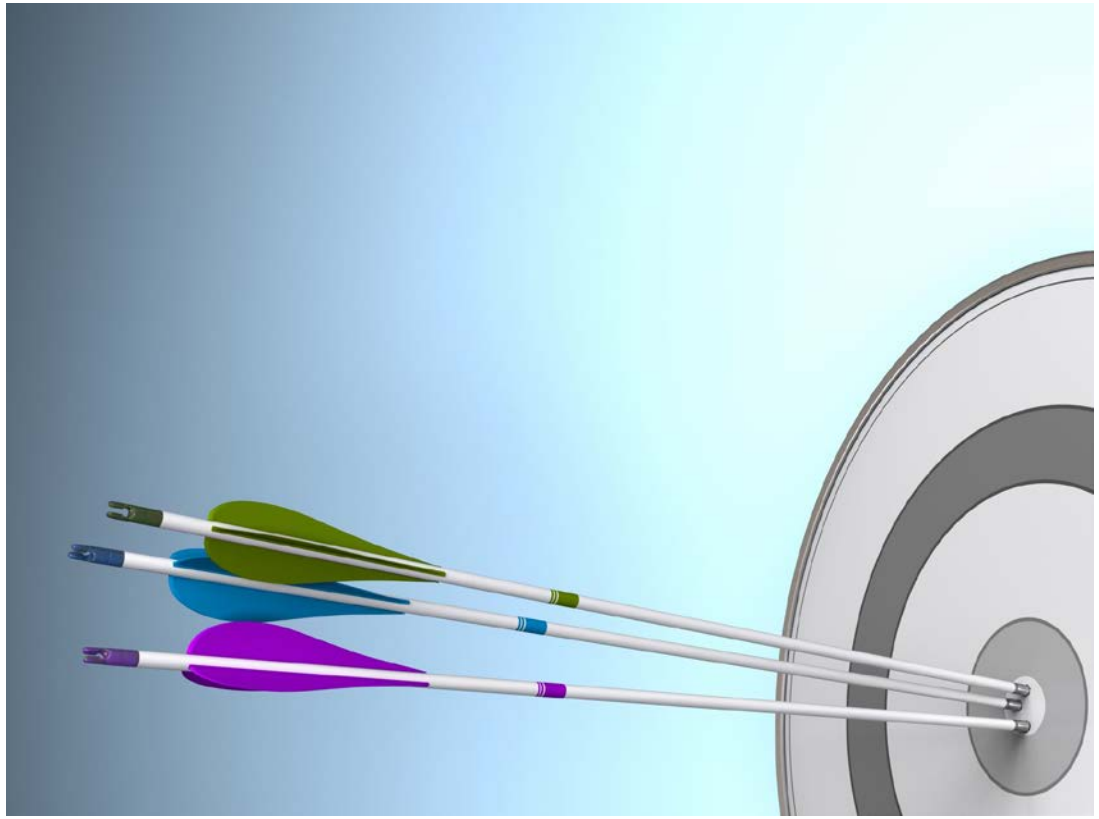


The pharmacy:

a. Outlines the scope of services within the patient management program description, to include
   i. Clinical processes and workflows specific to each drug and/or disease state based on medical or scientific evidence and/or demonstrated clinical practice guidelines/protocols
   ii. Goals and objectives

PM 1-1: Demonstrating Compliance

- **Define** the scope of services including:
  - clinical processes and workflows based on evidence
  - The goals and objectives of the program

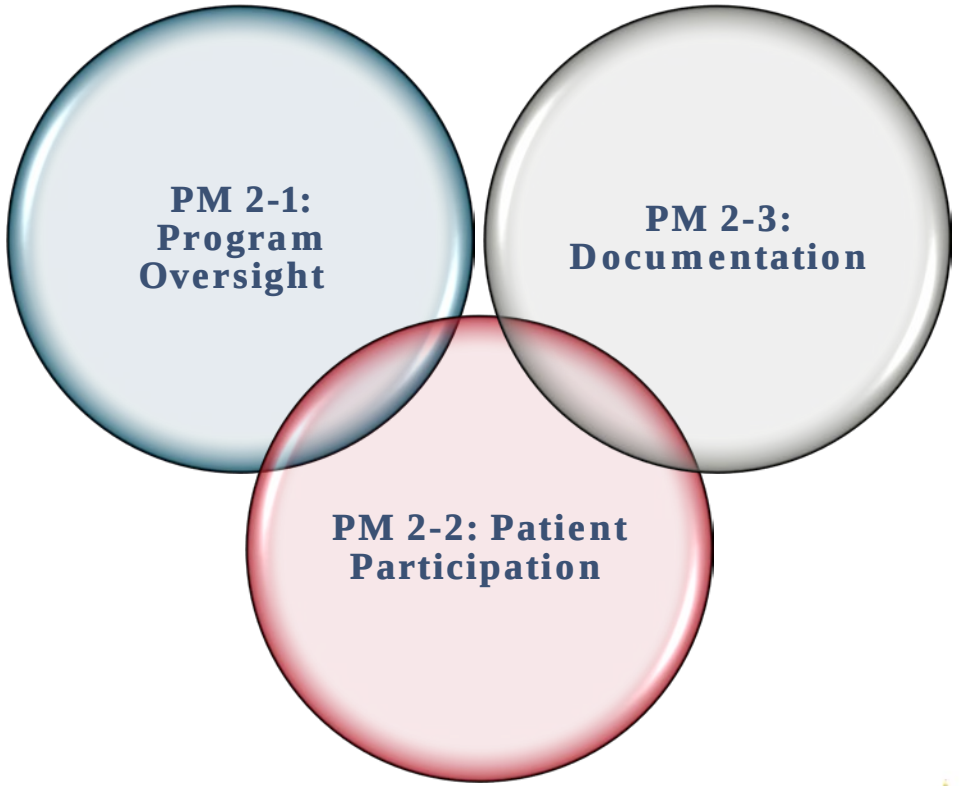


PM 2: Patient Management Program Overview

Standard

The organization's patient management program has appropriate oversight and is available to all patients receiving a specialty medication. The program is designed to provide quality patient care.

EPGs



PM 2-1: Program Oversight

The pharmacy:

a. Develops the patient management program with oversight by the clinical oversight body [4]

PM 2-1: Program Oversight, CONT.

The pharmacy:

b. Implements the patient management program to follow the specific drug and/or disease state clinical processes and workflows with: [8]
   i. Oversight by a pharmacist or qualified health professional
   ii. Provision of clinical services by a pharmacist or other qualified health professional
   iii. Criteria for when information gathered by a non clinician or system must be escalated for timely review by a clinician

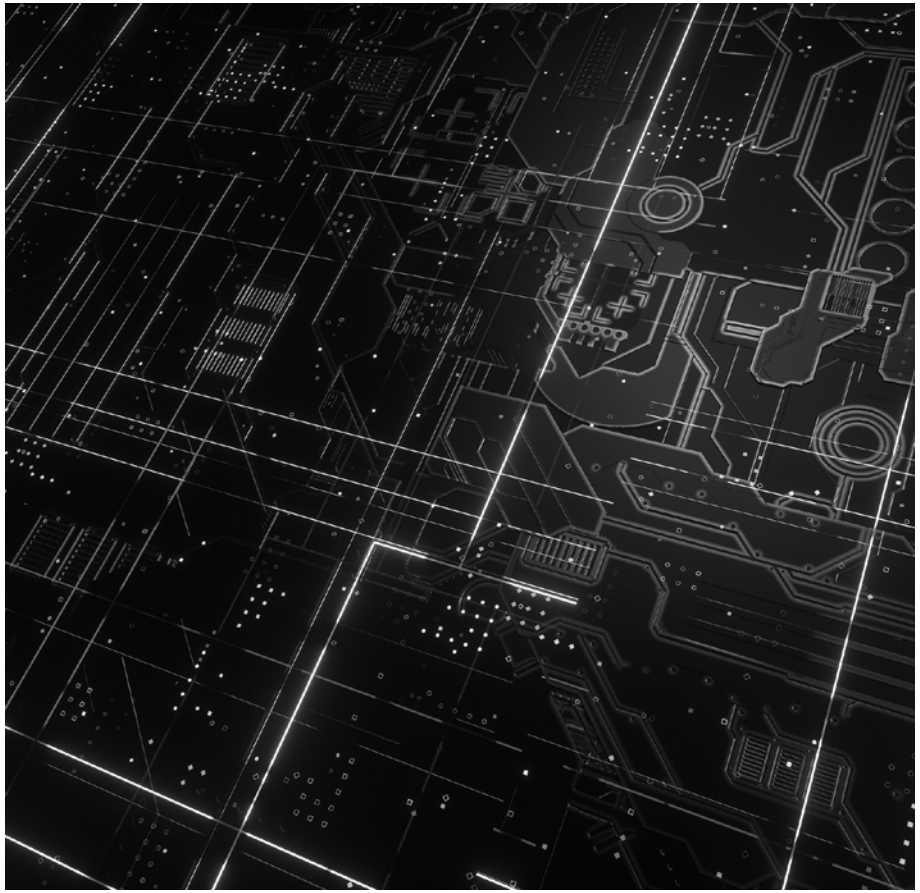
PM 2-1: Program Oversight, CONT.

The pharmacy:

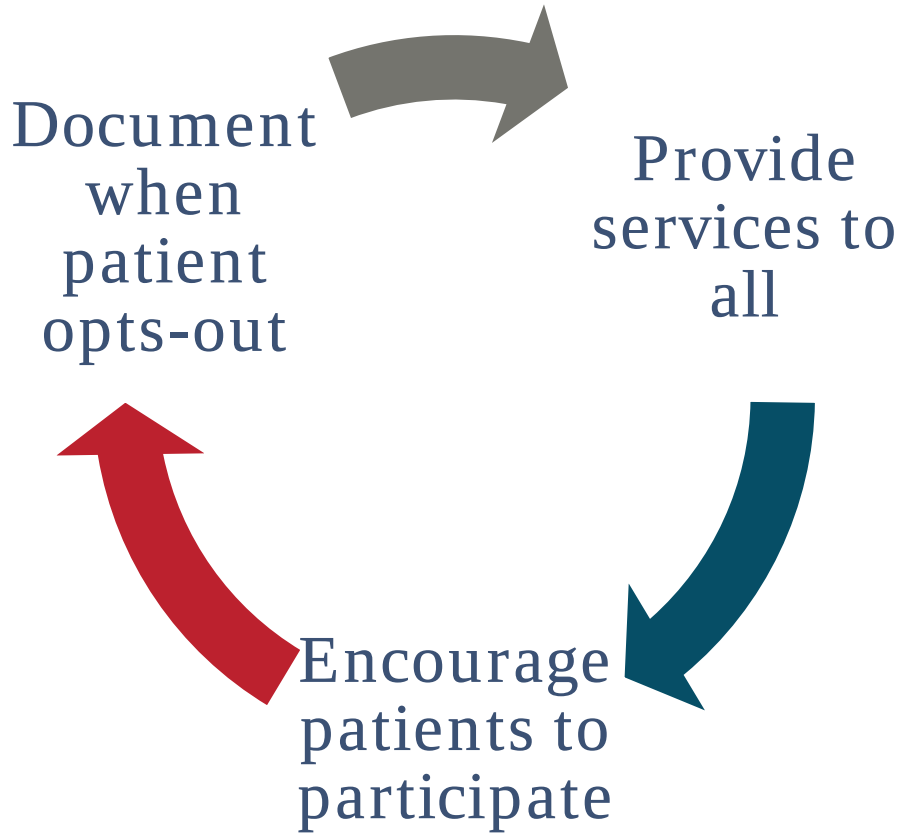
c. Demonstrates that the patient management program is reviewed, approved and updated, as needed, by the clinical oversight body at least annually, including the drug and/or disease state specific clinical processes and workflows [4]

PM 2-1: Demonstrating Compliance

- Outline **how** the pharmacy
  - Implements the program to follow clinical processes and workflows
  - Reviews and updates the program at least annually
- **Evidence** the program was developed with oversight by the clinical oversight body
- **Sample documentation or template** demonstrating review and approval of the program by the oversight body



PM 2-2: Patient Participation



The pharmacy:

a. Provides patient management program services to all patients receiving a specialty prescription [8]
b. Encourages patients to participate in their care and the services provided by the patient management program [4]
c. Documents when a patient opts-out of the patient management program [2]

PM 2-2: Demonstrating Compliance

- **Require** patient management program services for all patients receiving a specialty medication
- Outline **how** the pharmacy
  - Encourages participation
  - Documents when a patient opts-out of the program

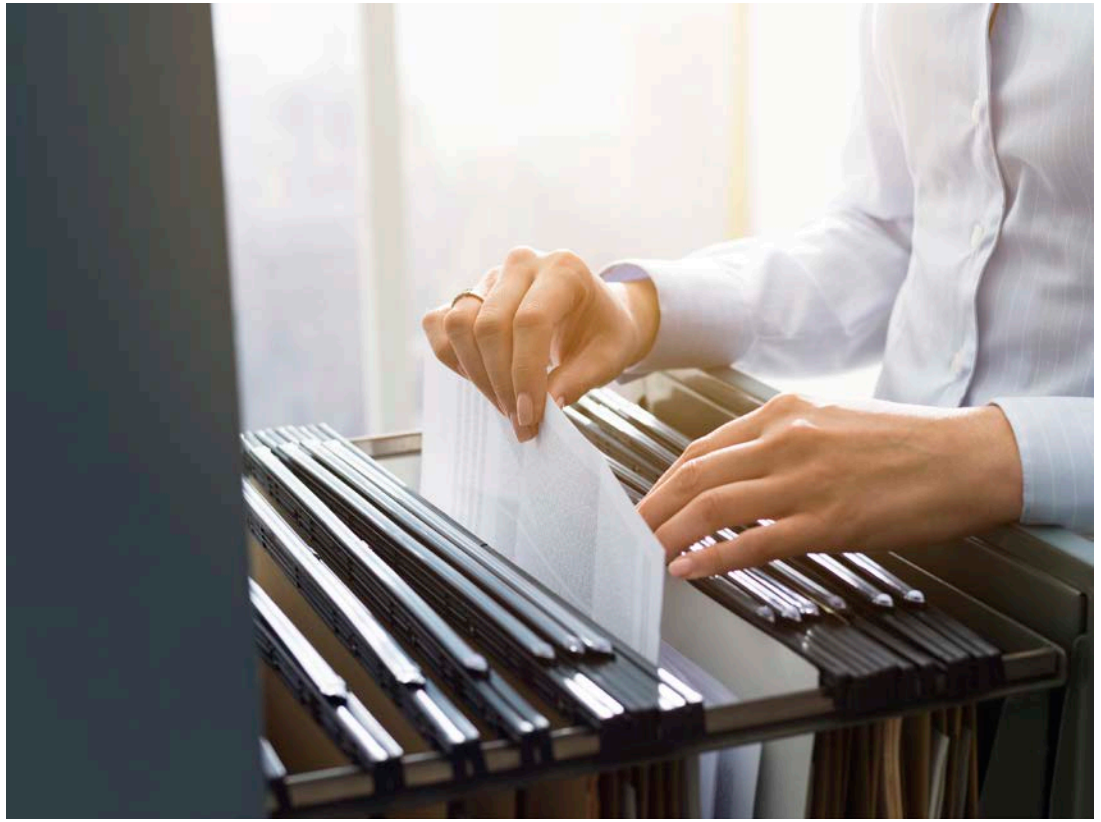
PM 2-3: Documentation

The pharmacy:

a. Documents all patient management information in a consistent location [2]

PM 2-3: Demonstrating Compliance

- Describe the **process** for documenting patient management information



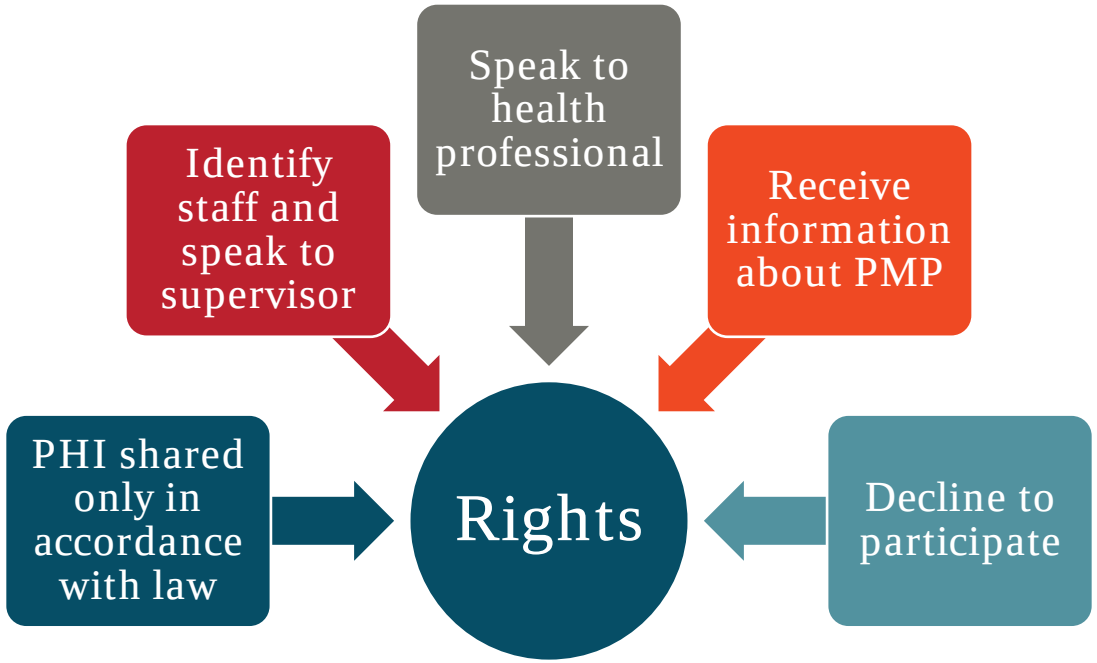
PM 3: Program Disclosures

Standard

The patient management program discloses the rights and responsibilities of the program to all patients.

EPGs

PM 3-1: Rights and Responsibilities



Upon enrollment, the pharmacy:

a. Shares with the patient their rights as they relate to the patient management program, to include the right to: [4]
   i. Have personal health information shared with the patient management program only in accordance with state and federal law
   ii. Identify the program's staff members, including their job title, and to speak with a staff member's supervisor if requested
   iii. Speak to a health professional
   iv. Receive information about the patient management program
   v. Decline participation, or disenroll, at any point in time

PM 3-1: Rights and Responsibilities, CONT.

Upon enrollment, the pharmacy:

b. Shares with the patient their responsibilities as they relate to the patient management program, to include the responsibility to: [4]
   i. Give accurate clinical and contact information and to notify the patient management program of changes in this information
   ii. Notify the treating prescriber of their participation in the patient management program

PM 3-1: Demonstrating Compliance

- Outline **how** the pharmacy shares patient management program rights and responsibilities with the patient
- **Evidence** demonstrating information shared with patients regarding their rights and responsibilities as they relate to the program

PM 4: Assessments

Standard

The patient management program services include clinical assessments and interventions that utilize drug and/or disease state specific clinical processes and workflows.

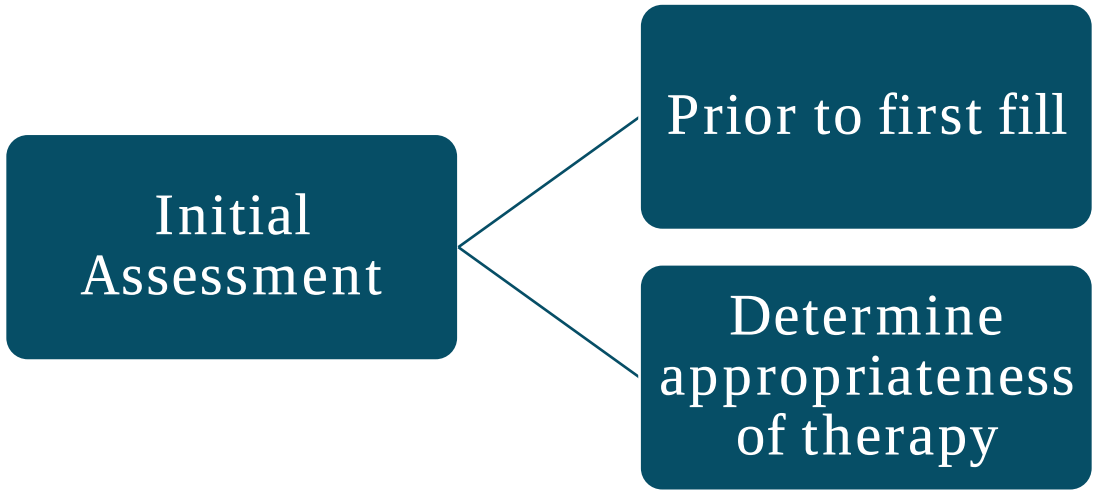
EPGs

PM 4-1: Initial Assessments

PM 4-2: Reassessments

PM 4-3: Clinical Interventions

PM 4-1: Initial Assessments



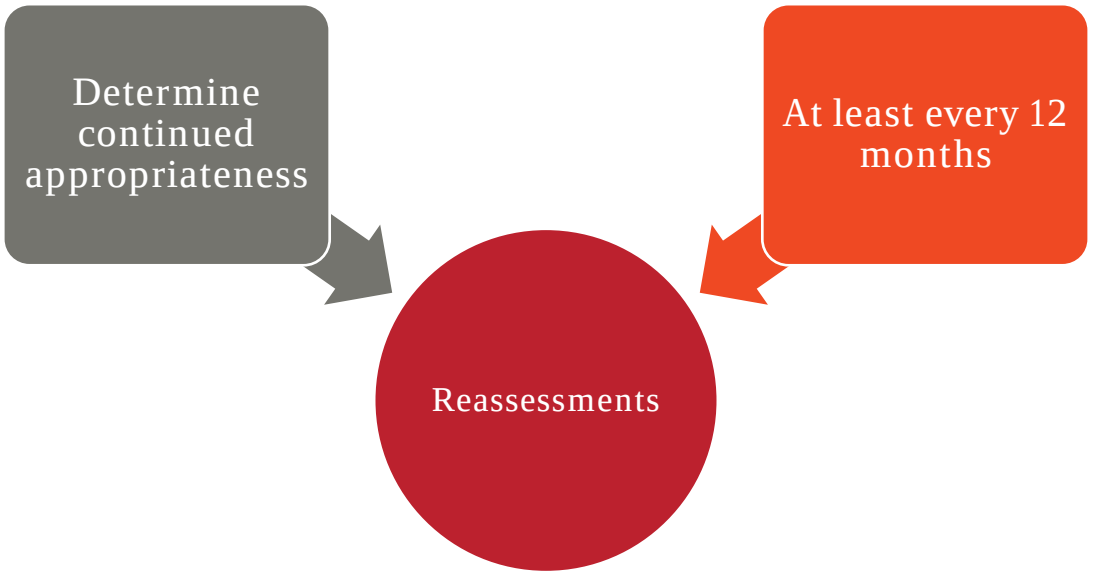
The pharmacy:

a. Conducts an initial patient assessment prior to the first fill of the medication to determine the appropriateness of the therapy, given the patient's: [8]
   i. Diagnosis
   ii. Medication list
   iii. Comorbidities
   iv. Allergies
   v. Medical history
   vi. Patient's ability to self-administer medication
   vii. Therapeutic goals based on possible outcomes of therapy

PM 4-1: Demonstrating Compliance

- Describe the **process** for conducting initial assessments
- **Sample documentation or template** demonstrating an initial patient assessment

PM 4-2: Reassessments



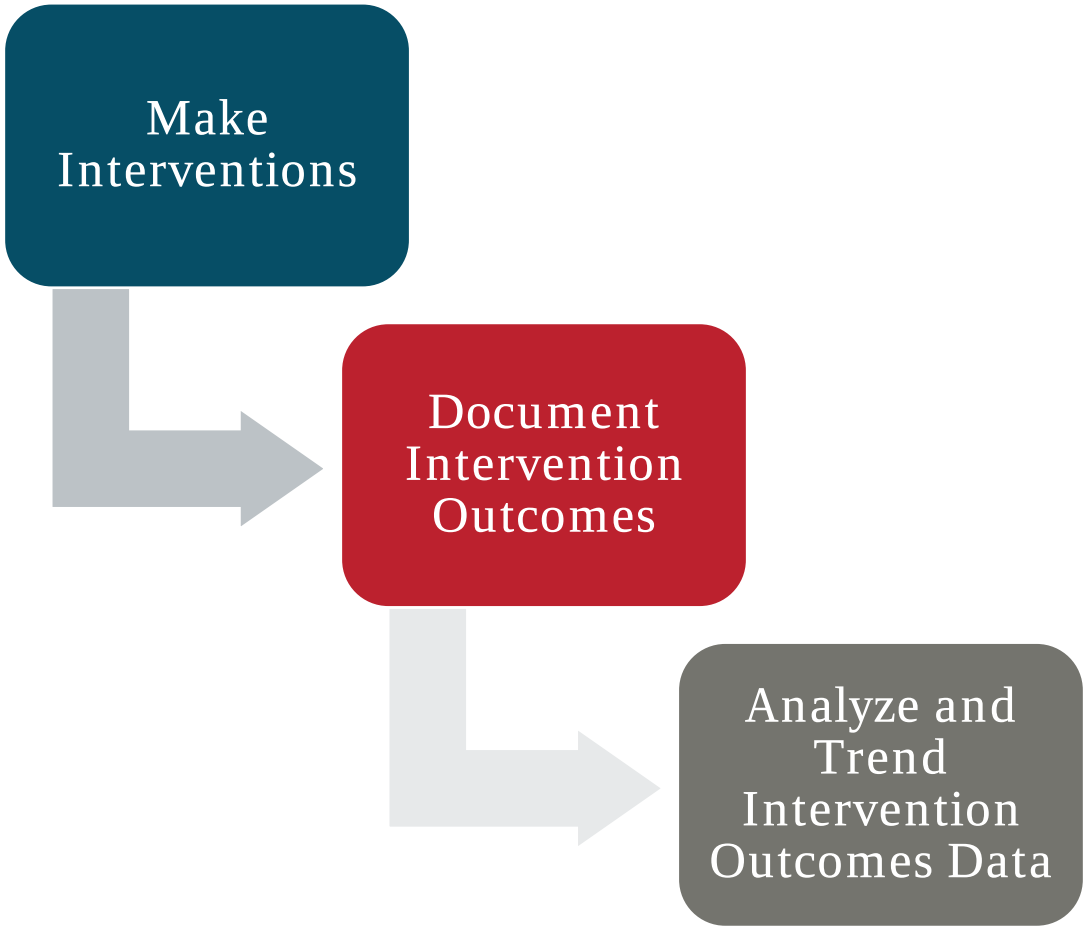
The pharmacy:

a. Conducts periodic reassessments, no more than 12 months from the previous assessment, to determine if the medication remains appropriate given the patient's: [8]
   i. Current medication list
   ii. Experience of adverse reactions to the medication
   iii. Adherence to therapy
   iv. Progress toward achieving patient's therapeutic goals based on outcomes of therapy

PM 4-2: Demonstrating Compliance

- Describe the **process** for conducting reassessments
- **Sample documentation or template** demonstrating a patient reassessment

PM 4-3: Clinical Interventions



The pharmacy:

a. Makes and documents targeted clinical interventions based on patient assessments and as needed [4]
b. Documents outcome(s) for clinical interventions [4]
c. Analyzes and identifies trends on clinical intervention outcomes data for review by the clinical oversight body at least quarterly [2]

PM 4-3: Demonstrating Compliance

- Outline **how** the pharmacy:
  - Makes and documents interventions
  - Documents intervention outcomes
  - Analyzes and trends clinical intervention outcomes data at least quarterly
- Sample documentation or template demonstrating COB review of clinical intervention outcomes analysis and trending

PM 5: Education and Support

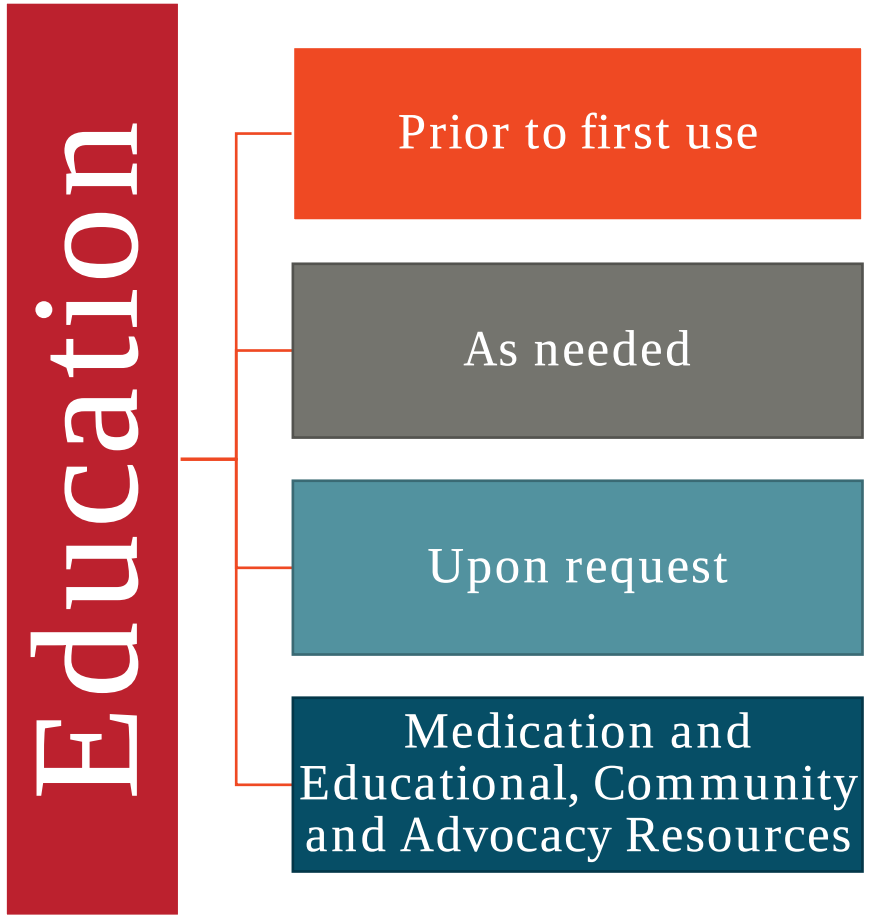
Standard

The patient receives education to promote safe and effective medication use.

EPGs

PM 5-1: Education Requirements

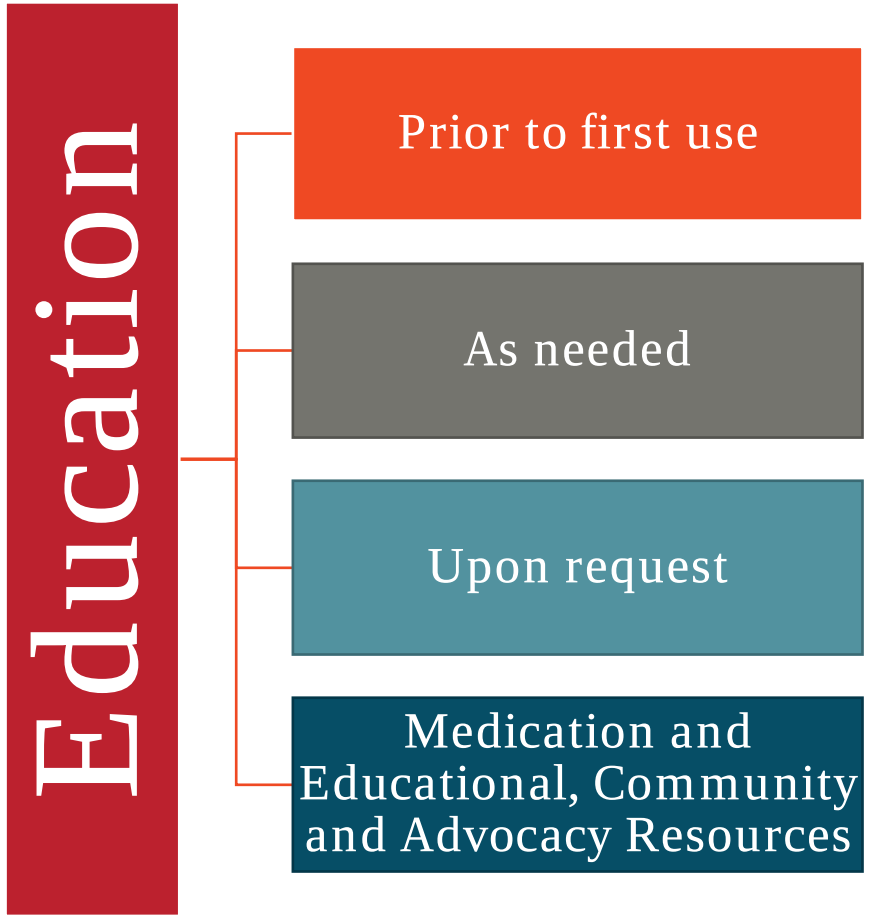
PM 5-1: Education Requirements



The pharmacy:

a. Provides patient and/or caregiver education prior to the first use of medication and includes: [8]
   i. Expectations and possible outcomes of therapy
   ii. Proper use, administration and duration of therapy
   iii. Side effects, including prevention, minimization, and management
   iv. Missed dose management
   v. Contraindications and safety precautions
   vi. Safe handling, storage, and disposal
   vii. When to report new or changed medications
   viii. Vaccinations, as appropriate

PM 5-1: Education Requirements, CONT.



The pharmacy:

b. Provides education as needed and upon request from the patient and/or caregiver, physician, or other health care provider [4]

c. Includes educational, community and advocacy resources as appropriate [4]

PM 5-1: Demonstrating Compliance

- Describe the **process** for educating patients prior to first use
- **Require** the pharmacy to provide education as needed and upon request
- Outline **how** the pharmacy includes educational, community, and advocacy resources when educating, as appropriate

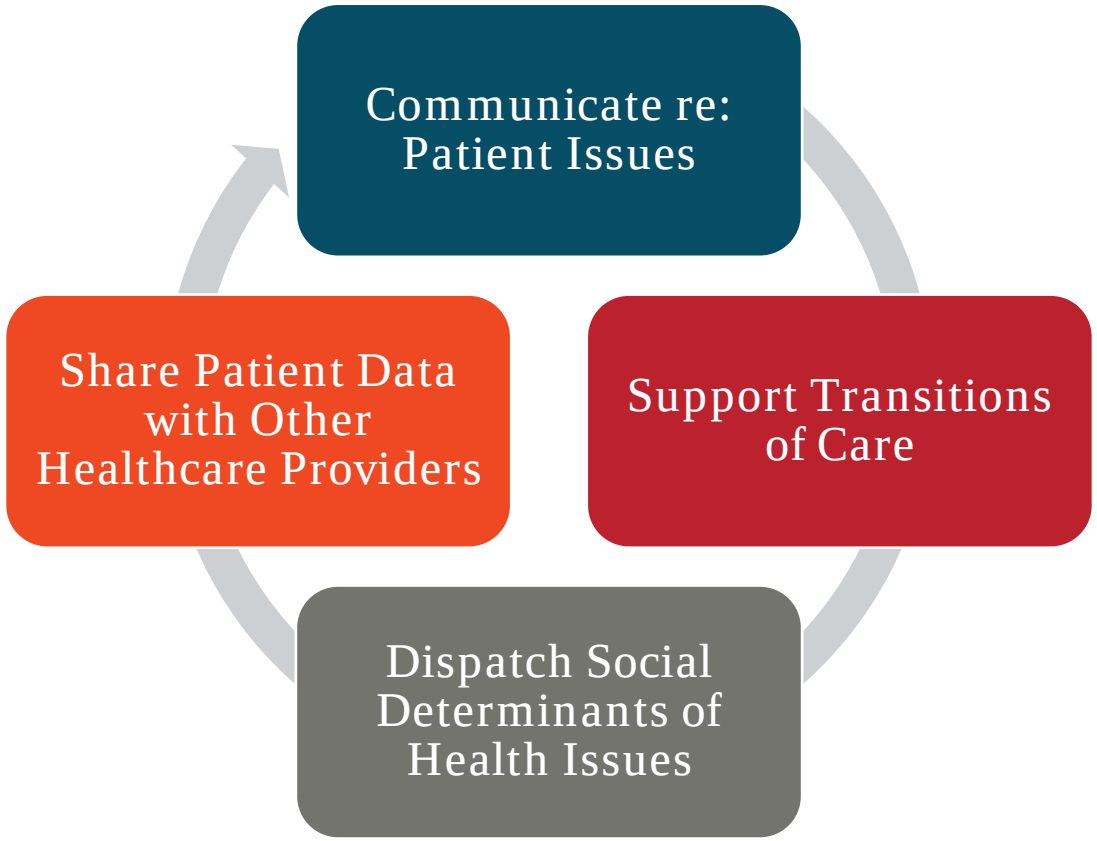
PM 6: Care Team Collaboration

Standard

Patient management information is clearly communicated to health care providers. The patient management program supports transitions of care.

EPGs

PM 6-1: Coordination of Care



The pharmacy:

a. Communicates with prescribers and other health care providers involved in the management of the patient regarding individual patient issues [8]

b. Supports transitions of care [4]

c. Dispatches issues with social determinants of health, when identified, for the appropriate entity to address [4]

d. Shares applicable patient data with other healthcare providers and stakeholders to promote comprehensive patient care [L]

PM 6-1: Demonstrating Compliance

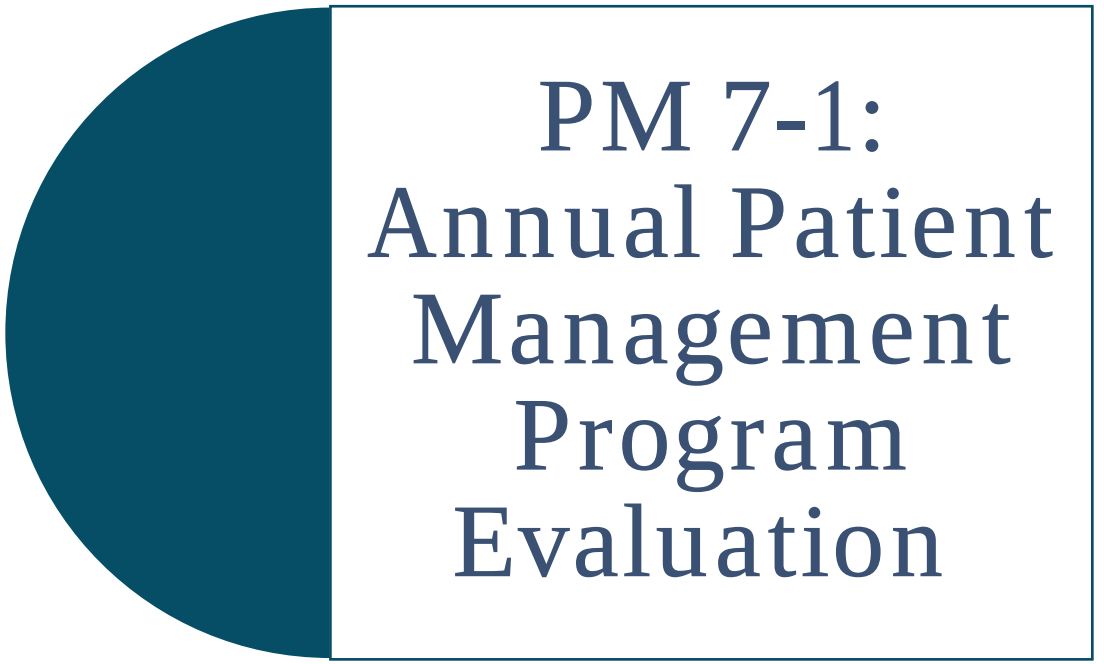
- Outline **how** the pharmacy
  - Communicates regarding individual patient issues
  - Supports transitions of care
  - Communicates about issues regarding social determinants of health (SDoH)
  - Shares applicable data with other healthcare providers [optional]

PM 7: Program Evaluation and Review

Standard

The patient management program is evaluated at least annually to improve value, effectiveness and patient care.

EPGs

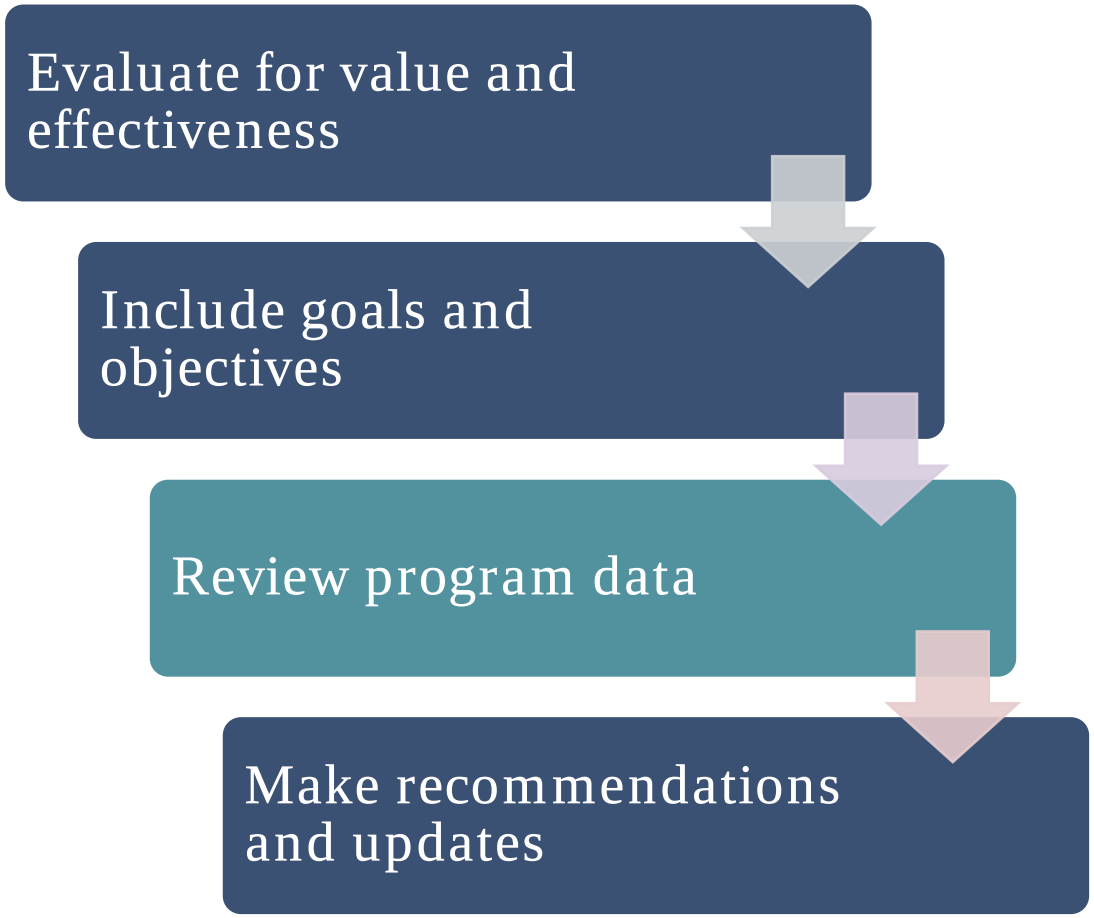


PM 7-1: Annual Patient Management Program Evaluation

The pharmacy:

a. Evaluates the patient management program for value and effectiveness with oversight by the clinical oversight body, including the goals and objectives of the program, at least annually [4]

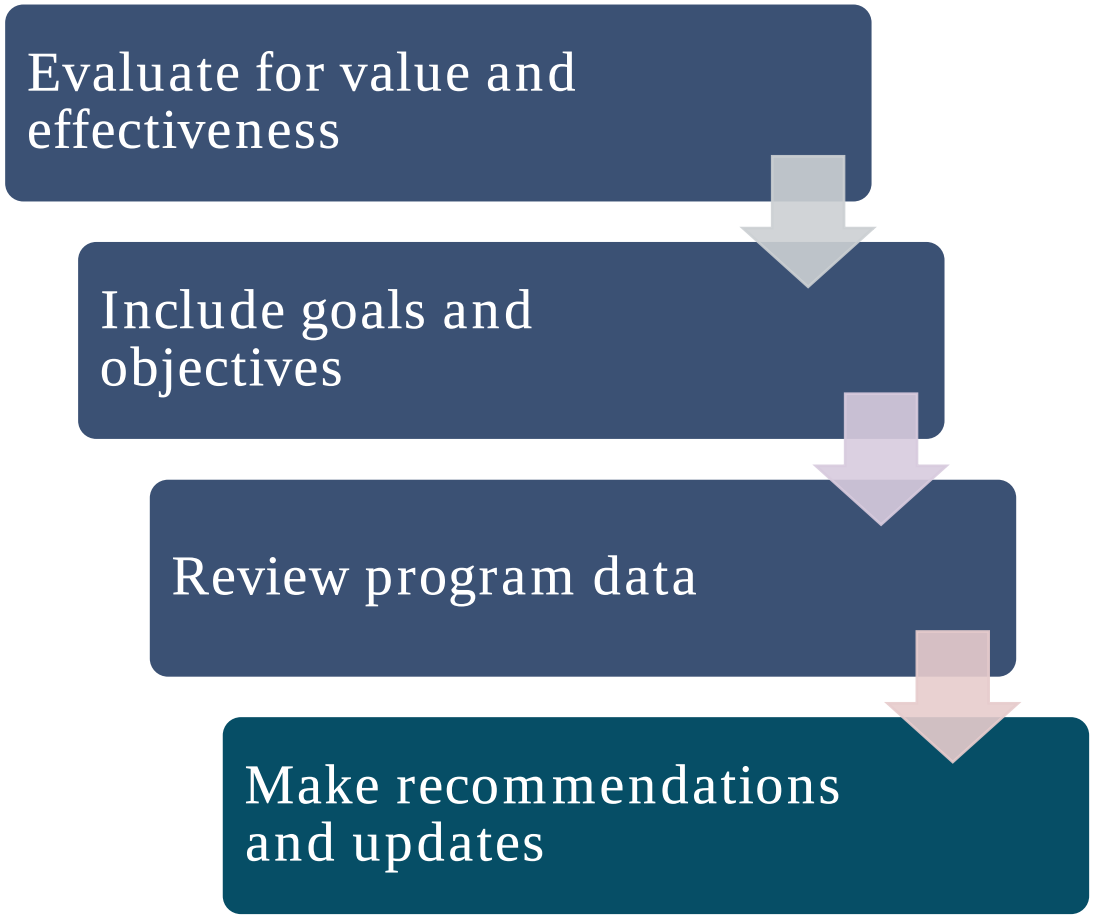
PM 7-1: Annual Patient Management Program Evaluation, CONT.



The pharmacy:

b. Reviews at least the following program data within the patient management program evaluation: [4]
   i. Clinical metrics
   ii. Financial metrics
   iii. Health related quality of life metrics
   iv. Clinical intervention outcomes

PM 7-1: Annual Patient Management Program Evaluation , CONT.



The pharmacy:

c. Demonstrates that the clinical oversight body makes recommendations and updates to the patient management program based on the evaluation [4]

PM 7-1: Demonstrating Compliance

- **Describe** the process for evaluating the program
- **Define** the program data reviewed within the program evaluation
- Outline **how** the clinical oversight body makes recommendations and updates to the program based on the evaluation
- Sample documentation or template demonstrating a PMP evaluation, including
  - The program data reviewed
  - Recommendations

PM Assessment Question

Which of the following are clinical intervention outcomes?

a) Prevention of hospitalization
b) Improved therapy adherence
c) Discontinuation of inappropriate therapy
d) All of the above

PM Assessment Answer

Which of the following are clinical intervention outcomes?

a) Prevention of hospitalization
b) Improved therapy adherence
c) Discontinuation of inappropriate therapy
d) All of the above

Reference: PM 4-3: Clinical Interventions