<table>
<thead>
<tr>
<th>Continuing Education Units/Credits</th>
<th>Attendance</th>
<th>Evaluation</th>
<th>Certificate</th>
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</table>
| • Approved for this education program | • Registered participants must attend the entire program | • Registered participants earn at least 70% on the post-test  
• Registered participants can access evaluation up to 30 days after this education program | • You will have the option to print your certificate(s) after providing some demographic |
Heather Bonome, PharmD
URAC’s Director of the Pharmacy Segment

(no conflicts to declare)
To promote continuous improvement in the quality and efficiency of health care management through processes of accreditation, education and measures

- Non-profit, independent entity
- Broad-based governance
  - Providers
  - Employers
  - Labor
  - Payers
  - Regulators
  - Consumers
  - Expert Advisory Panels (Volunteer)

- Consumer Protection and Empowerment
- Improving and Innovating Health Care Management
“Fast Facts” About URAC

Nonprofit, independent organization founded in 1990; originally chartered to accredit utilization review services.

URAC offers over 30 distinct accreditation programs across the entire continuum of care.

URAC currently accredits over 600 organizations operating in all 50 states and internationally.

URAC’s accreditation programs are nationally utilized by state and federal regulators to ensure the highest level of quality is delivered to consumers.
Health Plan Operations
- Core
- Health Plan*
- Health Plan w/Marketplace Measures*
- Health Network
- Credentials Verification Organization
- Claims Processing
- Health Provider Credentialing
- Dental Network (New ‘13)

Healthcare Management
- Health Utilization Management
- Case Management*
- Health Call Center
- Workers Compensation Health Utilization Management
- IRO
- Disease Management*
- Wellness*

Health IT & Information
- Health Website
- HIPAA Privacy
- HIPAA Security
- Consumer Education & Support
- Health Content

Provider
- Clinical Integration (New ‘13)
- Accountable Care (New ‘13)
- PCMH Practice Certification

Pharmacy Quality Management®
- Pharmacy Core
- Specialty Pharmacy*
- PBM*
- Mail Service Pharmacy*
- Workers Compensation PBM*
- Drug Therapy Management*
- Community Pharmacy (New ‘14)

Notes:
*indicates a program with measures
Scoring Methodology

Six distinct scoring categories

1 = Emerging practice
2 = Basic infrastructure
3 = Promotes quality
4 = Key stakeholder right / empowers consumers

M = Mandatory element with a direct or significant impact on consumer safety and welfare
L = Leading Indicator not weighted, optional element

All mandatory elements must be met at 100% in order to achieve a Full Accreditation
AccreditNet Application Instruction Booklet

Instructions for applicants on how to prepare the application for accreditation.
Learning Objectives

At the end of the Specialty Pharmacy/Mail Service Pharmacy v3.0 Standards, participants should be able to:

| Discuss the standards and what is needed to meet their intent |
| Explain the scoring of the standards and how they apply |
| Describe the documentation needed to submit with an accreditation application |
Desk Top Review Success Strategies

• Upload only the documents that pertain to the standard or element
• If seeking multiple accreditations, ensure the correct document is selected from the library for that accreditation’s desk top review
• Ensure all documents upload successfully
• Documents must be in final, approved form. “Draft” documents will not be accepted
• Ensure documents provided as evidence have a citation in the Notes field in AccreditNet that specifically identifies the information that supports the standard or element (e.g., p. 4, Section C, bullet 3, paragraph 2)
• Do not remove documents previously submitted as evidence on subsequent RFI rounds
Customer Service, Communications, and Disclosure (CSCD)

Applies to Specialty Pharmacy and Mail Service Pharmacy
Upon receipt of a prescription, the organization provides post-enrollment consumer information that covers the following areas: [--]

a. Consumer access to pharmacy information and support services, including:
   [ -- ]
   (i) Instructions on how to access program representatives; [4]
   (ii) Instructions on how to access a pharmacist and provider by phone and in person, including provision of phone numbers and addresses; [4]
   (iii) Information and tips to assist in interactions with the organization; [4]
   (iv) Instructions on how to access consumer advocacy support; [4]
   (Specialty only)
   (iv)[This standard element is a placeholder for Mail Service Pharmacy]; [ -- ]
   (Mail Service only)

b. Consumer financial responsibilities including out-of-pocket costs such as deductibles, co-pays, and co-insurance; [4]
CUSTOMER SERVICE, COMMUNICATIONS, AND DISCLOSURES

CSCD 1 – Post-Enrollment Consumer Information Requirements (cont.)

c. Consumer financial responsibilities, whereby if based on a consumer’s health benefit plan the organization is an out of network pharmacy, the cost charged by the organization for the medication is provided in writing to the consumer; [4]

d. Pharmacy product information, including: [--]  
   (i) Information about product selection, including suggestions of methods to obtain medications not available at the pharmacy where the product was ordered; [4]

   (ii) Information about a process for refilling prescriptions which would otherwise be limited by benefit design in order to ensure access to the types of drug therapy needed; [4]
d. Continued

(iii) Instructions on how to place an order properly, such as required submission time; [4]

(iv) Instructions on how to access medications if an emergency, disaster, or delay occurs; [4]

(v) Instructions on how to access order status; [4]

(vi) Information about order delays; [4]

(vii) Information about medication substitutions of prescriptions; and [4]

(viii) Information about client (i.e., health plan) transfers to different facility or Pharmacy Benefit Management organization that include how a prescription is transferred from one pharmacy service to another; [4]
CSCD 1 – Post-Enrollment Consumer Information Requirements

e. Pharmacy health and safety information, including: [--]
   (i) *Consumers’* rights and responsibilities; [4]
   (ii) *Evidence-based* health information and content for common conditions, diagnoses, and the treatment diagnostics and interventions; [4]
   (iii) Instructions on how to handle drug recalls; [4]
   (iv) Instructions on how to safely dispose of drugs, based on state and federal laws and regulations; [4]
   (v) Instructions on how to address adverse drug reactions; and [4]
   (vi) Information about drug substitution protocols; and [4]

f. How to report any concerns and/or suspected errors. [4]
Points to Remember

• Due to contracting arrangements, it is possible that some aspects of post-enrollment consumer information requirements may not be delegated to the pharmacy organization

• May be retained by the benefit sponsor or delegated to another organization

• URAC is not prescriptive on the method of communication (e.g., written or Web-based); however consideration of the needs of the audience should be made (see Multiple Format Communication Requirement)

• Be sure to address “in person” (i.e., walk up consumers), if applicable
CSCD 2 – Ongoing Communication Practices

This Standard is reserved as a place holder for numerical consistency across pharmacy accreditation programs. [--]

CSCD 3 – Disclosure on Refilling Prescriptions

This Standard is reserved as a place holder for numerical consistency across pharmacy accreditation programs. [--]
Upon a payer’s request, the organization has the ability to: [--]

a. Integrate its program into the payer’s existing health and service offerings; and [4]

b. Coordinate communications, materials, and procedures with the payer’s health and service offerings. [4]
If the *organization* contracts directly with *payers*, upon request the *organization* discloses to the *payer* the following information – if it is included in the payer contract: [--]

a. Existence of organizational arrangements that could potentially create a *conflict of interest* that affects clinical or financial decisions; [M]
b. Purchase discounts; [M]
c. Pricing structure for pharmacy services, such as: [--]
   (i) Rebate structure; and [M]
   (ii) Administrative fees; and [M]
(d) Subcontracting/delegation of services to other *organizations* relevant to the scope of URAC accreditation. [M]
The organization has a mechanism to allow its third party payers to verify the organization’s records to ensure that the disclosures in the standard on disclosure [CSCD 5(c)] are comprehensive and accurate, per the terms of the payers’ contract. [M]
Points to Remember

- If the organization does not have payer contracts that include specialty drugs, this standard is non-applicable.
- Element (a): Conflict of Interest
  - A conflict that affects the objectively between the organization’s financial interests and the organization’s obligations to the client.

**Example:** The organization steers the client or consumer to a particular manufacturer with a more expensive product than its competitors without clinical criteria justifying such a switch.

- Element (b) and (c): Purchase discounts, pricing structure
  - Client Contract Template must present an outline of this information, a blank page with these titles is not sufficient.

**Example:** Fees, Rebates, etc.
The organization provides ongoing support to *consumers* and *prescribers*, such that: [--]

a. At a minimum, during published business hours, support services are available via: [--]
   (i) E-mail; [4]
   (ii) Telephone; and [4]
   (iii) In person (if applicable); [4]

b. Available consumer information includes: [--]
   (i) Whether the pharmacy is in network or out of network for the *consumer’s health benefit plan*, and how this affects the cost to the *consumer*; [4]
   (ii) Prescription order status, co-pays, and related *complaint* resolution; [4]
   (iii) Where and how to obtain claims-related information; and [4]
   (iv) The acceptance of *complaints* for issues consistent with the PHARM Core standard on access to services [PHARM Core 34]; [4]
c. An escalation matrix is available to determine when calls should be transferred to a clinician; **and** [4]

d. For 24 hours a day, 7 days per week, the organization is equipped to handle: [---]

(i) Urgent and emergent calls; **and** [M]

(ii) Clinical questions. [M]
Points to Remember

• Element 7(c) – escalation matrix for non-clinical staff to transfer a call to a clinician
  • The intent of this standard is to have a policy in place to define for non-clinical staff - at any time of day – when referral to a clinician is necessary and how it should be done
  • Not strictly an after hours policy and procedure
The organization develops a mechanism and process to monitor, measure, and continuously review, at least monthly, all incoming calls. This is to include at least the following telephone performance indicators:

a. Average blockage rate; [2]

b. Average speed of answer by a live person; and [2]

c. Average abandonment rate. [2]
The organization meets the following minimum quarterly trending performance metrics:

a. Average blockage rate of 5% or less; [4]

b. Average speed of answer of 80% by a live person within 30 seconds; [4]

c. Average abandonment rate of 5% or less; and [4]

d. On at least a quarterly basis, report telephone performance metrics to the quality management committee or other quality oversight body responsible for quality management oversight. [4]
Points to Remember

• Applicant MUST have means to measure and report the Blockage, Average Speed to Answer (ASA) and Abandonment rates
• To state calls are “answered within 2 rings” does not meet the intent of the standard
• Measured after automated message/greeting has ended
• Applies to regular as well as afterhours
What are some of the methods/ mediums that an organization can provide information to consumers/patients?
The organization provides information to consumers in multiple (i.e., at least two) formats and media (e.g., Internet, print, live oral presentation, audio, video, e-mail, telephonic, and interactive) such that all consumers have access to relevant information (as per contract). [4]
The organization’s communication process shall include the following: [---]

a. If the organization receives communication other than through telephone, the organization maintains policies and procedures to address timeliness of responses [2]

b. For organizations that perform clinical consultative communication, a clinical staff person responds to clinical communications from consumers by: [M]

i. Answering the clinical communication directly; or [---]

ii. Receiving a direct transfer from a non-clinical staff person; or [---]

iii. Responding to clinical communications within an average of 30 minutes, if a clinical staff person is not immediately available and the consumer must leave a message; and [---]
The organization’s communication process shall include the following: [-]

c. If a clinical communication is not directly answered by a clinical staff person, the organization has a process that instructs the consumer via a recording or live person to choose at least one of the following options: [M]

i. Hang up and dial 911 or local emergency services if the situation is perceived by the consumer to be an emergency; or [-]

ii. Remain in a telephone waiting/holding queue for the clinical staff person; or [-]

iii. Leave a message for a clinical staff person. [-]
The organization has a process to provide information that: [--]

a. Conforms to the literacy levels of its patient population; [2]
b. Helps patients become aware of what effect a health care decision may have for their daily lives; [4]
c. Is displayed in a way that highlights information important to the patient; and [2]
d. Is presented and delivered in ways that are appropriate to the diversity of the organization’s enrollment, including: [--]

   (i) Language differences; [4]
   (ii) Cultural differences; and [4]
   (iii) Cognitive and physical impairments. [4]
Key Definitions

**Health Literacy** is defined as:
The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions regarding their health.

**Plain Language** is defined as:
Communication that uses short words and sentences, common terms instead of (medical) jargon, and focuses on the essential information recipients need to understand.
Health Literacy – Points to Remember

• The organization must implement a written policies and/or documented procedure addressing health literacy
• Establish a target grade level against which the organization would evaluate consumer materials
• P&P should include how the organization developed and tested the grade level and literacy
• There may be state and federal regulations as well as contractual requirements that affect implementation of processes to promote health literacy

www.health.gov
www.plainlanguage.gov
CSCD 13 – Electronic Prescribing

The organization’s pharmacy dispensing system supports electronic prescribing and is integrated with its medication management systems. [M]
SDrM 1-3 are addressed separately from MDrM 1-3 due to variations in the standards between programs; SDrM and MDrM 4-5 align exactly and therefore are addressed together.
MDrM 1 – Roles and Responsibilities

The mail service pharmacy demonstrates that it embodies the following roles and responsibilities: [--]

a. Provide oversight of the safety, appropriateness, and effectiveness of pharmaceutical care provided to patients as related to products dispensed through the pharmacy, and [M]

b. Educate patients, caregivers, and prescribers as appropriate. [M]

SDrM 1 – Roles and Responsibilities

The specialty pharmacy demonstrates that it embodies the following roles and responsibilities: [--]

a. Provide oversight of the safety, appropriateness, and effectiveness of pharmaceutical care provided to patients as related to specialty products dispensed through the specialty pharmacy; [M]

b. Educate patients, caregivers and prescribers as appropriate; [M]

c. Advocate for patient access to medications; [M]

d. Participate in treatment decision-making; [M]

e. Function in a clinical advisory role (to payers and prescribers); and [M]

f. Assist with appeals of coverage decisions. [4]
Points To Remember

Intent of SDrM 1(e) is to serve as a consumer advocate to help the patient gain access to specialty products

- Specialty pharmacy staff may assist with clinical information to support the approval of an appeal such as the diagnosis, lab work or previous medications tried and failed as appropriate
- The pharmacy may assist with education of patient, caregivers, and prescribers regarding coverage, appeals process and drug therapy
- Specialty pharmacies may assist the patient through sources outside of the third party payer if necessary including compassionate use or patient assistance programs
The *pharmacy* develops and implements services that: [--]  
  a. Promote clinical appropriateness; [M]  
  b. Promote safety related to the *patient’s* use of a medication; and [M]  
  c. Promote cost effective *medication management*. [M]

The *specialty pharmacy* develops and implements services that: [--]  
  a. Promote clinical appropriateness; [M]  
  b. Promote safety related to the *patient’s* use of a medication; [M]  
  c. Promote cost effective *drug management*; [M]  
  d. Take into account issues related to the ease of adherence and therapy management where there are multiple medications available; and [M]  
  e. If the *pharmacy* contracts directly with health plans and other *payers* without the *benefits* of P&T Committee recommendations, and have a *preferred drug list* or *formulary*, the *pharmacy* must disclose the drug list and define its *clinical oversight* process to *clients*. [M]
This Standard is reserved as a place holder for numbering consistency across pharmacy accreditation programs. [--]

Treatment recommendations and programs are based on appropriate and available clinical information, including: [--]

a. Best available *medical or scientific evidence* and/or demonstrated *clinical practice guidelines/protocols*; [M]

b. Efficacy of the medication, type and frequency of side effects, and potential medication interactions among alternate medication products, as they may be available; *and* [M]

c. Likely impact of a medication product on *patient* adherence when compared to alternate medication products, as they may be available. [M]
Points To Remember

• This standard requires that treatment coverage decisions and recommendations made by the specialty pharmacy are evidence based clinical decisions

• SDrM 3(a)
  – Addresses the scientifically valid data sources that must be addressed for each treatment recommendation

• SDrM 3(b)
  – Must provide documentation of valid data that supports the treatment recommendation

• SDrM 3(c)
  – Must have a documented process of analysis of the efficacy of alternative drug products. A clinical director must provide oversight to the clinical decision making process. The process should be reviewed annually

• SDrM 3(d)
  – The analysis of patient adherence among alternative products should be considered
The organization ensures drug utilization management mechanisms using the available information and data addressing the following, where appropriate: [M]

a. Therapeutic appropriateness; [--]
b. Over and underutilization; [--]
c. Generic use; [--]
d. Therapeutic interchange; [--]
e. Duplication; [--]
f. Drug-disease contraindications; [--]
g. Drug-drug or drug-allergy interactions; [--]
h. Drug dosage; [--]
i. Duration of treatment; [--]
j. Clinical abuse or misuse; [--]
k. Drug-age precautions; [--]
l. Drug-gender precautions; [--]
m. Drug-pregnancy precautions; [--]
n. Regulatory limitations. [--]
Points To Remember

Typically embedded electronically in the claims software, clinical decision support tools, and/or clinical review tools and alerts the program staff to take action per the organization’s policies and procedures.

Policy should address how the organization handles alerts that fire within the electronic tools listed above.
On at least a quarterly basis, the organization reports drug utilization management findings to the quality management committee or other quality oversight body responsible for quality management oversight. [4]
The organization’s management and patient programs have distinct systems for identifying, analyzing, and rectifying patient safety issues that:

a. Identify and report adverse drug events and describe how events are documented and reported to external entities; [M]

b. Identify and manage risk; [M]

c. Provide for a process to disclose errors of clinical significance to the affected patients and/or caregivers as needed; [M]

d. Identify when outbound communication is warranted with the prescriber, patient, and/or dispensing pharmacy for potential consumer safety events; and [M]

e. On at least a quarterly basis, report aggregate findings, including adverse drug events and errors, to the quality management committee or other quality oversight body responsible for quality management oversight. [4]
Pharmacy Operations (PHARM-OP)

Applies to Specialty Pharmacy and Mail Service Pharmacy
The organization: [--]

a. Defines its pharmacy operations with respect to: [--]
   (i) The types of pharmacy services offered; and [2]
   (ii) The geographic area served; [2]

b. When access or availability is an issue, provides alternative sources for patients to obtain their medications in the geographic area served; [4]

c. Measures actual performance compared to performance metrics established for its pharmacy operations; [4]
d. Analyzes process, satisfaction, and outcome trends that are directly related and relevant to quality and safety of services realized by the patient; [4]

e. Implements action plans as necessary to achieve and maintain its pharmacy operations’ performance requirements; and [4]

f. On at least a quarterly basis, reports on pharmacy operations performance to the quality management committee or other quality oversight body responsible for quality management oversight. [4]
What are some of the ways that a pharmacy can receive a prescription order?
The organization has written policies and documented procedures for processing prescriptions that address: [--]

a. Receipt of prescriptions via mail, telephone, in person, and electronically (e.g., fax, e-mail, and e-prescribing); [2]
b. Safety guidelines used to process the prescription intake; [M]

 ü Element 1 (a) – Receipt of a prescription via … in person
 ü Be sure to address “in person” intake process with a policy for walk-in customers (if applicable)
c. Obtaining and maintaining: [--]
   (i) *Patient* health history; [4]
   (ii) Medication history; [4]
   (iii) Allergies and past sensitivities; and [4]
   (iv) Any pertinent information necessary to consult with the prescriber and counsel the patient and/or caregiver; [4]

d. Identification of high risk groups; and [4]
e. Verification of a patient’s eligibility. [2]
The organization has written policies and documented procedures to address the following: [---]

a. *Prescription* source verification; [M]

b. *Prescription* legibility is clarified and verified, when necessary; [M]

c. Resolution of *prescription* discrepancies; **and** [M]

d. Pharmacist oversight of these processes prior to dispensing. [M]
The organization has established processes to label, package, and dispense products accurately, which include, at a minimum: [--]

a. Ensuring that prescription containers are labeled properly; [M]

b. Completing documentation and management of controlled substances; [4]

c. Prevention of contamination, which includes cross-contamination; [4]

d. Ensuring that medications are packaged to maintain stability and usability for patients; and [M]

e. Implementing a process to dispense emergency or interim supplies of medications, as needed, to prevent interruption of services in the event of emergencies and local disasters. [4]
The organization has implemented a process for a pharmacist to verify that medication orders are prepared in accordance with the prescriber’s prescription, which includes: [--]

a. Dispensing medications that match the prescription with regard to the correct: [--]
   (i) Patient; [M]
   (ii) Route of administration; [M]
   (iii) Dosage and strength; [M]
   (iv) Administration schedule or time; and [M]
   (v) Medications; and [M]

b. Distributing appropriate patient educational material from appropriate sources, such as manufacturer or other source, along with the dispensed medications. [M]
The organization has implemented written policies and documented procedures to promote effective shipping, which address:

a. Accuracy; [M]

b. Appropriate shipping requirements; [M]

c. Maintenance of product integrity, stability, and appropriate temperature based on the manufacturer’s recommendation; [M]

d. The ability to trace a product’s location after it leaves the organization’s facility; [4]

e. Notification to the patient and/or prescriber’s office if shipment will be delayed; and [4]

f. Processes to ensure that patients have a continuous supply of medications when shipment is delayed or lost. [4]
The organization has implemented a documented program to manage its cold chain distribution process, which includes:

a. Criteria for the selection of packaging products; [2]
b. Criteria for the selection of modes of transit; [2]
c. A validated distribution process with process controls that addresses:
   (i) Initial testing procedures for new packaging products designed for cold chain distribution; [M]
   (ii) Using the correct packaging; [M]
   (iii) Following the correct packing instructions; [M]
   (iv) Maintaining temperature within drug manufacturer’s guidelines throughout the entire shipping process (i.e., not too cold and not too hot); [4]
(v) Methods to determine if shipments should be held due to extreme weather; [4]
(vi) Methods to determine if shipments should be held due to expected delivery delays; [M]
(vii) The decision process for product handling in the case of a breakdown in the distribution process; [M]

d. Periodic monitoring, at least annually and when the packaging product is modified, of each packaging product under different temperature profiles and length of time in the shipping distribution system; and [4]

e. At least annual review, with updates as needed, by the quality management committee or other quality oversight body responsible for quality management oversight, which includes review of the: [--]

   (i) Validated distribution process with process controls; [M]

   (ii) Monitoring system; and [M]

   (iii) Complaints or concerns related to cold chain shipments raised by a patient or prescriber. [M]
Points To Remember

• Element (c): A “validated distribution process” means that the accuracy of the results can be proven or demonstrated. Organizations may use distribution processes validated by others.

• Element (c)(iii): The packing process should ensure that an adequate barrier is placed between the drug product and ice packs to prevent freezing of the medication. It is common practice to use bubble wrap, however, other barriers such as styrofoam barriers and compartmental boxes are also acceptable.

• Element (c)(iv): it is not the intent of this standard to require data loggers for every package shipped. Periodic monitoring is the standard.
The organization has implemented written policies and documented procedures to ensure: [-]  

a. Appropriate handling and storage of products that includes: [-]  
   (i) Accountability and security of pharmacy inventory; and [4]  
   (ii) Management of controlled substances; [M]  

b. Appropriate temperature management for handling and storage that addresses: [-]  
   (i) Refrigerator temperature; [4]  
   (ii) Freezer temperature; [4]  
   (iii) Ambient room air temperature; and [4]  
   (iv) Room humidity; [4]  

c. Appropriate inventory management to ensure that medications are stable and usable; and [4]  

d. Appropriate handling, storage, and disposal of hazardous materials and medications to provide for patient and pharmacy employee safety. [M]
The *organization* has implemented written policies and documented procedures that address: [---]

a. Drug authenticity, whereby the organization limits its medication purchases to the following types of entities: [M]
   
   (i) Licensed wholesalers who, by contract or attestation, agree to purchase medications from licensed wholesalers or drug manufacturers; **or** [---]
   
   (ii) Licensed distribution channels; **or** [---]
   
   (iii) Drug manufacturers; [---]

b. Ongoing monitoring of vendors, pursuant to the organization’s policy, to identify counterfeit drugs and initiate an action plan to resolve issues in accordance with the standard on handling and removal of unacceptable medications [PHARM-OP 12]; [M]

c. Handling out of stock or backorder products; **and** [4]

d. Returns, restocking, and distribution capacity that includes determining if: [---]
   
   (i) Returns are allowable according to state and federal laws and regulations; **and** [4]
   
   (ii) Medications can be safely re-dispensed. [M]
Points To Remember

• Element (b): Pharmacy must maintain logs (paper or electronic) documenting components (temperature and humidity) of this element.

• During the Onsite Review, temperature and humidity logs will be reviewed.

• Measurements do not have to be logged electronically.
The *organization* has a process to routinely evaluate and maintain its equipment used for dispensing and labeling medication to consist of the following: [--]

- a. Calibration; [M]
- b. Cleaning; [M]
- c. Auditing; **and** [M]
- d. Randomized testing. [M]
EXERCISE

What are some examples of equipment a pharmacy can use to dispense, label and ship medications?
Points To Remember

Common Equipment

- Laminar flow hoods
- Tablet counters
- Shipping scales

Laminar flow hood
- Schedule for changing filters
- Maintenance and cleaning policy and procedure
- Cleaning technique
The organization’s electronic claims processing complies with the National Council for Prescription Drug Program (NCPDP) standard transactions for pharmacy medication claims, eligibility, coordination of benefits, and related pharmacy services, where applicable. [M]
The organization has implemented written policies and documented procedures to address the removal and/or disposal of medications: [--]

a. Determined to have one or more of the following problems: [--]

   (i) Recalled; [M]
   (ii) Discontinued; [M]
   (iii) Expired; [M]
   (iv) Damaged; [M]
   (v) Adulterated; [M]
   (vi) Unacceptable; [M]
   (vii) Misbranded; and [M]
   (vii) Determined to be counterfeit; and [M]
b. Whereby for each type of problem identified in standard element (a), the following must be addressed in the documentation: [--]

(i) Notification from the manufacturer and/or the FDA; [M]

(ii) Notification and instruction provided to the appropriate staff; [M]

(iii) Notification and instruction provided to affected patients and prescribers; [M]

(iv) Review and removal of in-stock inventory; [M]

(v) Identification and removal of inventory in the process of being shipped or before it is shipped; and [M]

(vi) Appropriate disposal of medications. [M]
The organization provides appropriate management oversight of pharmacy operations, which includes: [--]

a. Clearly stated pharmacist roles and responsibilities for pharmacy oversight and safety, including dispensing and supervision of pharmacy operations and personnel; [M]

b. Clearly stated technician role in the dispensing process; [M]

c. Direct supervision of medication preparation and dispensing; and [M]

d. Complying with FDA mandates and self-imposed manufacturer restrictions on particular medications, as applicable. [M]
The *organization* provides appropriate facility oversight where necessary and promotes a safe and secure facility, which includes: [---]

a. Facility security: [---]

   (i) Designation of access levels to facility and/or area access within the facility; [M]

   (ii) Identification of which employees have appropriate access to machines and other equipment, along with the ability to lock, unlock, and secure machines and other equipment; [4]

   (iii) Appropriate management and security of controlled substances; and [M]

   (iv) Determine what type of security clearance is required to handle controlled substances; [M]
b. Facility technology, such that controls are implemented to minimize fraud that involves information technology and automated technology security; [M]

c. Facility safety, such that the Material Safety Data Sheets (MSDS) manual is accessible; and [M]

d. Employee safety; [--]
   (i) Emergency spill kits are available; and [M]
   (ii) Eye wash stations are easily accessible. [M]
Don’t just have them, know where they are!
The organization has an established process to:

a. Maintain a mechanism to identify and address concerns related to:

   (i) Quality and safety of medication inventory and distribution; and
   
   (ii) Quality of service;

b. Monitor dispensing of products for accuracy in the pharmacy, which includes:

   (i) Proactive risk assessment;
   
   (ii) Tracking of errors;
   
   (iii) Reporting of errors to internal and external entities as appropriate;
   
   (iv) Analysis of error data; and
   
   (v) At least annual review of published safety literature for prevention recommendations and best practices; and
c. On at least a quarterly basis, report findings in the following areas to the quality management committee or other quality oversight body responsible for quality management oversight: [--]

(i) Quality concerns addressed in element (a); and [4]

If the organization compounds medications, it has implemented written policies and documented procedures related to compounding that: [---]

a. Meet or exceed USP guidelines; and [M]

b. Meet state and federal laws and regulations. [M]
Patient Management (PM)

Applies to Specialty Pharmacy Only
The *organization’s* written program overview describes how its patient management program will address the identified needs of individual *patients*. [2]
Points to Remember

• Services offered to patients enrolled in the patient management program will be based on the needs of the **individual** patient

• This standard applies to all applicant organizations and covers **all patients receiving specialty medications**
Patient management program services must include: [--]

a. Access to patient-specific and individualized services or sets of services to the patient based on medical or scientific evidence and/or demonstrated clinical practice guidelines/protocols; [M]

b. A process to document patient management information in a central location, such as a patient care management plan; [M]

c. Processes and/or protocols to effectively communicate with prescribers and other healthcare providers involved in the management of the patient; [M]

d. Strategies and interventions to optimize appropriate therapeutic outcomes for patients through improved medication use based on available information; and [M]

e. Support for patient advocacy and empowerment of self-administration of medications. [M]
PM 3 - Additional Program Characteristics

Services offered through a patient management program: [--]

a. Are developed under the supervision of the clinical oversight body; [M]
b. Are provided in accordance with the third party payer’s coverage policies; [M]
c. Include strategies to actively facilitate participation of all individuals on specialty medications; [M]
d. Include identification of the following population characteristics for targeted interventions: [--]

(i) Lack adherence to medication therapy; [M]
(ii) Inappropriately use their medication; and [M]
(iii) Experience adverse events; [M]
e. Identify criteria as to when medication reconciliation is indicated; [M]
f. Provide for an initial assessment for appropriate and inappropriate medications, including medication reconciliation; [M]
g. Include a care management plan for providing and coordinating services;
h. Include education concerning side effects, medication interactions, food/drug interaction, safe disposal, and other safety precautions, such as proper handling; [M]

i. As needed, provide patients with information on community resources and support; [2]

j. Require monitoring and promotion of medication adherence; [M]

k. Minimize the incidence of adverse events; [M]

l. Promote referrals to other health care providers when appropriate; and [M]

m. Optimize therapeutic outcomes by: [--]
   
   (i) Promoting continuity of care during all patient care transitions, including medication reconciliation as needed; and [M]

   (ii) Facilitating collaboration among all of the patient’s healthcare providers. [M]
Points to Remember

• Element 3 (d) - Describe the elements of the initial assessment (e.g., documentation of a complete current medication list used to assess for medication problems, allergies/sensitivities, co-morbid diseases/conditions.)

• Element 3 (i) - How do you optimize therapeutic outcomes by ensuring continuity of care through all patient care transitions such as in/out of hospital, nursing home or other pharmacy? An example would be performing medication reconciliation where you would identify the most accurate list of drugs the patient is on at the time of the transition of care or the process to transition patient to/from another pharmacy.
Points to Remember

• At the Onsite Review, a random sample of thirty (30) patient records will be reviewed to verify implementation and documentation of the patient management program.

• Reviewers will look for documentation of the following in each patient record:
  – Initial patient assessment to include diagnosis, appropriateness of therapy, comorbidities, and documentation of medication list, allergies, etc.
  – Upon initiating specialty drug therapy, the patient received education, counseling, and resources to promote adherence to therapy
  – Reassessment after a clinically appropriate timeframe to assess:
    • Continued appropriateness of therapy
    • Continued effectiveness of therapy
    • Occurrence of adverse events
    • Adherence to therapy
PM 4 – Program Development and Review

The organization shall provide evidence that its patient management program was developed and annually reviewed by a clinical oversight body. [M]

PM 5 – Periodic Patient Reassessment Process

The organization has a process to periodically reassess the participating patient to determine if the patient is: [---]

a. Meeting criteria for conducting medication reconciliation; [M]

b. Going to continue with current prescription medications given the disease, patient response, and medical condition; [M]

c. Experiencing any adverse effects to the medications; [M]

d. Achieving therapeutic benefits from the medication(s); and [4]

e. Adhering to therapy. [4]
The organization: [--]

a. Selects and designs defined *interventions* that are: [--]
   (i) Consistent with, and supported by, current *medical or scientific evidence* and/or *clinical practice guidelines/protocols*; and [4]
   (ii) Approved by the *organization’s senior clinical officer*, clinical advisor, or *clinical oversight body*; and [M]

b. Upon request from a *payer, prescriber, or patient*, provides: [--]
   (i) A list of the evidence upon which the *interventions* are based; and [2]
   (ii) The level of such evidence. [2]
PM 7 – Staff Qualifications

Consistent with the Core standard on Staff Qualifications, the organization ensures that its patient management program services are supervised by a pharmacist and delivered by pharmacists or other qualified health professionals with experience and expertise in patient management. [M]

If a non-clinician gathers clinical data for the program (e.g., documentation of new medications, adverse events, etc.), there must be evidence that the data was evaluated or interpreted by appropriate clinical staff.
PM 8 – Coordination of Care

The organization is able to coordinate care for targeted individuals with *care management plans*. This care coordination includes: [---]

a. Establishing processes that allow appropriate sharing and communication of patient information among health care providers and community resource personnel who have a need to know; [4]

b. Identifying the information technology and other communication tools to be used; *and* [4]

c. Recording information in a centralized patient record (as required by standard PM 2(c)), which includes a *care management plan* (as required by standard PM 3(e)) that includes: [---]

(i) A statement of problems/needs determined upon assessment, including patient-specific transitions of care needs; [2]

(ii) Strategies to address the problems/needs; [2]

(iii) Measurable goals to demonstrate resolution based upon the problems/needs; [2]

(iv) A time frame to meet each goal; [2]

(v) Resources available to implement the *care management plan*; *and* [2]

(vi) The desires/ motivation of the patient. [2]
Points to Remember

• Element (c): If the patient record is integrated between the health plan, health system, and/or pharmacy organization, the care management plan may be housed within that centralized platform.

• At the Onsite Review, a sample of three (3) care management plans will be reviewed to verify that the components of the plan as required by the standard (elements (c)(i)-(vi)) are included
The organization implements written policies and documented procedures for the counseling and education of patients, which address the following:

a. Effective use of clinical and educational resources, decision support tools, and other materials to support patient decision-making; [4]

b. Engaging patients in shared decision-making between patients and clinicians; [4]

c. Patient self-management; and [4]

d. Counseling and education related to medication: [--]

(i) Proper use; [M]

(ii) Timely administration or intake; [4]

(iii) Side effects; [M]

(iv) Contraindications; [M]

(v) Safety precautions; [M]

(vi) Reconciliation, including prescribed and over-the-counter medications and supplements; [M]

(vii) Disposal; and [M]

(viii) Storage. [M]
The organization shall implement written policies and documented procedures covering communication by pharmacy providers to patients. Communication plans address:

a. Educational materials that:

   (i) Reflect the learning needs of the target population; [4]
   (ii) Reflect current best practices for patient management; [4]
   (iii) Are accessible in multiple formats (at least two); [4]
   (iv) When provided to individual patients, are documented in the patient’s care management plan; and [M]
   (v) Are reviewed at least annually and updated as needed; and [4]
b. *Patient* information about program operations that: [---]
   
   (i) Describe the potential health *benefits* and limitations of participating in the *patient management* program; [M]

   (ii) Include instructions on how to contact the *pharmacy’s patient management* program; and [2]

   (iii) Provide for *opt-out* procedures. [2]
The organization addresses the following areas in its patient management program: [--]

a. How a patient gains access to specialty medications; [4]

b. Logistics for obtaining a specialty medication (not otherwise available through the organization) for the patient; [4]

c. A utilization management plan specific to the medication and patient; [4]

d. How the organization will communicate the care management plan to the patient; [4]

e. How the organization will notify the prescriber of the patient’s care management plan; and [4]

f. How the organization will communicate a plan around coordination of care and/or third party payer programs and multi-disciplinary teams, as appropriate. [4]
Upon enrollment of an eligible patient, the patient management program conveys information on rights and responsibilities to participating patients including:

a. The right to know about philosophy and characteristics of the patient management program; [4]

b. The right to have personal health information shared with the patient management program only in accordance with state and federal law; [M]

c. The right to identify the program’s staff members, including their job title, and to speak with a staff member’s supervisor if requested; [4]

d. The right to speak to a health professional; [4]

e. The right to receive information about the patient management program; [4]
f. The right to receive administrative information regarding changes, in or termination of, the patient management program; [4]

g. The right to decline participation, revoke consent, or dis-enroll at any point in time; [4]

h. The responsibility to submit any forms that are necessary to participate in the program, to the extent required by law; [4]

i. The responsibility to give accurate clinical and contact information, and to notify the patient management program of changes in this information; and [4]

j. The responsibility to notify their treating provider of their participation in the patient management program, if applicable. [4]
PM 13 – Quality Improvement

The *organization* shall demonstrate a process to measure the quality of the *patient management* program. [4]

This standard relates to the internal review of the Patient Management program. Subsequent standards focus on evaluation of the program from an external perspective.
The organization has a process that evaluates a specific patient management program for: [--]

a. Clinical benefits (i.e., outcomes) using performance metrics based on: [--]
   (i) Objective data; **and** [2]
   (ii) Subjective data; [2]

b. Financial benefits (i.e., outcomes) using performance metrics based on financial data; [2]

c. Patient satisfaction with patient management program services; **and** [2]

d. Its impact on health-related, quality of life outcomes other than clinical and financial, using performance metrics based on: [--]
   (i) Objective data; **and/or** [2]
   (ii) Subjective data. [2]
Points to Remember

- Element (a)(i): Examples of objective data could include laboratory values, health screenings, adherence measurement (such as Proportion of Days Covered [PDC]), and resolution of health condition.
- Element (a)(ii): Examples of subjective data could include various types of patient self-reported data, such as perceived pain relief.
- Element (b): Examples of financial outcomes could include:
  - Savings resulting from participation in Patient Assistance Programs
  - Projected medical savings (avoided hospitalizations or MD office visits) from management of side effects, adverse events, compliance, etc.
  - Projected savings from avoidance of treatment failures from promoting adherence to therapy
  - Savings from factor assay management
  - Savings from consolidation of duplicative therapy or polypharmacy
Points to Remember

- **Element (d): Examples outcomes used to measure Quality of Life include:**
  - Quality of Life - Identify source of data and instrument (if used, SF 12, for example) [1]
  - Quality Adjusted Life Years (QALYs) - These are long term measures that may have economic implications [2]
  - Measurement of self-care – i.e., ability to perform Activities of Daily Living (ADL)

The organization reports the results of a patient management program evaluation: [--]

a. At a minimum, to current and prospective *payers* upon request; and [M]

b. For the types of outcomes described in standard PM 14 (i.e., clinical, financial, *patient* satisfaction, and health-related quality of life), program evaluation reports include: [2]

   (i) Past outcomes; or [--]

   (ii) Projected outcomes. [--]
Upon request, the organization discloses the following to current and prospective payers of its specified patient management program(s):

a. Description of the methodology used for the program evaluation; [M]

b. Description of the strengths and limitations of the program evaluation methodology employed; and [2]

c. Whether the organization has had at least one of its program evaluation methodologies externally validated. [L]
MEASURES: PERFORMANCE MEASURES AND REPORTING STANDARDS

Specialty PHARMACY AND MAIL SERVICE PHARMACY
Linking Measurement and Standards

Measurement in sync with URAC’s approach to accreditation: “mandatory” and “exploratory” (leading) framework/language

Starting with measure concepts addressed in the standards and measures familiar to the industry

Part of ongoing accreditation cycle, but data submissions more frequent than review cycle: at least annual, perhaps more frequent

Initial emphasis on internal performance improvement and reporting to clients; ultimately part of public reporting
Measurement Phases and Development Process

Phases of URAC’s Measurement Program

- **Phase 1**: Measures reported to URAC; focus on internal quality improvement
- **Phase 2**: Mandatory measures subject to external auditing/verification process; de-identified aggregate reports publicly available
- **Phase 3**: Audited measures included in unblinded public reporting formats on the URAC website

Measures Selection Process

- Pharmacy Standards Advisory Committee
  - Helps URAC define content areas of interest
- Measures Advisory Group
  - Reviews measures; helps refine them for public comment
  - Helps identify appropriate existing public domain measures
  - Where no measures exist, helps develop measures
Criteria for Measures

Importance: measures concepts important to stakeholders

Feasible: most organizations can implement the measure now

Scientifically Acceptable: measures are grounded in evidence

Useful: measures produce information that differentiates between programs and can be used for quality improvement
Anatomy of a Measure

- Numerator is clearly defined
- Denominator is clearly defined
- Is quantifiable and expressed as a percentage, a rate, or number
- The measure cannot be answered with a “yes” or “no”

Reporting Cycle

- Accredited organizations will report measures to URAC annually, beginning in the calendar year following their accreditation
- The measurement period is the calendar year
- Measures are due to URAC by June 30th of the year following the measurement period

Example:
Accreditation 2015 → Begin measurement 2016 → Report 6/30/17
Reporting Standard 1 – Performance Measurement and Reporting

The organization has the resources and mechanisms to produce and report on a specified set of performance measures on a periodic basis. These reports will be used for internal performance improvement, reporting to customers, direct reporting to the public, and as part of the ongoing URAC accreditation process inclusive of public reporting. [M]

Reporting Standard 2 – Participation in URAC Measures Program

The organization reports on the following performance measures [(measure domain in first set of parentheses) and (whether the measure is currently a mandatory or leading measure in second set of parentheses)]. [See the Specialty/Mail Service Pharmacy Measures Specifications on the next few slides for details] [M]
Proportion of Days Covered (PDC) measures percentage of patients 18 years and older who met the PDC threshold of 80% during the measurement period.

- Report for the Mail Service Pharmacy [M]
- Report by Medicare, Medicaid, and commercial populations.

Measure SP2012-01: Specialty Proportion of Days Covered

- Proportion of Days Covered (PDC) measures percentage of patients 18 years and older who met the PDC threshold of 90% during the measurement period (Antiretrovirals for at least 2 medications).
- Report for the Specialty Pharmacy [E]
- Report by Medicare, Medicaid, and commercial populations.
- Additional medication categories for future reporting: Multiple Sclerosis, Rheumatoid Arthritis, and Hepatitis C
Performance Measures

Measure DTM2010-04: Call Center Performance

This measure has two parts: Part A measures 30-second response rate; Part B measures call abandonment rate. [M]

Measure CM2013-04: Overall Consumer Satisfaction

Measures the percentage of program participants who completed > 50% of a consumer satisfaction survey and reported that they were “satisfied” overall with the services provided. [M]
### Performance Measures

<table>
<thead>
<tr>
<th>Measure DTM2010-05: Overall Client Satisfaction</th>
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<tbody>
<tr>
<td>The percentage of clients (i.e., purchasers of services) who completed a client satisfaction survey and reported that they were “satisfied” overall with the organization’s services. [M]</td>
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<tr>
<th>Measure MP2012-06: Dispensing Accuracy</th>
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<tr>
<td>This series of measures assesses the percentage of prescriptions that the organization dispensed inaccurately. [M]</td>
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Performance Measures

Measure MP2012-07: Distribution Accuracy

This measure assesses the percentage of prescriptions delivered to the wrong recipient. Part A measures the percentage of prescriptions mailed with an incorrect address; Part B measures the percentage of prescriptions mailed with a correct address that were not delivered to the correct location. [M]
Performance Measures

Measure MP2012-08: Prescription Turnaround Time

This 3-part measure assesses the average speed with which the organization fills prescriptions. Part A measures prescription turnaround time for clean prescriptions, Part B measures prescription turnaround time for prescriptions that required intervention, and Part C measures prescription turnaround time for all prescriptions. [M]
Upon enrollment of an eligible consumer, the patient management program conveys information on rights and responsibilities to participating consumers including: [--]

This measure has three parts:

- Part A measures the percentage of all prescriptions that were dispensed as generics;
- Part B measures the percentage of all prescriptions that were dispensed as generics, branded generics, or brands for which members paid the generic co-pay; and
- Part C measures the percentage of all prescriptions available as generics that were dispensed as generics. [M]
Research & Measurement Contact Information

For additional information, contact URAC’s Research & Measurement Department via email at: ResearchMeasurement@urac.org

Additional Contact:  
Marybeth Farquhar, PhD  
Vice President, Research & Measurement  

mfarquhar@urac.org
Summary of Major Revisions for Specialty/Mail Service Pharmacy

**Mail Service Pharmacy**
- 3 new standards
- 11 standards with major edits
- 15 standards with minor edits
- 5 standards with no changes
- 1 standard removed

**Specialty Pharmacy** (includes the “Patient Management” section)
- 3 new standards
- 22 standards with major edits
- 19 standards with minor edits
- 4 standards with no changes
- 7 standards removed
Highlights of the Revisions for Specialty/Mail Service Pharmacy

- Updated performance measures for Specialty Pharmacy and Mail Service Pharmacy
- Clarified the circumstances under which disclosure of the pharmacy service pricing structure is required
- Made it mandatory for organizations to be able to handle clinical issues 24/7, while eliminating the requirement to respond to claims-related inquiries
Highlights of the Revisions for Specialty/Mail Service Pharmacy (continued)

• Updated and enhanced telephone performance monitoring to align with current industry standards, including average blockage rates

• Expanded consumer safety requirements, including validation of the cold chain distribution process

• Enhanced quality management program design to include quarterly reporting to a quality management or other appropriate committee
Highlights of the Revisions Specific to Specialty Pharmacy

For the “Patient Management” section of Specialty Pharmacy:

- Identified all instances where medication reconciliation needs to be addressed
- Required active facilitation of participation for “at risk” individuals
- Specified communication and documentation requirements for coordination of care
- Clarified the areas to address to demonstrate Patient Management program value
URAC Education Programs, Events and Resources
URAC Education Programs and Events

OUR MISSION is to promote continuous improvement in the quality and efficiency of healthcare management through processes of accreditation, education, and measurement.

ACREDITATION

This section provides detailed information on URAC’s accreditation programs and standards as well as URAC’s measures, data analytics, and measurement reporting.

Health Plan

Learn about URAC’s new Health Plan Accreditation.
Workshops & Webinars Coming Soon…

**Webinars**

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<td>Pharmacy Core v 3.0</td>
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<td>May 13&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Specialty/Mail Service Pharmacy v 2.1</td>
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**Education & Events**

Workshops TBA

*Visit URAC’s Education at [www.urac.org/education]*
Continuing Education Units/Credits

- Approved for this education program

My Meetings Account

- Registered participants log into your “My Meetings” registration account to find the post-test link

Evaluation

- Registered participants must earn at least 70%
- Registered participants have up to 30 days to complete the test after this education program

Certificate

- You will have the option to print your certificate(s) after providing some demographic
Access your CEUs through Prime

1. Go to http://primeinc.org/credit

2. Enter Pharmacy Core program code: 67LV1514
Standards Interpretation – Submit an Inquiry

Standards Interpretations

Case Management Version 4.1
- General Question, Standards 1-28: File Review
- Standard 2: Case Manager Case Load
- Standard 4: Case Manager Qualifications
- Standard 6: Case Manager Supervisor Qualifications
Thank you!

For more information go to: www.urac.org/education