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SCORING INFORMATION

URAC standards are weighted 2-5; these weights determine the relative importance of each standard, such that a weight of 5 indicates that a particular standard must be met or the applicant cannot be granted a full accreditation. Throughout the accreditation process, the applicant’s ability to comply with a particular standard is rated 0-4 by the accreditation reviewer. The assigned weight is then multiplied by the rating, resulting in a score for that standard. The total possible score for all applicable standards then divides the sum of these scores. URAC committees use the resulting final percentage score and compliance with the mandatory standards when making an accreditation decision.

SCORING WEIGHT DEFINITIONS 2006

<table>
<thead>
<tr>
<th>Weight</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Organizations must comply with this standard to obtain full accreditation. These standards are basic to achieving quality of care or maintaining or provider basic health care rights. This is a mandatory standard.</td>
</tr>
<tr>
<td>4</td>
<td>Lack of compliance with more than one standard of this level makes it extremely difficult to obtain full accreditation. The types of structures or processes represented in this standard are consistent with good practice and may significantly affect quality of service for consumers and providers. This is not a mandatory standard.</td>
</tr>
<tr>
<td>3</td>
<td>Lack of compliance with multiple standards of this level makes it difficult to obtain full accreditation. The types of structures or processes represented in this standard are consistent with current industry practice and may have some effect on quality of service for consumers and providers. This is not a mandatory standard.</td>
</tr>
<tr>
<td>2</td>
<td>Implementation of the features of this standard typically indicate one of two scenarios: (1) that this may not yet be a common practice in the industry, but it is employed by the more progressive organizations, and is likely to become common practice in the future, and will likely receive an elevated weight in future revisions of URAC standards; or (2) that this is a common industry practice that does not have a direct impact on quality of care. This is not a mandatory standard.</td>
</tr>
<tr>
<td></td>
<td>There is no scoring weight of 1.</td>
</tr>
</tbody>
</table>
# DEFINITIONS

In the standards, defined terms are italicized. Being familiar with these definitions is critically important to accurate understanding of URAC Standards. Readers are encouraged to refer to the definitions section each time they encounter an italicized term until they feel that they have committed the meaning of that term to memory. Not all terms appear in each module.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access</td>
<td>The consumer’s ability to obtain services at the time which they are needed. The ease of access is determined by components such as the availability of services, their acceptability to the consumer, consumer wait time, and the hours of operation. Note: Consumers should not be denied access to treatment due to coverage.</td>
</tr>
<tr>
<td>Adverse Event</td>
<td>An clinical occurrence that is inconsistent with or contrary to the expected outcomes.</td>
</tr>
<tr>
<td>Advisory Board of Osteopathic Specialists (ABOS)</td>
<td>American Osteopathic Association (AOA) certification agent organized in 1939 for the purpose of establishing and maintaining standards of osteopathic specialization and pattern of training.</td>
</tr>
<tr>
<td>American Board of Medical Specialties (ABMS)</td>
<td>Organized originally in 1933 as the Advisory Board of Medical Specialties, the ABMS (1970), in collaboration with the American Medical Association (AMA), is the recognized certifying agent for establishing and maintaining standards of medical specialization and pattern of training.</td>
</tr>
<tr>
<td>Appeal</td>
<td>Formal request for review of an organizational determination (i.e., services have been denied, reduced, etc.) Note: Prospective review for non-formulary drugs or edits to the system are not considered appeals; rather requests for services that if denied could be appealed.</td>
</tr>
<tr>
<td>Note: Specific terms used to describe appeals</td>
<td>vary, and are often determined by law or regulation. URAC’s drug use management standards apply to first-level appeal.</td>
</tr>
<tr>
<td>Appeals Consideration</td>
<td>Clinical review conducted by appropriate clinical peers, who were not involved in peer clinical review, when a decision not to certify a requested admission, procedure, or service has been appealed. Sometimes referred to as “third level review.”</td>
</tr>
<tr>
<td>Availability</td>
<td>Meeting the needs of consumers according to the criteria posed to the organization by its clients.</td>
</tr>
<tr>
<td>Barrier Analysis</td>
<td>Post-baseline interpretation of performance data that identifies root causes and key improvements and evaluates the effectiveness of improvements by comparing actual to expected results.</td>
</tr>
<tr>
<td>Board-Certified</td>
<td>A certification – approved by the American Board of Medical Specialties, the American Osteopathic Association, or another organization as accepted by URAC – that a physician has expertise in a particular specialty or field. To the extent that future URAC standards include other certifications, URAC will specify further approved boards.</td>
</tr>
</tbody>
</table>
**Note:** URAC recognizes that ABMS- and AOA-approved board certifications may not be the only certification programs that may be acceptable for *health professionals* in URAC-accredited organizations. For example, non-physician professionals will have appropriate certifications that are not ABMS- or AOA-approved. Any applicant wishing to have URAC recognize another board certification program should notify URAC early in the accreditation process. URAC will then take this recommendation to URAC’s Accreditation Committee. The Accreditation Committee will review all requests, and will decide to approve or reject the certification. The Accreditation Committee will consider the following criteria in judging whether a certification is acceptable:

- Is the certification accepted within its target community of health professionals?
- Was the certification developed through an open, collaborative process?
- Does the certification reflect accepted standards of practice?
- Is the certification administered through an objective process open to all qualified individuals?

All approved organizations will be listed in relevant materials provided by URAC. Note also that the term board certification appears only once in the Core Standards, in standard 19, which relates to the clinical qualifications of senior clinical staff people who are physicians.

<table>
<thead>
<tr>
<th><strong>Case</strong></th>
<th>A specific request for medical or clinical services referred to an <em>organization</em> for a determination regarding the medical necessity and medical appropriateness of a health care service or whether a medical service is experimental/investigational or not.</th>
</tr>
</thead>
</table>
| **Certification** | A professional credential, granted by a national organization, signifying that an individual has met the qualifications established by that organization. To qualify under these standards, the *certification* program must:
- Establish standards through a recognized, validated program;
- Be research-based; and
- Be based (at least partially) on passing an examination. |
| **Certification (DUM)** | An approval of a prescription drug claim based on the clinical requirements for medical necessity, appropriateness, level of care, or effectiveness. |
| **Client** | A business or individual that purchases services from the organization. **Note:** Here are some examples of client relationships:
- If a health plan provides health coverage to an employer, the employer is the client.
- If a health plan contracts for utilization management or case management services from a utilization management organization, the health plan is the client.
- If a PPO contracts for credentialing services with a CVO, the PPO is the client. |
<table>
<thead>
<tr>
<th><strong>Clinical Decision Support Tools</strong></th>
<th>Protocols, guidelines, or algorithms that assist in the clinical decision-making process.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Director</strong></td>
<td>A <em>health professional</em> who: (1) is duly <em>licensed</em> or <em>certified</em>; (2) is an employee of, or party to a contract with, an <em>organization</em>; and (3) who is responsible for clinical oversight of the <em>drug utilization management</em> program, including the credentialing of professional <em>staff</em> and quality assessment and improvement functions.</td>
</tr>
<tr>
<td><strong>Clinical Peer</strong></td>
<td>A physician or other <em>health professional</em> who holds an unrestricted <em>license</em> and is in the same or similar specialty as typically manages the medical condition, procedures, or treatment under review.</td>
</tr>
<tr>
<td><strong>Clinical Rationale</strong></td>
<td>A statement that provides additional clarification of the clinical basis for a <em>non-certification</em> determination. The <em>clinical rationale</em> should relate the <em>non-certification</em> determination to the <em>consumer</em>’s condition or treatment plan, and should supply a sufficient basis for a decision to pursue an <em>appeal</em>.</td>
</tr>
<tr>
<td><strong>Clinical Review Criteria</strong></td>
<td>The written screens, decision rules, medical protocols, or drug treatment guidelines used by the <em>organization</em> as an element in the evaluation of medical necessity and appropriateness of services under the auspices of the applicable prescription benefits plan.</td>
</tr>
<tr>
<td><strong>Clinical Staff</strong></td>
<td>Employees or contracted consultants of the health care organization who are clinically qualified to perform <em>clinical triage</em> and provide <em>health education</em> services.</td>
</tr>
<tr>
<td><strong>Comparable</strong></td>
<td>Data about performance is compared to an historical baseline (which may be internal) and ongoing progress is recorded in regular intervals (e.g., monthly, quarterly, or annually). External benchmarks also may be used for purposes of comparison.</td>
</tr>
</tbody>
</table>
| **Complaint**                     | An expression of dissatisfaction regarding the organization’s products or services.  
**Note:** This term is sometimes referred to as “grievance.” This definition does not include appeals. |
| **Concurrent Review**             | *Drug utilization management* conducted during a *consumer*’s ongoing drug benefit use. |
| **Condition**                     | A diagnosis, clinical problem or set of indicators such as signs and symptoms a *consumer* may have that define him/her as eligible and appropriate to participate in a clinical program. |
| **Conflict of Interest**          | Any relationship or affiliation on the part of the organization or a reviewer that could compromise the independence or objectivity of the independent review process. Conflict of interest includes, but is not limited to:  
- An ownership interest of greater than 5% between any affected parties;  
- A material professional or business relationship;  
- A direct or indirect financial incentive for a particular determination;  
- Incentives to promote the use of a certain product or service;  
- A known familial relationship;  
- Any prior involvement in the specific case under review. |
| **Consumer** | An individual person who is the direct or indirect recipient of the services of the *organization*. Depending on the context, consumers may be identified by different names, such as “member,” “enrollee,” “beneficiary,” “patient,” “injured worker,” “claimant,” etc. |
| **Note:** A *consumer* relationship may exist even in cases where there is not a direct relationship between the *consumer* and the *organization*. For example, if an individual is a member of a health plan that relies on the services of a *utilization management* organization, then the individual is a *consumer* of the *utilization management* organization. |
| Consumer Safety | The prevention of harm to *consumers*. |
| **Contractor** | A business entity that performs delegated functions on behalf of the organization.  
Note: For the purposes of these standards, the term “contractor” includes only those contractors that perform functions related to the key processes of the organization. It is not URAC’s intent to include contractors that provide services unrelated to key processes. For example, a contractor that provides catering services would not fall within the definition of “contractor” in these standards. Conversely, a company that provides specialty physician reviewers to a utilization management organization would clearly fall within the definition of “contractor.” |
| **Criteria** | A broadly applicable set of standards, guidelines, or protocols used by the *organization* to guide the *clinical* processes. Criteria should be:  
- written;  
- based on professional practice;  
- literature-based;  
- applied consistently; and  
- reviewed annually. |
| **Delegation** | The process by which the *organization* permits another entity to perform functions and assume responsibilities covered under these standards on behalf of the *organization*, while the *organization* retains final authority to provide oversight to the delegate. |
| **Error** | The failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). |
| **Evidence-Based** | Recommendations based on valid scientific outcomes research, preferably research that has been published in peer reviewed scientific journals. Evidence-based information can be used to develop protocols, pathways, standards of care or clinical practice guidelines and related educational materials. |
| **Expedited Appeal** | An appeal of a non-certification in a case involving urgent care. |
| **Formulary** | A continually updated list of medications (could include transaction lists and preferred lists) and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health. (Adapted from AMCP’s Principles of a Sound Drug Formulary System.) |
| **Formulary System** | An ongoing process whereby a health care organization, through its physicians, pharmacists and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost effective to best serve the health interests of a given patient population. (Adapted from AMCP’s Principles of a Sound Drug Formulary System.) |
| **Generic Substitution** | The substitution of generic drug products that contain the same active ingredient(s) and are chemically identical in strength, concentration, dosage form, and route of administration to the brand drug product prescribed. Health professionals and consumers can be assured that FDA approved generic drugs have met the same rigid standards as the innovator drug. To gain FDA approval, a generic drug must:
- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products (Adapted from AMCP’s Principles of a Sound Drug Formulary System and the FDA website.) |
| **Health Professional** | An individual who: (1) has undergone formal training in a health care field; (2) holds a license in a health care field issued by a state and the license allows the professional to practice within the scope of the license without the supervision of another licensed professional; (3) has professional experience in providing direct patient care; and (4) holds a post-secondary degree in health care. A post-secondary degree is defined as any college, university, or nursing school diploma obtained after graduating from high school (nursing diploma or associates, bachelors, masters, or doctorate degree). |
| **Individually-Identifiable Health Information** | URAC uses the Health Insurance Portability and Accountability Act (HIPAA) definition of this term. |
| **License** | A license or permit (or equivalent) to practice medicine or a health profession that is (1) issued by a state regulatory body or jurisdiction in the United States; and (2) required for the performance of job functions. |

**Note:** In this definition, the word “equivalent” includes certifications, registrations, permits, etc. Specific terms will vary by state and health.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Director</strong></td>
<td>A doctor of medicine or doctor of osteopathic medicine who is duly licensed to practice medicine and who is an employee of, or party to a contract with, an organization, and who has responsibility for clinical oversight of the organization’s utilization management, credentialing, quality management, and other clinical functions.</td>
</tr>
<tr>
<td><strong>Medication Therapy Management (MTM/MTMP)</strong></td>
<td>A distinct service or group of services that optimize therapeutic outcomes for individual consumers. (Adopted from AMCP’s Principles of a Sound Drug Formulary System.)</td>
</tr>
<tr>
<td><strong>Non-Certification</strong></td>
<td>A determination by an organization that a pharmacy benefit service has been reviewed and, based on the information provided, does not meet the clinical requirements for medical necessity, appropriateness, or effectiveness under the auspices of the applicable prescription benefits plan.</td>
</tr>
</tbody>
</table>
| **Opt-In** | Affirmative consent actively provided by a consumer to participate in an activity or function of the medication therapy management program, provided after the medication therapy management program has fully disclosed the terms and conditions of participation to the consumer, including:  
· The duration of the opt-in (is it indefinite or does it apply for a specified period?);  
· The type of information to be collected from the user, the purposes for which the information will be used, to whom the information may be disclosed; and  
· The mechanism by which the user may opt out. |
<p>| <strong>Opt-Out</strong> | A process by which a consumer declines to participate in an activity or function of the medication therapy management program. |
| <strong>Organization</strong> | A business entity that seeks accreditation under these standards. |
| <strong>Outcome</strong> | An outcome is a measure that indicates the result of the performance (or nonperformance) of a program, service, or intervention. The evaluation measures may include: clinical, financial, utilization, economic, quality, and humanistic outcomes (e.g. patient and provider satisfaction). |
| <strong>Participant (participating)</strong> | An eligible consumer that has had one or more inbound or outbound contacts with the medication therapy management program, and if a consumer, has not opted out of the program. |
| <strong>Pharmacy Distribution Channels</strong> | A group of pharmacy entities with which the organization provide pharmacy services to consumers (e.g. retail pharmacy network, mail order pharmacy, and specialty pharmacy). |
| <strong>Pharmacy Network</strong> | A group of retail pharmacies with which the organization provide pharmacy services to consumers. |</p>
<table>
<thead>
<tr>
<th><strong>Pharmacy &amp; Therapeutics (P&amp;T) Committee</strong></th>
<th>An advisory committee that is responsible for developing, managing, updating, and administering the drug formulary system. (Adopted from AMCP's Principles of a Sound Drug Formulary System.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participating Pharmacies</strong></td>
<td>A pharmacy that has entered into an agreement with the organization to be part of a pharmacy network.</td>
</tr>
<tr>
<td><strong>Participating Provider</strong></td>
<td>A provider that has entered into an agreement with the organization to be part of a provider network.</td>
</tr>
</tbody>
</table>
| **Patient** | The enrollee, covered person, or consumer for whom a prescription has been written and for which the certification may or may not have been filed. The term “patient” may include an agent or representative authorized to act on the patient’s behalf.  

*Note:* Try to clarify when the term “patient” includes an agent or representative authorized to act on the patient’s behalf (sometimes defined in benefit contract or by law). |
| **Population** | Depending on the model of the medication therapy management program, the population for which it is responsible may be all of the consumers or the population may be only those consumers identified to the medication therapy management program by client referral or another mechanism. In some instances the medication therapy management program may be responsible for identification of the population, and in other instances the client may conduct identification (and stratification) activities. |
| **Practitioner** | An individual person who is licensed to deliver health care services without supervision. |
| **Prescriber** | A licensed health care professional that writes prescriptions for consumers within their scope of practice. |
| **Prescription** | Medication prescribed to a patient or obtained for treatment and prevention of disease or conditions. This may include OTC drugs and related supplies. (From the AMCP Consensus document). |
| **Professional Competency** | The ability to perform assigned professional responsibilities. |
| **Prospective Review** | Drug utilization management conducted prior to a prescription, service or course of treatment. Sometimes it can be called “pre-certification review”, “pre-service”, or “prior authorization.” |
| **Provider** | Any person or entity that provides health care services. Includes both practitioners and facilities. |
| **Rationale** | The reason(s) or justification(s) – commonly based on criteria – for a specific action or recommendation. |
| **Quality Improvement Project** | A process that documents the variation of performance or variance from baseline standards in order to achieve a better outcome for the organization’s consumers. |
| **Quality Management Program** | A systematic data-driven effort to measure and improve consumer and client services and/or health care services including consumer safety. |
| **Retrospective Review** | Review conducted after prescription services have been provided to the patient.  
**Note:** Retrospective medical necessity determinations are considered *drug utilization management* (and subject to these standards). |
|-------------------------|--------------------------------------------------------------------------------------------------|
| **Reviewer(s)** | The individual (or individuals) selected by the *organization* to consider a case. All reviewer(s) who are health care *practitioners* must have the following qualifications:  
- Active licensure;  
- Recent experience or familiarity with current body of knowledge and medical practice;  
- At least 5 years experience providing health care;  
- If the reviewer is a pharmacist, a valid pharmacy license.  
- If the reviewer is an M.D. or D.O., board certification by a medical specialty board approved by the American Board of Medical Specialties or the American Osteopathic Association.  
- If the reviewer is a D.P.M., board certification by the American Board of Podiatric Surgery. |
| **Staff** | The *organization’s* employees, including full-time and part-time employees. |
| **Standard Appeal** | An *appeal* of a *non-certification* that is not an *expedited appeal*. In most cases, *standard appeals* will not relate to *cases involving urgent care*. However, *standard appeals* may also include *secondary appeals* of *expedited appeals*. |
| **Therapeutic Interchange** | Authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system. (Adopted from AMCP’s Principles of a Sound Drug Formulary System.) |
| **Treating Provider** | The treating *provider* is the individual or *provider group* who is primarily managing the treatment for a *consumer* participant in the *medication therapy management program*. The treating *provider* is not necessarily the consumers’ primary physician. The *consumer* may have a different treating *provider* for different conditions. |
| **Utilization Management (Drug Use Management)** | Evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and *facilities* under the provisions of the applicable *health benefits plan*; sometimes called “utilization review.”  
**Note:** In the case of the Pharmacy Benefits Management Standards, utilization management refers to "drug utilization management". |
| **Valid** | Based on accepted principles of study design, research methodology, and statistical analysis. |
| **Written Agreement** | A document – including an electronic document – that specifies the terms of a relationship between the *organization* and a *client, consumer*, or *contractor*. This term may include a contract and any attachments or addenda. |
| **Written Notification** | Correspondence transmitted by mail, facsimile, or electronic medium. |
Module 1: Core Standards, Version 2.0
## Organizational Structure

| Standards Core 1 - Organizational Structure & Core 2 - Organization Documents |
|---|---|
| **Core 1** | The *organization* has a clearly defined organizational structure outlining direct and indirect oversight responsibility throughout the *organization*. |
| **Core 2** | *Organization’s* documents address:  
| | (a) Mission statement;  
| | (b) Organizational framework for program;  
| | (c) A description of the services delivered by the *organization* and how those services are delivered;  
| | (d) The *population* served; **and**  
| | (e) Organizational oversight and reporting requirements of the program. |

### Scoring Information

| Core 1 | Weight = 3 |
| Core 2 | Weight = 2 |

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- The organizational structure should clearly identify those departments with responsibility for key program functions, and their relationship to each other and the overall organization.
- The organization should have a clearly defined mission statement and a vision for how it will provide services to fulfill that mission.
- Service refers to both clinical and non-clinical services.
POLICIES AND PROCEDURES

<table>
<thead>
<tr>
<th>Standard Core 3 – Policy and Procedure Maintenance, Review, and Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization:</td>
</tr>
<tr>
<td>(a) Maintains and complies with written policies and procedures that govern all aspects of its operations;</td>
</tr>
<tr>
<td>(b) Maintains a master list of all such policies and procedures;</td>
</tr>
<tr>
<td>(c) Reviews policies and procedures no less than annually and revises as necessary; and</td>
</tr>
<tr>
<td>(d) Includes the following on all policies and procedures:</td>
</tr>
<tr>
<td>(i) Effective dates, review dates, including the date of the most recent revision; and</td>
</tr>
<tr>
<td>(ii) Identification of approval authority.</td>
</tr>
</tbody>
</table>

Scoring Information

Weight = 5 (Mandatory Standard)
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Documented policies and procedures establish accountability for providing quality services to clients and consumers.
- The organization should monitor its internal operations for compliance with policies and procedures, especially operations that relate to key processes within the organization.
- A document control sheet can be used to show the annual history of policies and procedures.
- Hard-copy signatures are no longer required; however the organization must be able to clearly demonstrate that policies have been approved.


**Staff Qualifications**

<table>
<thead>
<tr>
<th>Standards Core 4 – Job Descriptions, Core 5– Staff Qualifications, &amp; Core 6 - Credentialing</th>
</tr>
</thead>
</table>

### Core 4

The *organization* has written job descriptions for *staff* that address:

- (a) Required education, training, and/or professional experience;
- (b) Expected *professional competencies*;
- (c) Appropriate *licensure/certification* requirements; and
- (d) Scope of role and responsibilities.

### Core 5

*Staff* meets qualifications as outlined in written job descriptions.

### Core 6

The *organization* implements a policy to:

- (a) Verify the current *licensure* and credentials of *licensed* or certified personnel/consultants upon hire, and thereafter no less than every 3 years;
- (b) Require staff to notify *organization* in a timely manner of an adverse change in *licensure or certification* status; and
- (c) Implement corrective action in response to adverse changes in *licensure or certification* status.

### Scoring Information

- Core 4  Weight = 2
- Core 5  Weight = 3
- Core 6  Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.
Interpretive Information/Commentary

- Written job descriptions and verification of licensure requirements will help to ensure that staff, both clinical and non-clinical, is qualified to provide program services.
- Specific credentials, as mentioned in Core 6(a), will vary by organization and health profession. Typical credentials include: education, training, experience, and professional certifications.
- Organizations may specify which credentials they verify for health professionals in light of their services and the types of health professionals utilized.
- The intent of Core 6 (b) is for the organization to determine the timeframe for adverse licensure/certification changes depending on the type of services provided and the relevance of the licensure/certification; e.g. case manager certification might have lapsed but that individual may still be a nurse, thus reporting may not be needed as immediately as if nurse licensure had lapsed.
### STAFF MANAGEMENT

**Standard Core 7– Staff Training Program**

The *organization* has a training program that includes:

(a) Initial orientation and/or training for all *staff* before assuming assigned roles and responsibilities;

(b) Ongoing training, at a minimum annually, to maintain *professional competency*;

(c) Training in URAC Standards as appropriate to job functions;

(d) Training in state and regulatory requirements as related to job functions;

(e) *Conflict of interest*;

(f) Confidentiality;

(g) *Delegation* oversight, if necessary; **and**

(h) Documentation of all training provided for *staff*.

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Orientation and ongoing training programs help to ensure that staff are kept up-to-date and have the knowledge and resources to provide quality program services.

- Training may vary by profession and the type of organization. Examples of training include:
  - Obtaining continuing education credits in a relevant field
  - Attendance at meetings or conferences related to job functions
  - In-house on performance of job functions.

- Ongoing training should be documented in personnel files.

- Regarding Core 7(c) and (d): Staff need only be trained in those URAC standards and regulations that apply directly to their job and not all standards and regulations that affect the organization.
STAFF MANAGEMENT

Standards Core 8 – Staff Operational Tools and Support & Core 9 – Staff Assessment Program

Core 8

The organization provides staff with:

(a) Written operational policies and procedures appropriate to their jobs; and

(b) Clinical decision support tools as appropriate.

Core 9

The organization maintains a formal assessment program for individual staff members that includes an annual performance appraisal and a review of relevant documentation produced by that individual staff member.

Scoring Information

Core 8   Weight = 4
Core 9   Weight = 3

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Pursuant to the definition of “clinical decision support tools,” these tools include protocols, guidelines, or algorithms that assist in the clinical decision-making process.
- Using a formal assessment program, staff can be held accountable for appropriate implementation of documented program operations and tools.
- Occasionally union contracts or collective bargaining agreements will stipulate formal assessment programs with different timeframes than presented in standard 9.
Clinical Oversight

Standards Core 10 – Senior Clinical Staff Requirements & Core 11 – Senior Clinical Staff Responsibilities

Core 10

The organization designates at least one senior clinical staff person who has:

(a) Current, unrestricted clinical license(s) (or if the license is restricted, the organization has a process to ensure job functions do not violate the restrictions imposed by the State Board);

(b) Qualifications to perform clinical oversight for the services provided; and

(c) Post-graduate experience in direct patient care; and

(d) Board certification (if the senior clinical staff person is an M.D. or D.O.).

Core 11

The senior clinical staff person:

(a) Provides guidance for all clinical aspects of program;

(b) Is responsible for clinical aspects of program; and

(c) Has periodic consultation with practitioners in the field.

Scoring Information

Core 10  Weight = 5 (Mandatory Standard)
Core 11  Weight = 4

See the section on “scoring information” at the beginning of this document.
A clinically qualified and experienced staff person in a leadership position is the most appropriate person to oversee the clinical aspects of an organization’s program.

Regarding the issue of “unrestricted” licenses in Core 10(a): URAC intends for this term to apply to those restrictions that would have a material impact on a clinical staff person’s ability to perform relevant job functions for the organization. For example, a surgeon’s restrictions due to arthritis do not have an impact on the ability to provide medical guidance to the organization. On the other hand, restrictions due to unethical conduct would be relevant.

Qualifications in Core 10(b) include experience, credentials, certifications, etc.

URAC generally expects that in organizations that provide general health services, products, or management, the senior clinical staff person is an M.D. or D.O. In any case, the senior clinical person must be qualified to guide the clinical aspects of the organization’s operations.

Residencies and similar programs are sufficient to meet the intent of Core 10(c).

URAC does not currently require any certifications for senior clinical staff persons that are not M.D.s or D.O.s.
## INTER-DEPARTMENTAL COORDINATION

<table>
<thead>
<tr>
<th>Standard Core 12 – Inter-departmental Coordination</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> establishes and implements mechanisms to promote collaboration, coordination, and communication across disciplines and departments within the <em>organization</em>, with emphasis on integrating administrative activities, quality improvement, and where present, clinical operations.</td>
</tr>
</tbody>
</table>

### Scoring Information

**Weight = 4**

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- In order to provide quality services, departments and disciplines within an organization must communicate and coordinate their activities.
- Examples of “mechanisms to promote coordination and communication across disciplines and departments within the organization” can include (but is not limited to) your choice of the following:
  - Periodic and documented meetings among department heads and/or with designated staff members to discuss coordination of functions;
  - Assignment of representatives of departments to serve as liaisons to other departments, including participation in internal committees;
  - Quality improvement projects that include the participation of multiple departments.
## INFORMATION MANAGEMENT

<table>
<thead>
<tr>
<th>Standard Core 13 - Information Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> implements information system(s) (electronic, paper or both) to collect, maintain, and analyze information necessary for organizational management that:</td>
</tr>
<tr>
<td>(a) Provides for data integrity;</td>
</tr>
<tr>
<td>(b) Provides for data confidentiality and security;</td>
</tr>
<tr>
<td>(c) Includes a disaster recovery plan that;</td>
</tr>
<tr>
<td>(i) Is tested at least every two years; <strong>and</strong></td>
</tr>
<tr>
<td>(ii) Addresses identified areas for improvement; <strong>and</strong></td>
</tr>
<tr>
<td>(d) Includes a plan for storage, maintenance, and destruction.</td>
</tr>
</tbody>
</table>

### Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Proactive information systems management helps to maintain confidentiality and consistent information flow, supporting an organization’s ability to provide appropriate and timely services.
- In this context, “data integrity” means data accuracy and trace-ability. For example, when an organization pulls up a consumer’s records, what steps has it taken to ensure that it has pulled the correct record, and how accurate is the information in the record? Examples of “providing for data integrity” include (but are not limited to):
  - Monitoring data entry personnel for accuracy;
  - Cross-checking databases for consistency;
  - Using unique identifiers for consumer data; and
  - Prevention of and checking for duplicate entries.
- Specific methods to meet Core 13(a)-(d) will vary depending on an electronic or paper environment.
- Core 13 (c) (ii) Testing is company specific and the company should determine how comprehensive disaster recovery testing should be.
- It is not the intent of the standard to require organizations to make all documents electronic, but rather in the event of a disaster, key documentation needs to be maintained so the organization can resume business without substantial problems. So for example, this standard should not be interpreted by organizations which credential providers to be a requirement that each provider credential be collected and maintained electronically.
- This standard refers to recovery of key documents, not physical facilities.
### BUSINESS RELATIONSHIPS

#### Standard Core 14 – Business Relationships

The *organization* maintains signed *written agreements* with all *clients* describing the scope of the business arrangement.

<table>
<thead>
<tr>
<th>Scoring Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight = 2</td>
</tr>
<tr>
<td>See the section on “scoring information” at the beginning of this document.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretive Information/Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clearly defined, written service requirements allow an organization to measure and improve its service performance.</td>
</tr>
</tbody>
</table>
# Oversight of Delegated Functions

## Standards Core 15 – Delegation Review Criteria & Core 16 – Delegation Review

### Core 15

The *organization* establishes and implements criteria and processes for an assessment prior to the *delegation* of functions.

### Core 16

Prior to *delegating* functions to another entity, the *organization*:

(a) Conducts a review of the potential *contractor’s* policies and procedures and capacity to perform *delegated* functions; **and**

(b) Outlines and follows criteria and processes for approving *contractors*.

### Scoring Information

<table>
<thead>
<tr>
<th>Core</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>4</td>
</tr>
</tbody>
</table>

See the section on “scoring information” at the beginning of this document.
### Interpretive Information/Commentary

- Core 15, 16 and 18 (delegation standards) are not applicable if the applicant does not delegate part of the health care-related services that it provides to its clients. However, the applicant may choose to submit documentation to meet these standards if it has established processes and criteria for delegation anticipating potential delegation in the future.

- To the extent that contractors perform delegated functions and are accredited by URAC for those services they provide to the organization, the organization shall be exempt from standards Core 15, 16, and 18.

- Prior assessment of a contractor’s capabilities helps to promote good working relationships and ensure quality services to consumers.

- Assessments required under Core 15 may not always be on-site. The criteria should specify which potential contractors would receive site visits. The criteria need not specify that every potential contractor receive a site visit. For example, the criteria might specify that contractors perform a certain type of function – credentialing, for instance – would receive a site visit. Or the criteria might specify that contractors that are expected to perform a certain volume of services might require a site visit.

- **Scope of Delegation:** Delegation is defined as when an organization contracts for a function that is within the scope of accreditation, for which it gives to that delegated entity discretion, i.e. the delegated entity performs independently of the organization. The exception to this definition is that provider contracting in a pharmacy distribution channel setting is excluded. The organization is required to list which specific parts of the process/standards are being delegated.
Oversight of Delegated Functions

Standard Core 17 – Delegation Contracts

The organization enters into written agreements with contractors that:

(a) Specify those responsibilities delegated to the contractor and those retained by the organization;

(b) Require that services be performed in accordance with the organization’s requirements and URAC standards;

(c) Require notification to the organization of any material change in the contractor’s performance of delegated functions;

(d) Specify that the organization may conduct surveys of the contractor, as needed;

(e) Require that the contractor submit periodic reports to the organization regarding the performance of its delegated responsibilities;

(f) Specify recourse and/or sanctions if the contractor does not make corrections to identified problems within a specified period;

(g) Specify the circumstances under which activities may be further delegated by the contractor, including any requirements for obtaining permission from the organization before any further delegation; and

(h) Specify that, if the contractor further delegates organizational functions, those functions shall be subject to the terms of the written agreement between the contractor and the organization and in accordance with URAC standards.

Scoring Information

Weight = 5 (Mandatory Standard)
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Core 17 applies to all delegated entities, both URAC-accredited and non-accredited companies.
- Clearly defined, written service requirements allow an organization to hold contractors accountable for delegated program functions and provides recourse, which may include canceling the contract, when contractor performance does not meet agreed upon quality performance standards.
- If an organization is delegating a function to another organization the delegating organization should check to see if the delegated organization has a current accreditation certificate and a signed contract to state that they are working together.
OVERSIGHT OF DELEGATED FUNCTIONS

**Standard Core 18 – Delegation Oversight**

The organization implements an oversight mechanism for delegated functions that includes:

(a) A periodic review (no less than annually) of the contractor’s policies and procedures and documentation of quality activities for related delegated functions;

(b) A process to verify (no less than annually) the contractor’s compliance with contractual requirements and policies and procedures; and

(c) A mechanism to monitor financial incentives to ensure that quality of care or service is not compromised.

**Scoring Information**

Weight = 3

See the section on “scoring information” at the beginning of this document.
### Interpretive Information/Commentary

- Core 15, 16 and 18 (delegation standards) are not applicable if the applicant does not delegate part of the health care-related services that it provides to its clients. However, the applicant may choose to submit documentation to meet these standards if it has established processes and criteria for delegation anticipating potential delegation in the future.
- To the extent that contractors perform delegated functions and are accredited by URAC for those services they provide to the organization, the organization shall be exempt from standards Core 15, 16, and 18.
- An oversight mechanism allows an organization to monitor services provided by a contractor and take corrective action as needed.
- Under Core 18(a), the organization should check to ensure that the contractor has a process to monitor the quality of services it provides to the organization (or the organization’s clients and consumers). In cases where the contractor’s performance does not meet quality expectations, the organization should ensure that the contractor has a process to improve quality. The quality management section of these standards may provide guidance for a contractor’s QM program.
- Core 18(c) requires the organization to monitor the impact that financial incentives (if they are present) have on the performance of delegated activities. For example, if a health plan provides a bonus to a delegated utilization management organization based on turnaround time for medical reviews, then the health plan must have a process to monitor or audit the medical reviews to ensure that quality does not suffer. The health plan could implement this monitoring system by doing case audits, evaluating overall utilization patterns, checking for complaints regarding the review process, surveying consumers or providers going through the review process, etc.
### REGULATORY COMPLIANCE

**Standard Core 19 – Regulatory Compliance**

The *organization* implements a regulatory compliance program that:

(a) Tracks applicable laws and regulations in the jurisdictions where the *organization* conducts business; and

(b) Ensures the *organization’s* compliance with applicable laws and regulations.

### Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- It is URAC’s goal to ensure that its programs fit within the context of existing regulatory structures. Since these structures vary, it is not always possible to develop standards that are consistent with existing legal requirements. The purpose of Standard Core 19 is to ensure that organizations understand and comply with regulatory requirements in the specific jurisdictions where they operate.

- Organizations can demonstrate compliance with Core 19 by:
  - Maintaining copies of relevant laws and regulations;
  - Designating a staff person with responsibility for compliance, and providing sufficient resources for the compliance program;
  - Providing copies of state licenses (where such licenses are required);
  - Documenting specific actions taken to meet regulatory requirements (such as regulatory filings or correspondence with regulators).

- During the accreditation review, URAC will interview organization staff to evaluate their familiarity with laws and regulations in their jurisdictions.
**FINANCIAL INCENTIVES**

**Standard Core 20 – Financial Incentive Policy**

If the *organization* has a system for reimbursement, bonuses, or incentives to *staff* or health care *providers* based directly on *consumer* utilization of health care services, then the *organization* implements mechanisms addressing how the *organization* will ensure that *consumer* health care is not compromised.

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Financial incentives could negatively influence the provision of health care services.
- In this context, “consumer utilization of health care services” includes (but is not limited to):
  - Costs (either as a total amount or a savings percentage);
  - Total utilization in a population;
  - Utilization rates.
COMMUNICATIONS

Standard Core 21 – Communication Practices

The organization follows marketing and communication practices that include:

(a) Mechanisms to clearly and accurately communicate information about services to consumer and clients;
(b) Safeguards against misrepresentations about the organization’s services;
(c) A formal process of inter-departmental review of marketing materials before dissemination; and
(d) Monitoring of existing materials for accuracy.

Scoring Information

Weight = 3

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The intent of this standard is to ensure that services represented in marketing materials are accurate. URAC requires policies and procedures related to the development of marketing materials. These procedures are expected to include review of the marketing materials by the operational units that are responsible for conducting these services. Appropriate parties are expected to review marketing materials and document the review/approval. Examples of compliance with this standard include emails, sign-off documents, and meeting minutes. URAC expects companies to comply with the URAC marketing guidelines outlined in the document “Marketing and Press Release Guidelines for Accredited and In Process Companies”. This document is distributed with the accreditation application and certificate.
- During the onsite review, URAC will interview the person responsible for developing marketing materials for the lines of business under the scope of the accreditation.
- Inaccurate marketing information and materials can mislead consumers and clients.
COMMUNICATIONS

Standard Core 22 – Consumer Communication Plan

The organization documents and has a mechanism for informing consumers and clients of their rights and responsibilities, including:

(a) How to obtain services; and

(b) How to submit a complaint or appeal.

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- It is incumbent upon an organization to inform consumers and clients of their rights and responsibilities, establishing avenues of communication and a relationship between the individual and the organization.
- When the organization has been delegated the service function, but not delegated the responsibility to inform the consumer of their rights, the organization must refer the consumer back to the delegating organization and document the process for so doing.
**CONSUMER PROTECTION**

<table>
<thead>
<tr>
<th>Standard Core 23 – Consumer Safety Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> has a mechanism to respond on an urgent basis to situations that pose an immediate threat to the health and safety of <em>consumers</em>.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scoring Information</th>
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</thead>
<tbody>
<tr>
<td>Weight = 5 (Mandatory Standard)</td>
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<tr>
<td>See the section on “scoring information” at the beginning of this document.</td>
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</table>

<table>
<thead>
<tr>
<th>Interpretive Information/Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The intent of this standard is for the organization to establish at least one process within their organization that addresses the ability of the organization to respond in a timely manner to situations that may expose consumers to health and safety risks. Standard Core 23 may relate to or have the intent fulfilled by the Consumer Safety Quality Improvement Project (QIP) identified by the organization. See Core 37 related to Consumer safety.</td>
</tr>
</tbody>
</table>
CONSUMER PROTECTION

Standard Core 24 – Confidentiality of Individually-Identifiable Health Information

The organization establishes and implements a policy and procedure to protect the confidentiality of individually-identifiable health information that:

(a) Identifies how individually-identifiable health information will be used;

(b) Specifies that individually-identifiable health information is used only for purposes necessary for conducting the business of the organization, including evaluation activities;

(c) Addresses who will have access to individually-identifiable health information collected by the organization;

(d) Addresses oral, written, or electronic communication and records that are transmitted or stored;

(e) Address the responsibility of organization employees, committee members, and board members to preserve the confidentiality of individually-identifiable health information;

and

(f) Requires employees, committee members, and board members of the organization to sign a statement that they understand their responsibility to preserve confidentiality.

Scoring Information

Weight = 5

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Participating providers are covered in DC 7.
- Electronic systems could include all forms of wireless communication, internet, fax, etc.
### Consumer Satisfaction

**Standard Core 25 – Consumer Satisfaction**

The *organization* implements a mechanism to collect or obtain information about *consumer* satisfaction with services provided by the *organization*.

**Scoring Information**

Weight = 3

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Examples of mechanisms to collect or obtain information about consumer satisfaction include (but are not limited to) surveys, focus groups, complaints/grievances, etc.
- URAC recognizes CAHPS® studies as meeting the intent of URAC’s Consumer Satisfaction standards requiring a mechanism to collect or obtain information about *consumer* satisfaction with services provided by the organization. CAHPS® refers to a family of surveys that ask consumers to evaluate the interpersonal aspects of health care in which *consumers* are the best or an important source of information. The CAHPS® program is managed by the Agency for Healthcare Research and Quality.
### ACCESS TO SERVICES

<table>
<thead>
<tr>
<th>Standard Core 26 – Access to and Monitoring of Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em>:</td>
</tr>
<tr>
<td>(a) Establishes standards to assure that <em>consumers</em> or <em>clients</em> have access to services: <strong>and</strong></td>
</tr>
<tr>
<td>(b) Defines and monitors its performance with respect to the access standards.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scoring Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight = 5 (Mandatory Standard)</td>
</tr>
<tr>
<td>See the section on “scoring information” at the beginning of this document.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretive Information/Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Core 26 does not refer only to network adequacy. It refers to any services that the organization provides.</td>
</tr>
<tr>
<td>• This standard applies to access to the organization. DC 2 evaluates access to providers separately.</td>
</tr>
<tr>
<td>• It is up to the organization to define its own access standards and performance metrics.</td>
</tr>
</tbody>
</table>
COMPLAINTS AND APPEALS

<table>
<thead>
<tr>
<th>Standards Core 27 – Complaint and Appeal System, Core 28 – Appeal Process &amp; Core 29 – Complaint and Appeal Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core 27</strong></td>
</tr>
<tr>
<td>The <em>organization</em> maintains a system to receive and respond in a timely manner to <em>complaints</em> and, when appropriate, inform <em>consumers</em> of their rights to submit an <em>appeal</em>.</td>
</tr>
<tr>
<td><strong>Core 28</strong></td>
</tr>
<tr>
<td>The <em>organization</em> maintains a formal <em>appeal</em> resolution process that includes:</td>
</tr>
<tr>
<td>(a) Written notice of final determination with an explanation of the reason for the determination;</td>
</tr>
<tr>
<td>(b) Notification of the process for seeking further review, if available; <em>and</em></td>
</tr>
<tr>
<td>(c) A reasonable, specified time frame for resolution and response.</td>
</tr>
<tr>
<td><strong>Core 29</strong></td>
</tr>
<tr>
<td>The <em>organization</em> reports analysis of the <em>complaints</em> and <em>appeals</em> to the quality management committee (see Core 33).</td>
</tr>
</tbody>
</table>

**Scoring Information**

<table>
<thead>
<tr>
<th>Core 27</th>
<th>Weight = 5 (Mandatory Standard)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core 28</td>
<td>Weight = 5 (Mandatory Standard)</td>
</tr>
<tr>
<td>Core 29</td>
<td>Weight = 3</td>
</tr>
</tbody>
</table>

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Please note that due to the nature of contracting arrangements regarding pharmacy benefit management, often complaint and appeal requirements are not delegated to the organization providing pharmacy benefit management, but are instead retained by the organization sponsoring the benefits or the requirements are delegated to another organization. This standard only applies when the pharmacy benefit management organization is contracted to provide this service.
- Core 27 is not just referring to the individual consumer but also to a provider acting on their behalf.
- In this context, “analysis” includes aggregate information about rates, trends and outcomes of grievance and appeals.
### Quality Improvement/Management

#### Standards Core 30 – Quality Management Program & 31 – Quality Management Program Resources

**Core 30**

The *organization* maintains a *quality management program* that promotes objective and systematic measurement, monitoring, and evaluation of services and implements quality improvement activities based upon the findings.

**Core 31**

The *organization* employs *staff* and provides resources necessary to support the day-to-day operations of the *quality management program*.

#### Scoring Information

<table>
<thead>
<tr>
<th>Core 30</th>
<th>Weight = 5 (Mandatory Standard)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core 31</td>
<td>Weight = 3</td>
</tr>
</tbody>
</table>

See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- A viable quality management (QM) program has the requisite structures and processes in place to be able to evaluate and ensure quality services to clients and consumers.
- URAC recognizes that actual quality management activities will vary by organization, and URAC wishes to provide flexibility for an organization to implement its own quality management program. The intent of this section is to provide the framework for a quality management program within which an organization can focus on its unique needs.
- Core 30 is not intended to imply that every finding requires a QIP.
### Quality Improvement/Management

**Standard Core 32 – Quality Management Program Requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> has a written description for its <em>quality management program</em> that:</td>
</tr>
<tr>
<td>(a) Is approved by the <em>organization’s</em> governing body;</td>
</tr>
<tr>
<td>(b) Defines the scope, objectives, activities, and structure of the <em>quality management program</em>;</td>
</tr>
<tr>
<td>(c) Is reviewed and updated by the quality management committee at least annually;</td>
</tr>
<tr>
<td>(d) Defines the roles and responsibilities of the quality management committee; <strong>and</strong></td>
</tr>
<tr>
<td>(e) Designates a member of senior management with the authority and responsibility for the overall operation of the <em>quality management program</em> and who serves on the quality management committee.</td>
</tr>
</tbody>
</table>

**Scoring Information**

- Weight = 4
- See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- A well-articulated quality management (QM) program, approved by organizational leadership, helps to assure ongoing support for the program.
**QUALITY IMPROVEMENT/MANAGEMENT**

<table>
<thead>
<tr>
<th>Standard Core 33 – Quality Management Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> has a quality management committee that:</td>
</tr>
<tr>
<td>(a) Is granted authority for quality management by the <em>organization</em>’s governing body;</td>
</tr>
<tr>
<td>(b) Provides on-going reporting to the <em>organization</em>’s governing body;</td>
</tr>
<tr>
<td>(c) Meets at least quarterly;</td>
</tr>
<tr>
<td>(d) Maintains approved minutes of all committee meetings;</td>
</tr>
<tr>
<td>(e) If applicable, includes at least one <em>participating provider</em> or receives input from a <em>participating provider</em> committee (such as a Physician Advisory Group);</td>
</tr>
<tr>
<td>(f) Provides guidance to <em>staff</em> on quality management priorities and projects;</td>
</tr>
<tr>
<td>(g) Approves the <em>quality improvement projects</em> to undertake;</td>
</tr>
<tr>
<td>(h) Monitors progress in meeting quality improvement goals; <strong>and</strong></td>
</tr>
<tr>
<td>(i) Evaluates the effectiveness of the <em>quality management program</em> at least annually.</td>
</tr>
</tbody>
</table>

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- The body specified in these standards may be named something other than “quality management committee” as long as it meets the requirements of the standard.
- Core 33(e) may not apply to all organizations. It specifically applies to organizations that maintain networks of *participating providers*.
- The committee should consist of two or more individuals.
- Organizations may demonstrate that minutes are approved through signatures by a competent authority (such as a committee chairman).
- During the accreditation review, URAC will focus on committee minutes from the previous two years. However, URAC strongly recommends that organizations maintain committee minutes (and other important documents) for at least seven years.
- With respect to Core 33(f) and (g), URAC expects the quality management committee to focus on projects that relate to the key processes of the organization.
- The term governing body is intended to refer to the organization’s Board of Directors. If the organization does not have a Board, then the governing body refers to the organization’s Senior Management Team.
- On-going reporting is intended to be, at a minimum, once a year.
### Quality Improvement/Management

#### Standard Core 34 – Quality Management Documentation

The organization, as part of its quality management program, provides written documentation of:

(a) Ongoing monitoring for compliance with URAC Standards;
(b) Objectives and approaches utilized in the monitoring and evaluation of activities;
(c) Identification and tracking and trending of key indicators relevant to the scope of the entire organization and related to:
   (i) Consumer and health care services; or
   (ii) For organizations who do not interact with consumers, client services;
(d) The implementation of action plans to improve or correct identified problems;
(e) The mechanisms to communicate the results of such activities to staff; and
(f) The mechanisms to communicate the results of such activities to the quality management committee.

#### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.
Interpretive Information/Commentary

- Refer to Core 25 & 26
- Successful quality management programs communicate activities to staff and organizational leadership.
- In order to proactively manage problems, organizations need to track and trend data related to consumer and client services.
- The intent of this standard is integral to the organization understanding the quality management process and the monitoring of compliance with the URAC Standards for which the organization is accredited. This standard provides guidance to the organization on how to establish performance measures on activities within the program, the monitoring of these measures, and efforts to improve when these measures are not met.
- Given the nature of the health care industry and changes in business structure (i.e., increase in new members, acquisition/merger activity), URAC is less concerned with the organization not meeting the actual goals of these measures, and more concerned with the organization demonstrating efforts to “improve” services when the performance goals are not met (i.e., developing an action plan). The process should be similar to the following:
  1) identify key indicators within the program’s operations (under the scope of the accreditation) which are a measure of the program’s ongoing performance;
  2) once these key indicators are identified, track and trend these measures;
  3) if the goals are not met related to these key indicators, develop an action plan to meet the goal(s); and
  4) discuss action plan in quality committee and share with staff, so they are aware that this is a measurement goal for the program.

For example: A new client requires that the program’s telephone abandonment rate must average 5% or less per month and the organization meets this goal from July through December 2005. In January 2006, the organization accepts several new clients and the abandonment rate climbs to an average of 10% in January and February. The organization develops an action plan to address the abandonment rate that includes hiring new staff and the abandonment rate decreases to an average of 5% by April 2006.
- The organization may decide to develop a QIP based on this process.
QUALITY IMPROVEMENT/MANAGEMENT

Standards Core 35 – Quality Improvement Project Requirements & Core 36 – Quality Improvement Project Goals and Measurement

Core 35
For each *quality improvement project*, the *organization* utilizes *valid* techniques comparable over time to:
(a) Develop quantifiable measures;
(b) Measure baseline level of performance; and re-measure level of performance at least annually; and
(c) Establish measurable goals for quality improvement.

Core 36
For each *quality improvement project*, the *organization*:
(a) Designs and implements strategies to improve performance;
(b) Establishes projected time frames for meeting goals for quality improvement;
(c) Documents changes or improvements relative to the baseline measurement;
(d) Conducts at least one remeasurement prior to re-accreditation; and
(e) Conducts a barrier analysis, if the performance goals are not met.

Scoring Information
Core 35  Weight = 3
Core 36  Weight = 3
See the section on “scoring information” at the beginning of this document.
### Interpretive Information/Commentary

- Measurable goals and outcomes allow an organization to verify improvement.
- Measures for quality improvement projects will vary by the type of project. Examples include immunization rate, consumer satisfaction levels, turn-around times for cases, response times for telephone calls, etc. The key is that the organization establishes a measurable baseline of performance, so that it can evaluate any improvement and estimate how long it will take to get there.
- Improvement strategies will vary by the type of project. The key is that the strategy should have a reasonable expectation of producing the desired improvement. Example: For a project related to immunization rates, a strategy might be to send reminders to consumers, or to give some incentive to physicians to provide the immunization.
- Incremental performance measurement periods should be defined by the organization, but occur at least annually.
- For Core 36, the organization should use the QIP Form developed by URAC or establish their own QIP form to assist in meeting the intent of this standard.
- Documentation of QIPs should include the following either on a QIP form or in the quality management meeting minutes:
  - Project start date;
  - Identified quantifiable baseline measure(s) for the indicator and relevance to the clients and/or consumers served;
  - Quantifiable goals associated with the measure;
  - Improvement strategies and dates these were implemented;
  - Periodic progress measurements and documented discussions;
  - Any changes in improvement strategy and brief description of changes; and
  - Project end date.
- For 36(b), see Core 35(c).
- URAC recognizes HEDIS® studies as meeting the intent of URAC’s Quality Management (QM) standards requiring Quality Improvement Projects (QIPs). The Health Plan Employer Data and Information Set (HEDIS)® is a set of standardized performance measures designed to ensure that purchasers and consumers have the information they need to reliably compare the performance of managed health care plans.


**Quality Improvement/Management**

**Standard Core 37 – Clinical, Error Reduction, and Consumer Safety Requirements**

At any given time, the organization maintains no less than two *quality improvement projects*.

(a) At least one *quality improvement project* that:

   (i) Focuses on *consumers*; or for organizations who do not interact with *consumers*, *client* services;

   (ii) Relates to key indicators of quality as described in 34(c); and

   (iii) Involves a senior clinical *staff* person in judgments about clinical aspects of performance, if the *quality improvement project* is clinical in nature; and

(b) At least one *quality improvement project* focuses on *error* reduction and/or *consumer safety*.

   (i) *Consumer safety* QIPs are required of the following programs: Pharmacy Benefit Management, Health Utilization Management, Workers Comp Utilization Management, Health Call Center, Health Plan, Disease Management, Independent Review, and Case Management.

   (ii) *Error* reduction QIPs are required of all accreditation programs that do not conduct *consumer safety* QIPs.

**Scoring Information**

Core 37  Weight = 4

See the section on “scoring information” at the beginning of this document.
Interpretive Information/Commentary

- Core 37 requires each organization to maintain at least two total quality improvement projects per accreditation program.
- Additionally, one of those projects must focus on error reduction AND/OR consumer safety.
- A single QIP issue area can be addressed in multiple accreditation programs. For example, if the organization is accredited for Health UM and Case Management, the organization must have four QIPs, but the QIPs for Health UM and Case Management can be the same two issue areas.
- Theoretically, a single quality improvement project can meet the requirements of both (a) and (b) if it focuses on consumers safety AND relate to key indicators AND involves a senior clinical staff person, if clinical in nature.
- Quality improvement (QI) projects exemplify the process of continuous quality improvement, allowing organizations to refine and maintain quality consumer and client services and health care services.
- Note: In order for a quality management project to count as one of the two projects required by the standards, the organization must show that it has started to implement the improvement strategy at least by the time of the onsite review. If the project was completed within the past twelve months – back from the date that URAC receives the organization’s application for accreditation or reaccreditation – then the project may count towards the two that are required.
- Quality improvement projects may be clinical or non-clinical. Access to certain types of information, such as claims data, may determine an organization’s ability to conduct clinical studies.
  - Clinical performance improvement projects may include: prevention or care of acute or chronic conditions, high-volume or high-risk services, or continuity and coordination of care.
  - Non-clinical performance improvement projects may focus on such areas as: availability, accessibility, and cultural competency of services, interpersonal aspects of care (e.g., quality of provider patient encounters, or appeals, grievances, and other complaints.
- URAC’s intent is to move away from organization-focused QIPs which may, or may-not create a tangible consumer benefit to consumer-focused QIPs. The scope of what constitutes a safety QIP is very broad however.
- For detailed examples of QIP’s for each program refer to the document “Consumer Safety Quality Improvement QIP’s”.


Module 2: Customer Service, Communications, and Disclosure
### Standard CSCD 1 – Post-Enrollment Consumer Information Requirements

Upon enrollment, the organization demonstrates the capability to inform consumers about available information resources and assistance. Such information, as applicable, includes:

(a) A mechanism to access an up-to-date pharmacy directory;
(b) Covered benefits and general coverage guidelines;
(c) Financial responsibilities for consumers, including potential out-of-pocket costs, such as deductibles, co-pays, co-insurance, annual and lifetime co-insurance limits, and changes that could occur during the enrollment period;
(d) Options and implications of prescription benefits decision-making for consumers;
(e) Criteria for benefits coverage;
(f) Evidence-based health information and content for common conditions, diagnoses, and the treatment diagnostics and interventions;
(g) Information and tips to assist in interactions, such as “Financial decision-making for pharmacy benefits”; and
(h) Instructions on how to receive assistance via e-mail, telephone, or in person.

### Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Please note that due to the nature of contracting arrangements regarding pharmacy benefit management, often post-enrollment consumer information requirements are not delegated to the organization providing pharmacy benefit management, but are instead retained by the organization sponsoring the benefits or the requirements are delegated to another organization. This standard only applies when the pharmacy benefit management organization is contracted to provide post-enrollment consumer information.
- This standard is not prescriptive on the method of communication (written materials or web-based information), however the methods of communication should be utilized with consideration of the information needs of the audience (see Standard CSCD 9 – Multiple Format Communication Requirement). One method of compliance with this standard is to include the required information with other plan documents in the welcome packets that new enrollees typically receive.
- In addition to instructions on how to receive assistance, the program should include explicit instructions on how the prescription benefit account(s) can be accessed and how they may be linked.
- The information provided under (b) should provide enough information to allow a consumer to understand their prescription benefit provisions.
- Under (c) “Financial responsibilities” may include (but are not limited to): a description of what benefits are provided with first dollar coverage, the amount of deductible (whether per member or per family), any co-pays or co-insurance the consumer is responsible for, and the
Standard CSCD 1 – Post-Enrollment Consumer Information Requirements

out of pocket costs the consumer may incur by using the organization’s services. Description of co-pays/co-insurance should describe if the co-pay/co-insurance is part of a tiered benefit design, and/or if the co-pay will change depending on the drug price. In addition, annual and lifetime out-of-pocket cost limits should be mentioned if applicable. Also, possible changes in financial responsibilities during the course of an enrollment period should be mentioned if applicable.

- The information provided under this standard should relate to the specific pharmacy benefits option(s) available to the consumer including coverage requirements and criteria.
- URAC will not hold the organization responsible for “up-stream” communication of information. For example, if the organization provides accurate information to an employer/purchaser and the employer/purchaser summarizes or reformats the information for its employees, the organization is not accountable for the revised information.
- If communication is passed through from a third-party and is not edited, the information source and date of the information should be disclosed.
- All newly enrolled consumers should receive education about available information resources within a reasonable time period, and the organization should periodically remind and update existing consumers about resources so that consumers are aware of the information resources and assistance available to them from the organization.
- “Available resources” may include resources from both the organization and the community.
- In the absence of agreed upon, valid scientific evidence, the organization will use its best judgment under the direction of clinical management to provide information to support the consumer’s decision-making.
- Regular enrollee newsletters are not required under this standard.
- The individual consumer’s medication history is not required under this standard, however one of industry’s “bright ideas” is to provide consumer’s with their medication history.
### Standard CSCD 2 – On-going Communication Practices

The *organization* follows on-going communications practices (required under Core 22) that monitor existing materials for accuracy, and updates them as changes are made to clearly and accurately communicate information about:

(a) Currently *participating pharmacies*;
(b) *Formulary* design, *formulary* changes, and their financial implications;
(c) Benefit design, benefit changes, and their financial implications; and
(d) FDA Class 1 drug recalls.

### Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Please note that due to the nature of contracting arrangements regarding pharmacy benefit management, often post-enrollment consumer information requirements are not delegated to the organization providing pharmacy benefit management, but are instead retained by the organization sponsoring the benefits or the requirements are delegated to another organization. This standard only applies when the pharmacy benefit management organization is contracted to provide post-enrollment consumer information.
- The organization must ensure that consumers are able to access an up-to-date list of participating pharmacies.
- Access to the pharmacy directory on a web site is generally acceptable. However, the organization must have provisions for instances when a consumer does not have Internet access such as periodic mailings, as requested by the client.
- Notification of reduction in formulary must be communicated at least 90 days in advance of formulary change.
- Notification can occur via web site, written materials, or email.
- Description of formulary should include if it is any open or closed formulary; if generics are included, what drugs are excluded; and tier design.
- Notification of formulary change should include when a drug moves from one tier to another; when a drug is newly included or excluded in the formulary.
- While not required by federal regulation, organizations should have a communication protocol in place to assist consumer notification regarding Food and Drug Administration (FDA) Class 1 drug recalls, which are defined as recalls for dangerous or defective products that predictably could cause serious health problems or death. An example of a product that could fall into this category is a label mix-up on a life saving drug. The pharmacy benefit management industry has shown interest in cooperating with the FDA and its regulated industries over the years to develop quick and reliable methods to assist in the removal of potentially dangerous products from the market.
Standard CSCD 3 – Communication Safeguards

The *organization* implements communications safeguards for any communication with potential *consumers* and *clients* to ensure that marketing and sales activities performed by the *organization* do not misrepresent:

(a) Products and services, and  
(b) The *organization*’s ownership.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- The organization’s marketing activities must accurately represent the services that the organization is obligated to provide.  
- The organization’s employees and brokers should be trained to ensure that they are accurately representing the organization’s services,  
- Marketing activities should be consistent with the information provided under PDC-1. If the organization defines itself as providing certain services in a certain geographic area, then marketing materials should be consistent with those facts.
Standard CSCD 4 – Disclosure

Upon request, if included in the client contract, the organization discloses to clients the following financial model information:
(a) Existence of organizational arrangements that could potentially create a conflict of interest that affects clinical or financial decisions;
(b) Sources of revenue; and,
(c) Pricing structure for pharmacy benefit management services, such as:
   (i) Rebate structure; and
   (ii) Administration fees.

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The term clients in this context refers to organizations that contract for pharmacy benefit management services, not individuals.
- A conflict of interest in this context is a conflict that affects objectivity between the organization’s financial interests and the organization’s obligations to the client. An example of such a conflict would be if the organization steered the client to a particular manufacturer whose product was more expensive than its competitors because this manufacturer offered the organization a rebate and the organization did not share the rebate with the client and also did not disclose this action.
- The client contract should include a description of pricing structure; how it is defined and updated, including the source of the price updates. For example are drugs priced using average wholesale price (AWP); how is AWP defined and updated. Other possible descriptions of pricing structure are: straight pass-thru, maximum allowable charge (MAC), and usual and customary (U&C) charge.
- Pricing structures such as AWP, MAC, and U&C, which may be defined from organization to organization in a similar manner, however may produce different pricing depending on how often prices are updated and the source of price updates.
- A possible example of sources of revenue and rebate structure is disclosure of manufacturer’s rebates to organizations for volume purchases of drugs.
- A possible example of administrative fees is a transaction fee charged per prescription filled through a mail order pharmacy owned by the pharmacy benefit management organization.
Standard CSCD 5 – Audit

Upon request, if allowed by contract, the organization allows its contracted client to independently audit, by an auditor that is mutually acceptable to each party, the organization’s records to ensure that the disclosures in CSCD 4 are comprehensive and accurate.

Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The term clients in this context refers to organizations that contract for pharmacy benefit management services, not individuals.
- The intent of this standard is to ensure that the client audit right is honored in a manner that leads to discovery of the information the client is seeking, but also honors the right of the organization to ensure its proprietary business practices are not disclosed to its competitors and audit organizations which may use the information in future transactions.
- One method to obtain a mutually acceptable auditor would be for the organization to proffer a list of such auditors to the client.
**Standard CSCD 6 – Program Representative Availability**

The *organization* operates a toll free call center during the following hours in the time zones in its service area:

- (a) For enrolled *consumers*, 7 days a week, from 8 am to 8 pm;
- (b) For pharmacies, the same hours which network pharmacies are open and provides information on claims processing, benefit coverage, claims submission and claims payment; and
- (c) For physicians and other prescribers, not less than 8 am to 6 pm.

*The standard above is the same as the Medicare Part D standard. We are seeking comments regarding the applicability to the commercial population. Particularly for item (b).*

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Please note that due to the nature of contracting arrangements regarding pharmacy benefit management, often call centers are not required for consumers, pharmacy, and prescribers. This standard only applies when the pharmacy benefit management organization is contracted to provide these services.
- This standard is applied on a client-specific basis.
- The requirement related to time zones where at least two percent of the organization’s consumers reside. It is possible that the organization may receive calls from potential enrollees in time zones where the organization has less than 2% of its enrollees. This standard would not apply in those situations; unless required by contract.
Standard CSCD 7 – Call Center Operating Requirements

The call center for in-bound telephone calls described in CSCD 6 must maintain the following operating requirements for telephone calls from *consumers*, pharmacists, and prescribers:

(a) 80 percent of incoming calls must be answered within 30 seconds, and
(b) Abandonment rate of all incoming calls cannot exceed 5 percent.

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<tr>
<td>An automated interactive voice response telephone system is acceptable under this standard.</td>
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<tr>
<td>Incoming call speed of answer and abandonment rate is measured post automated interactive voice response. For example, if there is a pre-recorded message or greeting for the caller, the 30-second measurement begins after the message/greeting has ended.</td>
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<tr>
<td>Call center operations should be measured quarterly.</td>
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### Standard CSCD 8 – Scope of Telephonic Services

At a minimum, available telephonic services under CSCD 6 include:

- (a) For enrolled *consumers*, information about benefit, including co-payments, deductibles, network pharmacies;
- (b) For pharmacies, information on claims processing, benefit coverage, claims submission and claims payment;
- (c) For physicians and other prescribers, information about the appeals process; and
- (d) For (a-c), the acceptance of complaints (see Standard Core 27).

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- The organization should have documented evidence of consumer requests and a record of the resolutions of those requests.
## Standard CSCD 9 – Multiple Format Communication Requirement

The organization provides information to consumers in multiple formats and media (e.g., Internet, print, live oral presentation, audio, video, e-mail, telephonic, interactive) such that all consumers have access to relevant information (as per contract).

### Scoring Information

Weight = 4  
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- **Note:** This standard applies to all information exchanges between the organization and consumers or potential enrollees.
- The organization is not required to offer all formats mentioned in the examples. An example of a “live oral presentation” is a presentation to consumers at a face-to-face benefits orientation.
- As a practical matter, organizations can meet the “all consumers” requirement in this standard by providing telephonic access to assistance for consumers who do not receive or understand the materials provided through other formats or media.
- “Interactive” is defined as describing communication media in which the information presented to the consumer is adjusted based on consumer inputs.
- The organization is not required to maintain email addresses of enrollees.
Standard CSCD 10 – Health Literacy Communication Requirement

The organization has a process to provide information that:

(a) Lowers to the extent practicable the cognitive effort required to use the information;
(b) Helps consumers understand what effect a health care decision may have for their daily lives; and
(c) Displays the information in a way that highlights information important to the consumer.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- **Note:** This standard applies to all information exchanges between the organization and consumers or potential enrollees.
- URAC recognizes that effective communication of health information is still a developing science, and has drafted this standard to allow for a variety of approaches. When assessing compliance with this standard, URAC will focus on the organization’s methods for developing and assessing consumer information more than the actual format or content of the information. For example, URAC will not specify that consumer content be developed for a sixth-grade (or any) reading level. However, URAC will ask the organization to state what reading level it targets, the criteria it uses to test content against that reading level, and how it ensures that consumer content meets those criteria.
<table>
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<th>Standard CSCD 11 – Cultural Sensitivity Communication Requirement</th>
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<td>Information is presented and delivered in ways that are sensitive to the diversity of the organization’s enrollment, including:</td>
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<tr>
<td>(a) Literacy levels;</td>
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<td>(b) Language differences;</td>
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<td>(c) Cultural differences; and</td>
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<td>(d) Cognitive and/or physical impairment.</td>
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<td>• <strong>Note</strong>: This standard applies to all information exchanges between the organization and consumers or potential enrollees.</td>
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Module 3: Pharmacy Distribution Channel Standards
### Standard PHARM-DC 1- Scope of Services

The *organization* defines the scope of its services with respect to:

(a) The distribution channels offered (e.g. *pharmacy network*, mail order pharmacy, or specialty pharmacy);

(b) The types of pharmacy services offered within each distribution channel; **and**

(c) The geographic area served by each distribution channel.

#### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- The criteria and performance measurement should be established and meet individual client contractual requirements.
- Organizations must define the following:
  - *What services does the organization provide?* (PHARM-DC 1(a)) – What types of services are provided through the pharmacy network, mail order pharmacy or specialty pharmacy?
  - *Where does the organization provide its services?* (PHARM-DC 1(b)) – What is the geographic area within which the organization claims to provide the services described under PHARM-DC 1(a)? Is the organization national? Is its service area limited to certain states, counties, or regions?
- Throughout the accreditation process, URAC will evaluate the organization against the representations made under this standard. For example, if the organization states that its service area includes an entire state, then URAC will expect it to meet standards for access throughout that state.
## Standard PHARM-DC 2 - Access and Availability

With respect to *access* and *availability* of *pharmacy* to provide *access* to medications to *consumers*, for each distribution channel, the *organization*:

(a) Establishes *criteria*;

(b) Measures actual performance in comparison to those *criteria*; and

(c) Makes improvements where necessary to maintain the *pharmacy network* and meet contractual requirements.

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Under Standard PHARM-DC 1, the organization defined the “what, where, and who” of its services. Standards PHARM-DC 2 through PHARM-DC 3 require the organization to describe how it will actually go about meeting the service standards described under PHARM-DC 1.

- The organizations must establish, measure, and improve upon separate standards for both access and availability. PHARM-DC 2 also requires the organization to measure how well it is actually doing in comparison to its standards to make improvements where necessary.

- The criteria and performance measurement should be established and meet individual client contractual requirements.

- PHARM-DC 2 addresses the overall composition of the distribution channels. For example, the following questions should be answered: The number and types of pharmacies necessary to meet the needs of eligible persons within the network? How should these pharmacies be distributed in the service area? Following those general questions, more specifically, is a mail-order pharmacy available? Are their multiple mail-order distribution centers established regionally? Is a retail pharmacy network available? How many pharmacies are in-network?

- PHARM-DC 2 does not require the organization to meet access and availability criteria in every geographic area for every type of pharmacy because these criteria are measured on a per client contract basis. However, if the organization finds it is not meeting goals in a certain area, it should implement a plan to improve access and availability for that area.
The network pharmacy access criteria for the TriCare Pharmacy Program is a commonly cited access criteria. The TriCare criteria is as follows:

The contractor shall maintain a pharmacy network sufficient to meet the following minimum beneficiary access standards on an overall basis:

- Urban: a pharmacy within two miles estimated driving distance of 90% of the beneficiaries;
- Suburban: a pharmacy within five miles estimated driving distance of 90% of the beneficiaries;
- Rural: a pharmacy within fifteen miles estimated driving distance of 90% of the beneficiaries.

The organization can define its access and availability standards for medications by geographic dispersion. For example, the organization might establish a standard to have at least one full service retail pharmacy for every ten square miles in the service area. Alternatively, the organization might use travel times as a criterion. For example, the organization might establish a standard that there is a full service retail pharmacy within a thirty-minute travel time throughout the service area. In either case, the organization should establish separate, specific criteria for each of the types of pharmacy with whom it contracts.

Examples of improvement: in a densely populated area, the organization may need to contract with more pharmacies to ensure that eligible persons are able to obtain service without unnecessarily long waiting periods.
Standard PHARM-DC 3 – Quality and Safety Criteria

For each distribution channel, the organization establishes criteria that address:

(a) Quality and safety of medication utilization;

(b) Quality of service; and

(c) Selection criteria that meets the business needs of the organization.

Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The criteria and performance measurement should be established and meet individual client contractual requirements.
- The intent of the quality and safety criteria are not to create an overly prescriptive quality management program, but to instead ensure that the quality management program is measuring and tracking valuable information to promote quality improvement. Examples of the type of criteria for such a program are described below. These criteria will vary depending upon the extent that information is available and the organization has the ability to influence quality and safety within the distribution channels.
- Examples of criteria that could be measured within distribution channels if information is made available may include:
  A. Distribution Accuracy
     1. Correct drug;
     2. Correct directions;
     3. Correct dosage;
     4. Correct quantity;
     5. Correct patient;
     6. Correct labeling; and package insert.;
     7. Proper handling;
     8. Proper distribution to consumer/shipping.
  B. Medication Overuse
     1. Use Without Indication;
     2. Overdose/Toxicity;
     3. Improper Drug Selection.
### C. Medication Underuse
1. Untreated Indications;
2. Subtherapeutic Dosage;
3. Failure to Receive Medication.

### D. Adverse Drug Events
1. Adverse Drug Reactions;
2. Drug Interactions.

- The National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites Standards are an excellent source of quality and safety criteria; examples promulgated by this organization include assurance that pharmacies:
  - assure the authenticity of the Prescription Drug Order;
  - seek to prevent Prescription Drug Orders from being filled by multiple pharmacies;
  - ensure reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver; and
  - consumers and caregivers are educated about the appropriate means to dispose of expired, damaged, and unstable medications.

- Further examples of quality and safety criteria promulgated by the National Association of Boards of Pharmacy 2005 Verified Internet Pharmacy Practice Sites Standards include assurance that pharmacies:
  - assure the integrity of medications by storing and shipping within the environmental standards for medications established by the United States Pharmacopeia (USP); and
  - assure controlled substances are shipped via a secure means that ensures proper delivery.

- Other sources of information for safe medication practices are the Institute for Safe Medication Practices (ISMP) and the Institute of Medicine (IOM).

- Promotion of e-prescribing may serve to enhance information flow within pharmacy distribution channels and promote quality and safety activities.

- This standard also addresses how the organization establishes quality and safety criteria within its distribution channels. For example, if the organization needs the service of two pharmacy chains to meet its network access standards and receives three applications, what are the criteria it uses to select those to whom it will offer contracts?

- This standard should serve to assure that the organization has a mechanism to inform the members of its pharmacy network as to what is expected of them to participate in the network.
- At a minimum, pharmacy selection criteria must address quality of access to medications, quality of service, and the business needs of the organization. The pharmacy must be informed that they must meet these criteria. Most organizations include the criteria in their service agreements.

- In PHARM-DC 3(a), organizations may use their own definition of “quality of access to medications.”

- PHARM-DC 3(b) addresses such issues as responsiveness of the pharmacy staff, cleanliness of the pharmacy, hours of operation, etc.

- PHARM-DC 3(c) is intended to allow the organization flexibility in not accepting pharmacies that otherwise meet the criteria for quality and service. For example, if the organization already has enough qualified pharmacies, it might not accept another qualified pharmacy based on business needs.

- Pharmacy selection criteria may also address special needs of a population. For example, an organization serving an area with an abundance of Spanish-speaking individuals may want to ensure that a pharmacy includes some staff fluent in Spanish.
Standard PHARM-DC 4 – Out of Network Services

To the extent it is contractually responsible, the organization implements written policies that offer consumers a process to:

(a) Obtain covered services that are not available from participating pharmacies; and
(b) Obtain covered services outside the network service area.

### Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Please note that due to the nature of contracting arrangements regarding pharmacy benefit management, this standard only applies when the pharmacy benefit management organization is contracted to provide this service.
- Organizations have an obligation to provide consumers with a process to access to medications, including when it is not available within the pharmacy network, or when the consumer is outside of the network service area. For example, if a consumer’s prescription refill from a mail-order pharmacy did not arrive to the consumer in time, the consumer would be afforded access to a retail pharmacy to obtain the necessary medication.
Standard PHARM-DC 5 – Pharmacy Licensure

The organization verifies that all pharmacies in the distribution channels are licensed or registered in good standing to operate as a pharmacy.

**Scoring Information**

Weight = 5 (mandatory standard)

See the section on “scoring information” at the beginning of this document.
Standard PHARM-DC 6 – Participating Pharmacy Relations Program

The organization implements a participating pharmacy relations program to include:

(a) Implementation of a participating pharmacy communications plan, to address at least:
   i. Orientation of new participating pharmacies;
   ii. Updates of network activities;
   iii. Changes in fee schedules or contracting provisions;
   iv. Informing participating pharmacies how to obtain benefit, eligibility, formulary, and appeals information; and
   v. Mechanisms for the availability and distribution of current participating pharmacy manuals (or other documents describing the relationship between the organization and participating pharmacies).

(b) Assistance for participating pharmacies and their staff regarding pharmacy network issues; and

(c) Mechanism(s) to receive suggestions and guidance from participating pharmacies about how the pharmacy network can best serve consumers.

Scoring Information

Weight = 5 (Mandatory Standard)
See the section on “scoring information” at the beginning of this document.
Interpretive Information/Commentary

- Organizations must ensure that participating pharmacies are aware of the information necessary to provide service to the organization’s consumers and are able to comply with the organization’s administrative requirements.
- The organization may delegate the pharmacy communications program. In that case, Core Standards on delegation would apply.
- Methods of meeting this standard include (but are not limited to):
  o An orientation packet sent to each new participating pharmacy;
  o A newsletter sent periodically to participating pharmacies;
  o Designated staff available to answer pharmacies’ questions.
- “Orientation” under PHARM-DC 6(a)(i) means providing enough information so that the pharmacy can effectively participate in the network. This might include policies and procedures that the pharmacy must follow, billing procedures, an orientation meeting with the pharmacy, and the contact information.
- PHARM-DC 6(a)(v) – mechanisms can be electronic sources. Also see PHARM-DC 11.
- “Mechanisms” under PHARM-DC 6(c) includes any means through which the pharmacy can provide feedback regarding the performance of the organization. This might include contact information for a pharmacy relations representative or the organization’s senior clinical staff person.
## Standard PHARM-DC 7 – Participating Pharmacy Written Agreements

| The organization has written agreements with all participating pharmacies. |
| Scoring Information |
| Weight = 5 (Mandatory Standard) |
| See the section on “scoring information” at the beginning of this document. |
| Interpretive Information/Commentary |
| • Written agreements with pharmacies are the fundamental building blocks of a pharmacy network. Standard PHARM-DC 7 requires that a written agreement is in place for each pharmacy. |
| • PHARM-DC 7 is straightforward – there must be a written agreement with every participating pharmacy. Template written agreements for all types of pharmacy must include each sub-standard listed in PHARM-DC 8. |
| • When contracting with pharmacy chains, the organization may have a single written agreement with the entire chain of pharmacies or pharmacy services administrative organization. |
Standard PHARM-DC 8 – Written Agreement Inclusions

All new and revised written agreements (see PHARM-DC 6) executed by the organization include the following elements:

(a) A listing of all entities that are party to the written agreement;
(b) Conditions for participation as a participating pharmacy;
(c) Obligations and responsibilities of the organization and the participating pharmacy, including any obligations for the participating pharmacy to participate in the organization’s management, complaint, or other programs;
(d) Events that may result in the reduction, suspension, or termination of network participation privileges;
(e) Term of the contract and procedures for terminating the contract;
(f) Protocols for pharmacy audits;
(g) The specific circumstances under which the organization may require access to applicable consumers’ records;
(h) Pharmacy services to be provided and any related restrictions;
(i) Requirements for claims submission and any restrictions on billing of consumers;
(j) Participating pharmacy payment methodology and fees;
(k) Mechanisms for dispute resolution by participating pharmacies;
(l) Requirements with respect to preserving the confidentiality of patient health information; and
(m) Prohibitions regarding discrimination against consumers.
### Scoring Information

Weight = 4  
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- PHARM-DC 8 requires the organization to have a written agreement that complies with PHARM-DC 8(a) through (m) (a “compliant written agreement”). At the time of initial accreditation, the organization is not required to have all existing written agreements based on the compliant written agreement. However, the compliant written agreement must be implemented on a “going forward” basis. In other words, starting at the time of application for accreditation, all new contracts must be based on the compliant contract.
- PHARM-DC 8(a) -- it is not necessary to name every single client of the organization.
- The term “written agreement” is defined to include the contract and any attachments or addenda. Therefore, if the organization needs to revise contracts to comply with this standard, it may amend existing contracts, issue an addendum, or make changes to the provider manual (if the provider manual is a binding document), rather than re-executing the contracts in their entirety.
- In addition to meeting the requirement of PHARM-DC 8 that the organization “fill in the gaps” in its pharmacy contracts through the use of other documents that describe the organization/pharmacy relationship, the organization must bring the noncompliant contracts into compliance the next time it revises those contracts.
<table>
<thead>
<tr>
<th>Standard PHARM-DC 9 – Written Agreement Subcontracting</th>
</tr>
</thead>
</table>

To the extent that a *written agreement* allows for sub-contracting with *participating pharmacies*, the *written agreement* specifies that all sub-contracts will be subject to the terms of the *written agreement* as they pertain to the elements required in DC 7.

### Scoring Information

- **Weight = 4**
- See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- DC 9 is intended to apply in circumstances when the organization contracts with an intermediary that, in turn, has contracts with individual pharmacies. DC 9 requires that the contract between the organization and the intermediary comply with DC 8.
- DC 9 requires that the intermediary bind sub-contracting pharmacies, within the scope of delegation, to the same requirements held by the organization seeking accreditation.
- During the accreditation process, URAC will examine contracts between the pharmacy benefit management provider and the intermediaries to ensure these conditions are met. URAC will not examine contracts between the intermediaries and their sub-contracting pharmacies.
Standard PHARM-DC 10 – Other Participating Pharmacy Agreement

Documentation

For existing *pharmacy written agreements* not in compliance with PHARM-DC 7, the *organization’s* documents describing the relationship between the *organization* and *participating pharmacies*:

(a) Address the items listed in PHARM-DC 8 and not addressed in the *written agreement*; or

(b) Provide instructions on how to obtain the items listed in PHARM-DC 8 and not addressed in the *written agreement*.

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- PHARM-DC 10 is not applicable if all of the *organization’s* written agreements comply with PHARM-DC 8. If some of the written agreements do not comply, then the *organization* needs to include the appropriate information in its other documents. For example, if the written agreements do not include a description of dispute resolution mechanisms (see PHARM-DC 8(i)), then other documents would have to include that information.
### Standards PHARM-DC 11 – Participating Pharmacy Violation Mechanism

The *organization* implements a mechanism consistent with its *written agreements* to address alleged violations by *participating pharmacies* of the requirements of the *organization*.

### Scoring Information

**Weight = 4**  
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- These standards require the organization to implement processes to address significant disputes or problems with participating pharmacies. The processes must respect pharmacies’ rights but must also protect consumers.
### Standard PHARM-DC 12 – Participating Pharmacy Dispute Resolution Scope

The *organization* implements a mechanism to resolve disputes with *participating pharmacies* regarding actions by the *organization* that relate to either:

(a) A *participating pharmacy*’s status within the *pharmacy network*; or  
(b) Any action by the *organization* related to a *pharmacy*’s competency or conduct; or  
(c) Any contractual issues related to the distribution channel.

#### Scoring Information

Weight = 4  
See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- Disputes that are found in favor of the pharmacy at any level do not need to go to the next level.  
- Financial disputes are within the scope of this standard.
Standard PHARM-DC 13 – Participating Pharmacy Suspension Mechanism for Consumer Safety

The *organization* implements a mechanism to immediately suspend, pending investigation, the participation status of a *participating pharmacy* which, in the opinion of the pharmacy director (or *clinical director*), is engaged in behavior or who is practicing in a manner that appears to pose a significant risk to the health, welfare, or safety of *consumers*. The *organization*:

(a) Investigates such instances on an expedited basis; and
(b) Makes the dispute resolution process available to any *participating pharmacy* subject to suspension of participation status.

**Scoring Information**

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- PHARM-DC 13 ensures that the organization can immediately suspend a pharmacy, however it also permits the pharmacy access to a dispute mechanism to appeal the decision.
- Under these standards, to suspend means to block claims from the pharmacy under investigation.
The organization’s claims processing comply with the National Council for Prescription Drug Program (NCPDP) standard transactions for pharmacy drug claims, eligibility, coordination of benefits, and related pharmacy services.

### Scoring Information

<table>
<thead>
<tr>
<th>Weight</th>
<th>5 (mandatory standard)</th>
</tr>
</thead>
</table>

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- The National Council for Prescription Drug Program (NCPDP) standard transactions are the code set standards under HIPAA for the retail pharmacy environment.
Module 4: Drug Use Management Standards
**Standard DUM 1 – Drug Utilization Management Program Components**

When conducting drug utilization management, *organizations* must develop and comply with written policies and procedures that address *criteria* for:

(a) Identifying the optimal drug use;

(b) Evaluating the available drug submission data:
   
   (i) Comparing between optimal/appropriate and actual use in order to address discrepancies;

   (ii) Coordinating intervention when corrective action is warranted; and

   (iii) Evaluating the effectiveness of the drug use management program.

**Scoring Information**

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- For subsection (a), treatment guidelines which define optimal drug use should be reviewed and updated on a regular basis.
- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy; Concepts in Managed Care Pharmacy Series Document: “Drug Use Evaluation”.


Standard DUM 2 – Coverage Decisions Based on Clinical Information

Coverage decisions based on clinical information include but are not limited to the following:

(a) Assessing peer-reviewed medical literature, including: randomized clinical trials (especially drug comparison studies), pharmacoeconomic studies, and outcomes research data; and

(b) Employing published practice guidelines, developed by an acceptable evidence-based process; or

(c) Comparing the efficacy as well as the type and frequency of side effects and potential drug interactions among alternative drug products; or

(d) Assessing the likely impact of a drug product on patient compliance when compared to alternative products; or

(e) Basing formulary system decisions on a thorough evaluation of the benefits, risks and potential outcomes for consumers; risks encompass adverse drug events (adverse drug reactions and medication errors, such as those caused by confusing product names or labels).

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Drug use management edits can be developed internally or purchased from external sources (e.g. First Data Bank, Red Book, etc.)
- If an external source is used, the organization should indicate how the edits were developed. Also include who (names and qualifications) was involved in this process and how often the edits will be reviewed and updated.
- The medical/clinical director and other physicians should review the edits verify their continued appropriateness. Also, if changes occur through a committee process, these changes should be reflected in the committee’s minutes or other documentation.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

Drug use management edits can be developed internally or purchased from external sources (e.g. First Data Bank, Red Book, etc.)
Standard DUM 3 - Review Criteria Requirements

The organization utilizes explicit clinical review criteria that are:

(a) Developed with involvement from appropriate prescribers with current knowledge relevant to the criteria;
(b) Based on current clinical principles and processes;
(c) Evaluated at least annually and updated if necessary by:
   (i) the organization itself; and
   (ii) appropriate, actively practicing physicians and pharmacists, with current knowledge relevant to the criteria, and;
(d) Approved by the medical director (or equivalent designate) or clinical director (or equivalent designate).

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.
**Standard DUM 4 – Prospective, Concurrent and Retrospective Drug Utilization Management**

With the available information and data, the organization ensures drug utilization management mechanisms that address where appropriate:

(a) Therapeutic appropriateness;

(b) Over and underutilization

(c) Appropriate Generic Use;

(d) *Therapeutic interchange*/duplication;

(e) Drug-disease contraindications;

(f) Drug-drug or drug-allergy interactions;

(g) Incorrect drug dosage;

(h) Inappropriate duration of treatment;

(i) Clinical abuse misuse;

(j) Drug-age precautions;

(k) Drug-gender precautions

(l) Drug-pregnancy precautions; and

(j) Regulatory and benefit design limitations.

**Scoring Information**

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy; Concepts in Managed Care Pharmacy Series Document: “Drug Use Evaluation”.

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## ACCESSIBILITY OF REVIEW SERVICES

### Standard DUM 5 – Review Service Disclosures

The *organization* requires customer services *staff* that provide drug use management information to identify themselves by name, title, and *organization* name upon request.

#### Scoring Information

- **Weight = 3**
- See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- Subcontractors should state the organization they are representing.

### Standard DUM 6 – Prospective Reviewer Qualifications

Individuals who conduct *prospective review*:

- (a) Are appropriate *health professionals*, pharmacy technicians or pharmacists; and
- (b) Possess an active professional relevant *license* in good standing with applicable states.

#### Scoring Information

- **Weight = 5 (Mandatory Standard)**
- See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- Prior-authorization reviewers may assist in the notification process for non-certifications.
- For subsection (a), adequately trained pharmacy technicians are acceptable for conducting the review provided they work under the supervision of a pharmacist.
### Standard DUM 7 – Automated Review

*Organizations* with an automated review process must:

(a) Define the algorithmic protocol being used; and

(b) Validate the initial automated algorithm.

#### Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

The automated review algorithm should be periodically reviewed to ensure that it:

- Is performing properly;
- Is updated with the most recent evidenced based medical knowledge; and
- Takes into account the appeal rate.

### Standard DUM 8 – Automated Review Oversight

*Organizations* must have policies and procedures in place to provide oversight of the automated review process which should include:

(a) Timeliness of the disposition of *appeal cases*;

(b) Timeframes for addressing *appeals*; and

(c) Measurement process for grievances.

#### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

#### Interpretive Information/Commentary

- The algorithm must be validated by using external peer review standards or through an internal predictive modeling process.
### Notice of Certification Decisions

**Standard DUM 9 – Certification Decision Notice and Tracking**

For certifications, the organization:

(a) Has a process for notification of the prescriber and consumer:

(b) Includes tracking information (such as reference number) in the notice of certification;

and

(c) Upon request from the prescriber or consumer, provides written notification of any certification.

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Notification of certifications will be timely and contain information pertinent to the review, including any tracking or reference number.
- If the notification is not within the scope of the contract for a delegated drug use management decision, then the delegate must refer the inquiry to the delegator.
- A request for written notification of a certification is provided to the individual making the request.
- The time frame specified in DUM 8 should be monitored on an on-going basis as part of the organization’s quality management program.
Notice of Non-Certification Decisions

Standard DUM 10 – Written Notice of Non-Certification Decisions & Rationale

For non-certifications, the organization issues written notification of the non-certification decision to the consumer and prescriber that includes:

(a) The principal reasons for the determination not to certify;

(b) A statement that the clinical rationale used in making the non-certification decision will be provided, in writing, upon request; and

(c) Instructions for:

   (i) Initiating an appeal of the non-certification; and

   (ii) Requesting a clinical rationale for the non-certification.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The clinical rationale provides additional clarification of the clinical basis for a non-certification decision, and specific reasons why the clinical review criteria was not met.
UM Procedures

Standards DUM 11 – Reversal of Certification Determinations

The organization does not reverse a certification determination unless it receives new information that is relevant to the certification and that was not available at the time of the original certification.

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The organization must document under what circumstance it will reverse a prior certification (non-certify a case that was previously certified). If the organization does not reverse certification decisions regardless of any new information provided, then this must be indicated in a written policy statement.
- With the automated review process, a doctor can call the organization and present new information at the time of the appeal.
### Standard DUM 12 – Scope of Review Information

The *organization*, when conducting *drug utilization management*:

(a) Accepts information from reasonably reliable sources that will assist in the *certification* process;

(b) Collects only the information necessary to certify the *prescription*;

(c) Requires only the section(s) of the medical record necessary in that specific *case* to certify medical necessity or appropriateness of the *prescription*; and

### Scoring Information

**Weight = 4**

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Policies and procedures should indicate that additional information should only be requested when there is difficulty in making a review determination.
- Consumer and prescriber confidentiality must be protected when obtaining or sharing medical information (see Core 24).
# Information Upon Which Drug Utilization Management is Conducted

## Standards DUM 13 – Prospective and Concurrent Review Determinations & DUM 14 – Retrospective Review Determinations

<table>
<thead>
<tr>
<th><strong>DUM 13</strong></th>
<th><strong>DUM 14</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>For <em>prospective review</em> and <em>concurrent review</em>, the <em>organization</em> bases review determinations solely on the clinical information obtained by the <em>organization</em> at the time of the review determination.</td>
<td>For <em>retrospective review</em>, the <em>organization</em> bases review determinations solely on the clinical information available to the <em>prescriber</em> at the time the medical care was provided.</td>
</tr>
</tbody>
</table>

### Scoring Information

<table>
<thead>
<tr>
<th>DUM 13 Weight</th>
<th>DUM 14 Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- The purpose of standards DUM 13 and DUM 14 is to ensure that review decisions are made based on information available at the time of the review; or for retrospective decisions, information available to the prescriber at the time the medical care was provided.
**INFORMATION UPON WHICH UTILIZATION MANAGEMENT IS CONDUCTED**

<table>
<thead>
<tr>
<th>Standard DUM 15 – Lack of Information Policy and Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> implements policies and procedures to address situations in which it has insufficient information to conduct a review. Such policies and procedures provide for: (a) Procedural time frames that are appropriate to the clinical circumstances of the review (i.e., prospective, concurrent, retrospective reviews); and (b) Resolution of cases in which the necessary information is not provided to the <em>organization</em> within specified time frames.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scoring Information</th>
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<tbody>
<tr>
<td>Weight = 4</td>
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<tr>
<td>See the section on “scoring information” at the beginning of this document.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretive Information/Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For URAC accreditation, the organization may set its own time frames under this standard. However, the Department of Labor claims regulations provide specific guidance on this issue.</td>
</tr>
</tbody>
</table>
**APPEALS CONSIDERATIONS**

<table>
<thead>
<tr>
<th>Standard DUM 16 - Non-Certification Appeals Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> maintains a formal process to consider <em>appeals</em> of <em>non-certifications</em> that includes:</td>
</tr>
<tr>
<td>(a) The <em>availability</em> of <em>standard appeal</em> for non-urgent <em>cases</em> and <em>expedited appeal</em> for <em>cases involving urgent care</em>; and</td>
</tr>
<tr>
<td>(b) Written <em>appeals</em> policies and procedures that:</td>
</tr>
<tr>
<td>(i) Clearly describe the <em>appeal</em> process, including the right to <em>appeal</em> of the <em>consumer</em> or <em>prescriber</em>;</td>
</tr>
<tr>
<td>(ii) Provide for explicit time frames for each stage of the <em>appeal resolution</em> process; <strong>and</strong></td>
</tr>
<tr>
<td>(iii) Are available, upon request, to any <em>consumer</em> or <em>prescriber</em>.</td>
</tr>
</tbody>
</table>

**Scoring Information**

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- The appeals process will be written and communicated to stakeholders in the process. These appeal processes and time frames closely follow those specified in the Department of Labor claims regulation.
- It is acceptable for organizations to make available a written description or summary of the policies and procedures or appeals.
**APPEALS CONSIDERATIONS**

<table>
<thead>
<tr>
<th>Standard DUM 17 – Appeals Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>As part of the <em>appeals</em> process:</td>
</tr>
<tr>
<td>(a) The <em>organization</em> provides the <em>consumer</em> or <em>provider</em> the opportunity to submit written comments, documents, records, and other information relating to the <em>case</em>;</td>
</tr>
<tr>
<td>(b) Takes all such information into account during the <em>appeals</em> process without regard to whether such information was submitted or considered in the initial consideration of the <em>case</em>;</td>
</tr>
<tr>
<td>(c) Ensures the <em>appeal</em> is reviewed by a <em>clinical peer</em> of the original prescriber; and</td>
</tr>
<tr>
<td>(d) In instance of a first level <em>appeal</em>, the <em>organization</em> implements the decision of the first level clinical <em>appeal</em> if it overturns the initial denial.</td>
</tr>
</tbody>
</table>

**Scoring Information**

| Weight = 4 |
| See the section on “scoring information” at the beginning of this document. |

**Interpretive Information/Commentary**

- The appeals process allows for additional information to be submitted, all of which is to be taken into consideration when making the appeal determination.
- The organization has the option to pay for the claim even if the first level clinical appeal denies it.
APPEALS CONSIDERATIONS

Standard DUM 18 – Appeal Peer Reviewer Qualifications

Appeals considerations are conducted by health professionals who:

(a) Are physicians, pharmacists or clinical peers;

(b) Hold an active, unrestricted license to practice medicine or a health profession;

(c) Are board-certified (if applicable) by:
   (i) A specialty board approved by the American Board of Medical Specialties (doctors of medicine); or
   (ii) The Advisory Board of Osteopathic Specialists from the major areas of clinical services (doctors of osteopathic medicine);

(d) Are in the same profession and in a similar specialty that typically manages the medical condition, procedure, or treatment as mutually deemed appropriate; and

(e) Are neither the individual who made the original non-certification, nor the subordinate of such an individual.

Scoring Information

Weight = 5 (Mandatory Standard)
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- “Subordinate” in DUM 18 (e) means someone who directly reports to the individual who made the original non-certification. This is a Department of Labor regulation.
- The prohibition in DUM 18 (e) would apply in situations where an associate medical director as an employee of the organization, is asked to consider an appeal of a decision made by the medical director.
- One of the goals of this standard is to ensure that the health professionals rendering appeal decisions are capable of conducting an informed dialogue with providers. This is accomplished by requiring that reviewers are knowledgeable and up-to-date in the clinical area under review as shown by their experience, licensure, and requisite board certifications.
# Appeals Considerations

## Standard DUM 19 – Expedited Appeals Process Timeframe

*Expedited appeals* are completed, with notification of determination within 72 hours of the request followed by a written confirmation of the notification within 3 calendar days.

### Scoring Information

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Types of notification include: verbal (should be documented in case review notes), voice mail, electronic means including email and fax, or mailed letter. The term “appeals” includes both expedited and standard appeals.
- Appeals notification will be timely, will be provided in writing as well as other acceptable means, and will include the information needed to provide the basis for any additional level of appeal as available.

## Standard DUM 20 – Standard Appeals Process Timeframe

*Standard appeals* are completed, and *written notification* of the *appeal* decision issued, within 30 calendar days of the receipt of the request for *appeal*.

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- Types of notification include email, fax, or mailed letter. The term “appeals” includes both expedited and standard appeals.
- Appeals notification will be timely, will be provided in writing as well as other acceptable means, and will include the information needed to provide the basis for any additional level of appeal as available.
<table>
<thead>
<tr>
<th>Standard DUM 21 – Written Notification of Upheld Non-Certifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>For <em>appeals</em> determinations, the <em>organization</em> issues <em>written notification</em> of the adverse <em>appeal</em> decision to the <em>consumer</em> and <em>prescriber</em> that includes:</td>
</tr>
<tr>
<td>(a) The <em>principal reasons</em> for the determination to uphold the <em>non-certification</em>;</td>
</tr>
<tr>
<td>(b) A statement that the <em>clinical rationale</em> used in making the <em>appeal</em> decision will be provided, in writing, upon request; <strong>and</strong></td>
</tr>
<tr>
<td>(c) Information about additional <em>appeal</em> mechanisms available, if any.</td>
</tr>
</tbody>
</table>

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Types of notification include email, fax, or mailed letter. The term “appeals” includes both expedited and standard appeals.
- Appeals notification will be timely, will be provided in writing as well as other acceptable means, and will include the information needed to provide the basis for any additional level of appeal as available.
- For DUM 21 (c) it is not necessary to list the specific appeal mechanisms. Alternatively, the organization may list contact information for where a consumer may get more information about their appeal right.
- The additional appeal mechanisms under DUM 21 (c) may be internal mechanisms, external mechanisms available through the health plan or plan sponsor, or mechanisms administered by the State.
## Appeals Considerations

<table>
<thead>
<tr>
<th>Standard DUM 22 – Appeal Record Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <em>organization</em> maintains records for each <em>appeal</em> that includes:</td>
</tr>
<tr>
<td>(a) The name of the <em>consumer, or prescriber</em>; and</td>
</tr>
<tr>
<td>(b) Copies of all correspondence from the <em>consumer</em> and the <em>organization</em> regarding the <em>appeal</em>;</td>
</tr>
<tr>
<td>(c) Dates of <em>appeal</em> reviews, documentation of actions taken, and final resolution;</td>
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<td>(d) Minutes or transcripts of <em>appeal</em> proceedings (if any);</td>
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<td>(e) Name and credentials of the <em>clinical peer</em>;</td>
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<td>(f) A statement from the physician that dictates to ancillary personnel why the decision was necessary.</td>
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### Scoring Information

- **Weight = 4**
- See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- For purposes of risk management, liability, and quality management, the organization must keep complete appeal records.
- The records do not need to be all in one location (file) but they need to be readily accessible.
- Storage mechanisms will vary from organization to organization, and will often include hard copy, electronic, or a combination of both. “Copies” can be generated in any reliable format; see DUM 22 (b).
- For element (f), since the automated process will not allow for this, the review agent should collect a statement from the physician as to why the decision was medically necessary.
Module 5: Formulary Development / P & T Standards
Standard PTFD 1 – P & T/ Formulary Development Process

The *organization* has a process to ensure that it promotes rational, clinically appropriate, safe, and cost-effective drug therapy which shall include a:

(a) *P & T Committee*;

(b) *Formulary* management decision making process;

(c) Non-formulary exceptions/appeals process;

(d) Process for *transitional situations*; and a

(e) Benefits design.

**Scoring Information**

Weight = 5 (Mandatory Standard)

See the section on “scoring information” at the beginning of this document.
Standard PTFD 2 – Consumer Safety

The organization’s drug use management, formulary process and benefit design procedures have distinct systems for identifying and rectifying consumer safety issues including:

(a) A system for identifying and communicating drug-drug interactions at point-of-service;

(b) A system of drug use management tools, such as prospective and concurrent DUM, that identify situations which may compromise the safety of the consumer, including:
   (i) Therapeutic appropriateness;
   (ii) Over and underutilization;
   (iii) Appropriate Generic Use;
   (iv) Therapeutic interchange/duplication;
   (v) Drug-disease contraindications;
   (vi) Drug-drug or drug-allergy interactions;
   (vii) Incorrect drug dosage;
   (viii) Inappropriate duration of treatment;
   (ix) Clinical abuse misuse;
   (x) Drug-age precautions;
   (xi) Drug-gender precautions;
   (xii) Drug-pregnancy precautions;

Scoring Information

Weight = 5 (Mandatory Standard)
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Communication of drug-drug interactions will include level of clinical significance.
- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy; Concepts in Managed Care Pharmacy Series Document: “Drug Use Evaluation”.


Standard PTFD 3 – Formulary Management Decision Making

The organization has a clearly defined formulary management process that includes the following:

(a) Drugs’ therapeutic advantages (safety and efficacy) must be considered when selecting formulary drugs.

(b) Established and documented procedures to assure appropriate drug review and inclusion.

(c) Formulary management decisions are based on scientific evidence and standards of practice, and may also be based on pharmacoeconomic considerations to achieve appropriate, safe and cost effective drug therapy.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Note: Clients may require that the health plan or PBM formulary be customized to meet the particular needs of their benefit plans. It is up to the client to ultimately decide on the exact formulary that will be used.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

Standard PTFD 4 - Economic Formulary Considerations

Economic considerations include, but are not limited, to the following:

(a) Basing *formulary* system decisions on cost factors only after the safety, efficacy and therapeutic need have been established.

(b) Evaluating equivalent alternative drug products and therapies in terms of their impact on total health care costs.

(c) Permitting financial incentives when they promote cost management as part of the delivery of quality medical care.

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- For subsection (b), new drug therapies, that have been approved by the FDA and shown to be beneficial in peer-reviewed scientific studies, and where there is no equivalent, should not be excluded.
- For subsection (c), financial incentives or pressures on practitioners that may interfere with the delivery of medically necessary care are unacceptable.
- The organization must comply with applicable rules and regulations.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.
**Standard PTFD 5 - Formulary Maintenance and Monitoring**

The *formulary* system:

(a) Provides drug product selection and *formulary* maintenance (see above).

(b) Provides drug use management to enhance quality of care for *consumers* by assuring appropriate drug therapy.

(c) Provides for the periodic evaluation and analysis of treatment protocols and procedures to ensure that they are up-to-date and are consistent with optimum therapeutics.

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</table>
Standard PTFD 6 – Organizational Specifications

The organization should:

(a) Inform physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions, including: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs.

(b) Proactively inform consumers and prescribers about changes to the formulary or to other pharmaceutical management procedures.

(c) Provide consumer education programs that explain how formulary decisions are made and the roles and responsibilities of the consumer, especially the importance of consumer compliance with drug therapy to assure the success of that therapy.

(d) Disclose the existence of formularies and have copies of the formulary readily available and accessible.

(e) Provide rationale for specific formulary decisions when requested.

Scoring Information

Weight = 3

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The organization must comply with applicable rules and regulations.
- This standard is as agreed to by the plan sponsor.
- The organization will give constructive notice but not on an individual basis.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.
###Standard PTFD 7 – P&T Committee Membership

Members of the *Pharmacy and Therapeutics Committee* include:

(a) Various clinical specialties that represent the needs of the plans beneficiaries;

(b) Representation of “high volume specialists”;

(c) A majority must be practicing physicians, practicing pharmacists or both;

(d) At least one practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons; and

(e) At least one practicing pharmacist and one practicing physician independent and free of conflict (health plan & pharmaceutical manufacturers).

**Scoring Information**

Weight = 3  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Other Committee Members could include ethicists and consumer representatives.
- This standard is modeled off of information provided in the MMA 2007 Final Guidelines for Formularies.

###Standard PTFD 8 – P&T Committee Conflict of Interest

Members of the *Pharmacy and Therapeutics Committee* should sign a *conflict of interest* statement revealing economic interests or relationships that could influence committee decisions.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- This standard is modeled off of information provided in the MMA 2007 Final Guidelines for Formularies and the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System.”
### Standard PTFD 9 – P & T Committee Policies and Procedures

**Formulary** system policies should:

(a) Exclude product sponsor representatives from *Pharmacy and Therapeutics committee* membership and from attending *P & T committee* meetings.

(b) Require *Pharmacy and Therapeutics committee* members to adhere to the *formulary* system’s policy on disclosure and participation in discussion as it relates to *conflict of interest*.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- The organization must comply with applicable rules and regulations.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

### Standard PTFD 10 – P&T Committee Meeting Administration

The *Pharmacy and Therapeutics Committee* has regular meetings that occur not less than once a quarter, and documents in writing decisions regarding *formulary* development or revision.

**Scoring Information**

Weight = 3  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- The meetings need not be face-to-face.
- This standard is modeled off of information provided in the MMA 2007 Final Guidelines for Formularies.
**Standard PTFD 11 – P & T Committee**

The *Pharmacy and Therapeutics Committee*:

(a) Objectively appraises, evaluates, and selects drugs for the *formulary*.

(b) Establishes policies and procedures to educate and inform health care providers about drug products, usage, and committee decisions.

(c) Reviews and recommends quality improvement and drug use management programs.

(d) Develops protocols and procedures for the use of and *access* to non-formulary drug products.

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**Interpretive Information/Commentary**

- The organization must comply with applicable rules and regulations.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

**Standard PTFD 12 – Timely Consideration of New Drugs**

The *Pharmacy and Therapeutics Committee* will document that a reasonable effort is made for timely consideration of new chemical entities covered under the pharmacy benefit once released onto the market.

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**Interpretive Information/Commentary**

- The organization must define its process for timely consideration of new drugs.
- This standard is modeled off of information provided in the MMA 2007 Final Guidelines for Formularies.
Standard PTFD 13 – P&T Review Functions

The Pharmacy and Therapeutics Committee has a clearly defined process for reviewing for clinical appropriateness protocols and procedures for the following:

(a) Timely use of and access to both formulary and non-formulary drug products; and

(b) Formulary management activities, such as prior authorizations, step therapies, quantity limits, generic substitutions, drug utilization activities, and other things that are not covered and that affect access.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Under sub-standard (A) drugs may be subject to benefit exclusions—this does not preclude a benefit from being structured in this manner.
- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.
# Appeals / Non-Formulary Exceptions

## Standard PTFD 14 – Exceptions

The *organization* provides a process that allows *consumers* to request coverage of a *prescription* drug if the drug is not covered.

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## Standard PTFD 15 – Appeals

The *organization* should provide *access* to a formal *appeal* process if a request for a non-covered drug is denied.

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## Standard PTFD 16 – Appeals Process Consumer Rights

The *organization* must provide information to the *consumer* on how to request an exception or *appeal*.

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<tr>
<td>• This standard is modeled off of information provided in Chapter 18 of the Medicare Prescription Drug Benefit Manual.</td>
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### Standard PTFD 17 – Appeals Process

As part of the *appeals* process:

(a) The *organization* provides the *prescriber* the opportunity to submit written comments, documents, records, and other information relating to the *case*;

(b) The reviewer takes all such information into account during the *appeals* process in a timely manner; and

(c) The *organization* implements the decision of the *appeal* if it overturns the initial non-*certification*.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.

### Standard PTFD 18 – Appeals Reviewer Qualifications

*Appeals considerations* are conducted by *health professionals* who:

(a) Are physicians, pharmacists, or *clinical peers*; and

(b) Hold an active, unrestricted *license* to practice medicine or pharmacy.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.
Standard PTFD 19 – Written Notice of Appeals Denials

For appeals determinations, the organization issues written notification of the adverse appeal decision to the consumer and prescriber that includes:

(a) The principal reasons for the determination to uphold the denial;

(b) A statement that the clinical rationale used in making the appeal decision will be provided, in writing, upon request; and

(c) Information about additional appeal mechanisms available, if any.

Scoring Information
Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary
- Organizations may give a verbal notification of denial followed by a written letter.

FORMULARY MANAGEMENT IN TRANSITIONAL SITUATIONS

Standard PTFD 20 – General Transition Process Requirements

The organization demonstrates evidence of a process for formulary management in transitional situations (change between plans, benefits or care settings), such that the drug classes included cover common diseases and conditions.

Scoring Information
Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary
- This standard is modeled off of information provided in document “Modification of Transition Process Requirements for Part D Sponsors”, April 2006.
Module 6: Medication Therapy Management Standards
Standard MTM 1 – Program Principles

The organization should demonstrate that it has established a Medication Therapy Management program that is based on the following principles:

(a) Strives for appropriate therapeutic outcomes for targeted consumers through improved medication use based on available information; and

(b) Reduces the incidence of adverse events.

Scoring Information

Weight = 3
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Medication Therapy Management Programs (MTMPs) will recognize that prescription medication therapies are most effective when the following occurs
  - The right medication is prescribed at the right dose and for the proper duration.
  - The medication is accessible to the consumer. The consumer is getting the prescription filled and is adherent to the therapy.
  - The consumer is monitored to ensure that best outcomes are achieved, that the objectives of therapy are being met and that adverse events are minimized.
  - Consumers and caregivers are properly educated and counseled and their medication therapy properly managed.

- MTMPs span a range of services, from simple to complex. MTMPs may include elements designed to promote:
  - Enhanced consumer understanding;
  - Increased adherence to medication regimens;
  - Detection of adverse drug events and patterns of over-use and under-use of prescription drugs.

- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”, the Federal Register, and MMA Operational User Group Call March 15, 2006.
### Standard MTM 2 – Development Staff Qualifications

The *organization* shall provide evidence that its *Medication Therapy Management program* was developed in cooperation with *licensed* and practicing pharmacists and physicians.

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<tr>
<td>• The MTM program should be reviewed annually and updated by clinical content expert(s) such as pharmacists or physicians with expertise in MTM.</td>
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<tr>
<td>• MTM Programs may be reviewed and developed by the organizations P &amp; T Committee.</td>
</tr>
<tr>
<td>• This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”, the Federal Register, and MMA Operational User Group Call March 15, 2006.</td>
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### Standard MTM 3 – Implementation Staff Qualifications

Consistent with Core 6, the organization ensures that its Medication Therapy Management programs are delivered by at least one of the following providers:

(a) Pharmacists employed by a pharmacy, health plan, PBM, hospital, other health care entity or as an independent provider of care; or

(b) Other qualified health care professionals.

### Scoring Information

Weight = 3

See the section on “scoring information” at the beginning of this document.

### Interpretive Information / Commentary

- If using personnel outside of the organization, the organization will describe how the resources will be used and the time required to provide the prescribed services (e.g., number of FTEs, type of personnel such as pharmacist).

- The MTM program defines the allowable scope of activities for licensed or certified clinical staff and non-licensed or non-certified clinical staff in carrying out its MTM activities that:
  - Is consistent with standards of practice for licensed personnel;
  - Prohibits non-clinical staff from conducting evaluation or interpretation of individual clinical data; and
  - Defines and provides for oversight of non-clinical staff in the MTM program by licensed or certified health care staff.

- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs” and MMA Operational User Group Call March 15, 2006.
## Standard MTM 4 – Coordination of Care

The *organization* is able to coordinate care with care management plans for targeted individuals. Coordination may include one or more of the following:

(a) Establishing processes that allow appropriate sharing and communication of *consumer* information among health care providers who have a need to know (such processes should be able to identify those practitioners who need to have *access* to this information); or

(b) Maximizing the productivity of *Medication Therapy Management* providers through appropriate use of information technology and other communication tools; or

(c) Providing a capability that allows one provider to refer *consumers* to another.

### Scoring Information

Weight = 3  
See the section on “scoring information” at the beginning of this document.

### Interpretive Information / Commentary

- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs” and MMA Operational User Group Call March 15, 2006.
Standard MTM 5 – Medication Therapy Management Process Structure

The organization has a process that promotes rational, clinically appropriate, safe, and cost-effective medication therapy management, which shall include:

(a) Incorporation of rigorously applied evidence-based medicine;

(b) Communication and population specifications; and

(c) Defined service offerings.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- In part (b) communication could be amongst different stakeholders, consumers, and providers of MTM services.
- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”.

Standard MTM 6 – Consumer-Centered Approach

The Medication Therapy Management program uses a consumer centered approach based on the best available science.

Scoring Information

Weight = 4
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The MTM program should be reviewed annually and updated to meet the needs of the consumers.
- The organization should reference publicly available evidence-based reports that can be accessed by or provided to participating providers as the basis for establishing objectives to help educate the consumer and improve outcomes of medication therapy.
- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”.
Standard MTM 7 – Medication Use Communication

The organizations shall implement policies and procedures that address the communication by the providers to consumers. Communication plans should:

(a) Address the proper use of medications;

(b) Be regular and ongoing;

(c) Describe the potential health benefits and limitations of receiving the Medication Therapy Management program services;

(d) Include instructions on how to contact the medication therapy management program for urgent and non-urgent situations;

(e) Include Opt-in and Opt-out opportunities;

(f) Include the process of disenrolling; and

(g) Describe how long consumers remain enrolled once they enter the program.

Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Programs should use methods appropriate to meet the needs of the targeted consumer population, accounting for consumer demographics, health conditions, residence, cultural diversity, health literacy and language barriers.
- Programs should safeguard against discrimination based on the nature of the medication therapy management interventions (i.e. TTY if phone based, Braille if mail based, etc.).
- This information may be provided to consumers via mail, fax, email, a web site, or other written communications modality.
- URAC will review samples of consumer communications to determine that all elements of the standard have been met. The communication may be directly from the medication therapy management program. It is acceptable for the communications materials to be branded as or generated by the medication therapy management program’s client.
- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs” and MMA Operational User Group Call March 15, 2006.
### Standard MTM 8 – Population Specifications

The *organizations* shall implement policies and procedures that address the identification of target *populations*.

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<tr>
<td>• A health care provider could be one of the individuals involved in identifying the consumers.</td>
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### Standard MTM 9 – Consumer Identification and Recruitment

The *organization* will implement a program to identify and enroll at risk individuals for a lack of adherence to medication therapy, inappropriate medication use, and adverse events.

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<tr>
<td>• This standard is intended to specify how the medication therapy management program identifies consumers who will be eligible for program interventions. The intent is to ensure that the organization develops rules to identify potential eligible consumers, and that it applies the rules in a timely and consistent manner. This process includes identification of program population exclusions.</td>
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<tr>
<td>• This standard is intended to allow for pilot medication therapy management programs.</td>
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<tr>
<td>• This standard is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”.</td>
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Standard MTM 10 – Service Offerings

The organization shall define the services it will offer to meet the needs of individual consumers and its target population group.

Scoring Information

Weight = 5
See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The medication therapy management program will utilize evidence based medicine as appropriate.
- Interventions are based on appropriate pharmaceutical care.
- Interventions may be supported by written or other education material.
- The description of the MTMP will include the type, frequency and recipient of interventions. (Ops Call, March 15, 2006)
- Services should include but are not limited to the following, according to the individual needs of the consumer:
  - Providing education and training designed to enhance consumer understanding and appropriate use of his/her medications.
  - Providing information and resources designed to enhance consumer adherence with his/her therapeutic regimens.
- This standard is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”.


## Standard MTM 11 – Program Criteria

Programs that provide coverage for *Medication Therapy Management* services shall include at a minimum:

(a) *Consumer*-specific and individualized services or sets of services to the *consumer*.

(b) *Consumers* shall have *access* to appropriate delivery methods.

(c) A process to identify *consumers* who should receive *Medication Therapy Management* services.

(d) Payment for *Medication Therapy Management* services consistent with contemporary *prescriber* payment rates that are based on the time, clinical intensity, and resources required to provide services.

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- In some situations, Medication Therapy Management services may be provided to the caregiver or other persons involved in the care of the consumer. These services are distinct from formulary development and use, generalized consumer education and information activities, and other population-focused quality assurance measures for medication use.

- Examples of current contemporary provider payment rates could include for example, Medicare Part A and/or Part B for Current Procedural Terminology [CPT] and Resource-Based Relative Value Scale [RBRVS].

- The organization providing the MTM program may distinguish between services in ambulatory and institutional settings.

- Delivery methods should take into account the cultural diversity, consumer demographics, health conditions, health literacy and language barriers of the target population.

- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”, the Federal Register, and MMA Operational User Group Call March 15, 2006.
**Standard MTM 12 – Documentation and Outcomes Measurement**

The *organization* shall create a process to document and measure *Medication Therapy Management* program results in order to determine overall program effectiveness.

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**Interpretive Information/Commentary**

- The description of the MTM program should include a description of the methods of measuring outcomes.
- Appropriate documentation and measurement could include consumer satisfaction, services provided and by whom (type of health care professional), and desired treatment outcomes and results achieved.
- Programs should include standardized documentation, including billing and payment systems for MTM services.
- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”, the Federal Register, and MMA Operational User Group Call March 15, 2006.

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**Standard MTM 13 – Quality Improvement**

The *organization* shall create a process to use measure the quality of the *Medication Therapy Management* program.

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**Interpretive Information/Commentary**

- Longitudinal assessment of program quality should be incorporated into program design to ensure program goals are met.
- Specific areas that could be addressed include achievement of quality targets measured by both internal and external metrics; identification and appropriate use of best practices; and application of evidence-based medicine, as appropriate.
- This standard and interpretive information is modeled off of information provided in the Academy of Managed Care Pharmacy Document: “Sound Medication Therapy Management Programs”.
Standard MTM 14 – Shared Decision-making with Consumers

The medication therapy management program establishes and implements policies and procedures to promote consumer decision-making that specify:

(a) What information the medication therapy management program will make available to support clinical decision-making of consumers;

(b) What decision support tools it will make available to consumers;

(c) The process for engaging consumers in decisions regarding the medication therapy management plan; and

(d) How the medication therapy management program will establish, document, and monitor individual goals in collaboration with the consumer and other professional disciplines.

Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- Under subsections (a) and (b) information to support clinical decision-making by consumers may be provided in person, by mail, telephonically or online, and may include educational materials.
- Decision support tools may support consumer choices regarding behavioral change based on current knowledge and preferences.
- Under subsection (d), “other professional disciplines” could be providers, case managers, and or disease management professionals where appropriate.
## Standard MTM 15 – Reporting Requirements

The *medication therapy management* program measures program performance and effectiveness for the targeted *population* in a manner that:

(a) Establishes clinical process(es) and *outcome(s)* objectives;  
(b) Measures *outcomes*; and  
(c) Compares performance data to program *outcome* goals.

### Scoring Information

Weight = 5  
See the section on “scoring information” at the beginning of this document.

### Interpretive Information/Commentary

- In subsection (a), examples of objectives may include promotion of medication compliance and adherence, improvement in specified clinical or financial outcomes measures, education of consumers and providers, or an optimization of drug utilization management.  
- Clinical performance measures referred to in subsection (b) may include process measures or outcome measures. Specific measures will be based on the clinical conditions targeted by the medication therapy management program and the evidence on appropriate process and outcomes measures.  
- For subsection (c), URAC will expect to see evidence that the medication therapy management program’s quality management committee (or its equivalent) reviews data on program performance periodically. The quality management committee should periodically review data relating to completed quality improvement projects to assess the effect of the project over time. See also Core 30.  
- The process required by MTM 15 can be used for identifying actions to improve the program’s performance; i.e. identifying potential quality improvement projects (QIPs).
# Standard MTM 16 – MTM Program Provider Performance Feedback

The *medication therapy management* program provides feedback to participating providers as needed to promote quality of care and care coordination for participating *consumers*.

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## Interpretive Information/Commentary

- The type of feedback provided to providers may range from practice profile information based on claims data, to feedback on specific consumer treatment plans. Provider profiling is not required under this standard.
- Medication therapy management programs may establish claims volume or consumer volume thresholds for producing provider specific or provider-group specific feedback. More extensive feedback such as profiling data may be limited to providers treating a large number of the consumers participating in the medication therapy management program.
- URAC will validate compliance with the standard by looking for documentation of communication with providers about specific performance issues. This may be documentation of discussions with a provider about care of a specific consumer or samples of routine communications to providers containing performance information.
- Medication therapy management programs should have criteria for when they would report information on provider practices, including quality of care problems, to a client health plan.
Standard MTM 17 – MTM Program Consumer Education

The *medication therapy management program* provides ongoing education to *participating consumers* that:

(a) Addresses self-management and effective use of available clinical and educational resources with individual *consumers* related to their medications;

(b) Provides educational materials that reflect learning needs of the targeted *population*;

(c) Uses educational materials that reflect current best practices for *medication therapy management* and;

(d) Documents educational resources provided to individual *consumers*.

**Scoring Information**

Weight = 5

See the section on “scoring information” at the beginning of this document.
Interpretive Information/Commentary

- The medication therapy management program may use any type of educational media to reach target populations. The program may include written materials, in-person or telephonic instruction, group meetings, video or Internet communications or other methods.

- To meet subsection (b) the medication therapy management program should document information about the general demographic or cultural characteristics of the population that may affect learning needs. For example, a medication therapy management program serving an older population may need large-type materials; a program serving a low-income population may need low-literacy materials. Language and literacy are examples of things to consider with the target population.

- Subsection (b) also addresses the need for educational interventions that reflect individual consumer goals or needs consistent with standard MTM 14. For example, the medication therapy management program should be able to document educational interventions related to consumer goals, and the use of appropriate techniques (such as use of an interpreter for a non-English speaking consumer).

- The medication therapy management program must also document an annual review and update of educational materials. The medication therapy management program must conduct oversight of this process when development of materials is delegated to an external organization.

- Evaluation of effectiveness of education materials may be conducted in conjunction with other measurements of consumer behaviors or outcomes outlined in standards MTM 12 and 15. Evaluation of educational approaches may be conducted through a survey, interviews or focus groups, and may be a part of the assessment process. For example, the assessment tool could include questions to assess the consumer’s knowledge pre- and post-educational intervention.
Standard MTM 18 – Participating Consumer Rights and Responsibilities

Upon enrollment of an eligible consumer, the medication therapy management program conveys information on rights and responsibilities to participating consumers including:

(a) The right to know about philosophy and characteristics of the medication therapy management program;

(b) The right to have personally identifiable health information shared with the medication therapy management program only in accordance with state and federal law;

(c) The right to identify the staff member of the program and their job title, and to speak with a supervisor of the staff member if requested;

(d) The right to receive accurate information from the medication therapy management program;

(e) The right to receive administrative information regarding changes in or termination of the medication therapy management program;

(f) The right to decline participation, revoke consent or disenroll at any point in time;

(g) The responsibility to submit any forms that are necessary to participate in the program, to the extent required by law;

(h) The responsibility to give accurate clinical and contact information and to notify the medication therapy management program of changes in this information; and

(i) The responsibility to notify their treating provider of their participation in the medication therapy management program (if applicable).

### Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.
### Interpretive Information/Commentary

- On occasion, the medication therapy management program’s client (for example, a health plan,) may have a general document or protocol for conveying consumer rights and responsibilities. If that document contains information specific to the medication therapy management program and covers each of the elements above, then it can be used to meet the standard. However, URAC does not expect that client information will cover rights and responsibilities in this level of detail, and expects that fulfillment of this standard will be the direct responsibility of the medication therapy management program.
- For subsection (c), the company must be able to uniquely identify which company representative communicates with the consumer so that the consumer can provide specific feedback on their customer service experience to the company.
- Prior to enrollment also fulfills the “Upon enrollment” requirement.
- Rights and responsibilities should be conveyed within 30 days of enrollment.
Standard MTM 19 – MTM Program Telephone Access

The medication therapy management program provides a system for telephonic communication for participating consumers and providers that:

(a) Has capability for the medication therapy management program staff to receive and return calls;

(b) Has clearly specified hours of operation that are communicated to participants;

(c) Is operated consistently with criteria developed by the medication therapy management program for inbound and outbound calls, including instructions for inbound calls in emergency situations and inbound calls outside hours of operation;

(d) Instructs callers what to do in emergency situations or outside hours of operation; and

(e) Documents ongoing evaluation and reporting on performance.

Scoring Information

Weight = 4

See the section on “scoring information” at the beginning of this document.

Interpretive Information/Commentary

- The intent of this standard is not to require all medication therapy management programs to have outbound calling capability for the purposes of medication therapy management interventions. The intent is to ensure that programs provide telephonic access based on the scope of services offered, and that at minimum, programs have capability to accept and respond to calls concerning administration of the medication therapy management program.

- For subsection (b), medication therapy management programs must clearly specify their hours of operations and alternatives that are available to consumers during and outside of hours of operations. Program materials must address accessibility for rotary phone users, non-English-speaking consumers and consumers with special needs.

- Medication therapy management programs may provide information to consumers via a message response to inbound calls regarding what to do in an emergency.

- The medication therapy management program documents that it tracks and reports common industry measures for telephonic access, including call wait times, call blockage, time to speak to a clinical staff member, and call abandonment. URAC will validate the standard by looking for evidence that the medication therapy management program’s quality management committee or its equivalent addresses telephone access.

- The organization must comply with applicable rules and regulations.
Module 7: Benefits Design / Administration Standards
### Standard BDA 1 – Structure and Process P & P’s

The *organization* establishes and implements policies and procedures that address the structure and process components of their benefit design and administration.

**Scoring Information**

Weight = 5

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Organizations will develop policies and procedures defining the process used to determine the tiering of benefits and copays for the consumer.

### Standard BDA 2 – Economic Incentive P & P’s

The *organization* establishes and implements policies and procedures address how the benefit design process considers drug costs and financial incentives for *consumers*.

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

### Standard BDA 3 – Benefits Design and Administration Process Implementation

The *organization* establishes and implements policies and procedures that address how the benefit design process occurs after all clinical *formulary* decisions have been made.

**Scoring Information**

Weight = 4

See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- This standard was developed using information provided in the Academy of Managed Care Pharmacy Document: “Principles of a Sound Drug Formulary System”.

### Standard BDA 4 – Decisions on Limitations/Exclusions

The *organization* establishes and implements policies and procedures that address how decisions are made pertaining to limitations and exclusions within each therapeutic class, such as days supply and refill limitations, age and gender limitations, exclusion of cosmetic and lifestyle drugs.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.  
- The organization must comply with applicable rules and regulations that may govern access to specific drugs.

### Standard BDA 5 – Cost Containment Tools

The *organization* establishes and implements policies and procedures that address how specific cost containment tools provide value for the client and their respective members.

**Scoring Information**

Weight = 3  
See the section on “scoring information” at the beginning of this document.  

**Interpretive Information/Commentary**

- Cost containment tools may include tiered pharmacy benefit structures, co-payments and coinsurance, generic drug use, mail-service pharmacy, pharmacy network discounts, reference pricing and closed or partially closed formularies.
**Standard BDA 6 – Disclosure on Refilling Prescriptions**

The *organization* discloses to *consumers* the exceptions to refilling *prescriptions* (which would otherwise be limited by benefit design) in order to ensure access to the types of drug therapy needed.

**Scoring Information**

Weight = 4  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- Cases where this disclosure is needed include but are not limited to: natural disaster, lost supplies, prescriptions needed in advance of travel.
- It is up to the organization to define how it will handle controlled substances.
- The organization must comply with applicable rules and regulations.

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**Standard BDA 7 – P & P’s for Hard-edits**

The *organization* will develop policies and procedures to define how it will handle *non-formulary* drugs on an open *formulary* benefit.

**Scoring Information**

Weight = 3  
See the section on “scoring information” at the beginning of this document.

**Interpretive Information/Commentary**

- This standard intended to address the client-specific relationship in which benefits may be designed around specific drugs.

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**Standard BDA 8 – Generic and Mail Order Educational Information**

Mandatory generic and mail order programs must offer educational information for the *consumer*.

**Scoring Information**

Weight = 5  
See the section on “scoring information” at the beginning of this document.