

**Pharmacy Benefit Management Accreditation  
Standards, Version 1.0**

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## **Copyright for Pharmacy Benefit Management 2007**

Pharmacy Benefit Management Standards, Version 1.0, July 2007

Previous Versions:

None

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## Message from URAC

Dear interested party or applicant:

Quality-based operations should be the centerpiece of any company doing business in today's health care system. Quality improvement activities promote a wide range of benefits such as increasing operational efficiencies, reducing business risks and improving patient health outcomes. However, health care professionals must identify and implement a quality improvement methodology that really works for their particular business model and health care setting.

Through its modular approach to accreditation, URAC works with the industry and other key stakeholders to benchmark URAC standards against key organizational structures and business functions. Now in its 18<sup>th</sup> year of operation, URAC offers 20 different accreditation and certification programs. URAC has issued more than 10,000 accreditation certificates to companies operating in all 50 states and internationally. URAC also is recognized as part of the regulatory process in three-fourths of the states and by four federal agencies.

URAC, as a nonprofit, independent accreditation agency, brings to the table a nationally-recognized accreditation process and seal of approval. URAC's success is tied in large part to the broad-based, consensus-driven process by which hundreds of volunteers help URAC draft and update its standards and also oversee the accreditation system. These volunteers represent the interests of a wide variety of stakeholders including purchasers, regulators, consumers, providers and industry representatives.

All companies that apply for URAC accreditation make improvements to their operations as a result of the review process. The desktop review of the application identifies issues early on in the process and helps focus the onsite review, which is designed to confirm compliance with the standards. During the onsite visit, accreditation reviewers exchange information with applicants in what often becomes a mutual learning experience. URAC's goal is to identify and promote best practices for each market segment that it accredits.

Receiving the accreditation certificate signifies a job well done and distinguishes the organization as having met a standard of excellence. As a result, URAC accredited organizations join the ranks of a select community who have documented and verified their commitment to quality health care.

Please contact URAC if you would like to find out more about the accreditation process or to become involved with one of our committees, educational programs, research initiatives, or other projects. We look forward to hearing from you.





## Introduction for URAC Accreditation Standards and Accreditation Guides for Pharmacy Products

URAC offers two references addressing standards. The *Accreditation Standards* provides a copy of the standards produced by URAC and defined terms, which are *italicized* within the standards. It is a resource for government agencies and private entities wanting to examine the standards for their own purposes. For organizations contemplating accreditation, URAC's *Accreditation Guide* provides, in addition to the standards, information about the documentation to submit as evidence for meeting the intent of the standards as well as the types of materials and activities URAC's accreditation reviewers will be examining during an onsite visit. Both the Accreditation Standards and Guide are available through URAC's Business Development Department at (202)216-9010 or send an e-mail to [BusinessDevelopment@urac.org](mailto:BusinessDevelopment@urac.org). For detailed information about how to prepare an application for accreditation, please go to: <http://www.urac.org/healthcare/accreditation/accreditnet.aspx> for a copy of the *AccreditNet Instruction Booklet*, designed to complement the Accreditation Guide for applicant organizations.

**The Accreditation Standards and Accreditation Guide are intended to provide guidance only. The URAC Accreditation Committee and Executive Committee hold the final authority to make determinations regarding interpretation and application of standards, and an applicant's compliance with standards.**

The Accreditation Guide is provided to assist applicants understand the meaning or intent of the standards. That being said, it cannot cover all possible situations and subsequent interpretations that may apply. Therefore, applicants should be aware that the standards are subject to ongoing interpretation and as such, changes can be made to the Accreditation Guide.

Each company should carefully review URAC's accreditation standards and the defined terms *italicized* within the standards, then use the Accreditation Guide and AccreditNet Instruction Booklet to prepare an application for submittal to URAC.

### Modular Concept

URAC uses a “modular accreditation system” that is adaptable to the continuing evolution of the health care system. A module is a set of standards established for a particular health care function. The collection of standards contained within modules are unique to that health care service or function. The "Pharmacy Core" (PHARM Core) standards incorporate the basic elements necessary to promote quality and act as a “foundation” for function-specific accreditation programs such as Pharmacy Benefits Management , Drug Therapy Management, Mail Service, Specialty Pharmacy, and Workers’ Compensation PBM. Each pharmacy-related accreditation will include PHARM Core and the module(s) covering the functions.

**PHARM Core Standards + Module(s) = Specific Accreditation**

For applicants, the modular system provides the flexibility to choose from a variety of accreditation programs. For example, an applicant may choose to apply for Pharmacy Benefits Management (PBM) accreditation initially, and when up for reaccreditation, add the Drug Therapy Management (DTM) module.

**Core with Single-Module Application**  
(Example: PHARM Core & PBM only)

**Core with Multi-Module Application**  
(Example: PHARM Core & PBM + DTM)

With several choices available, an applicant can tailor the accreditation to its current needs and business goals. If you are not sure what modules would best fit your organization, URAC’s Business Development Department can be reached at [BusinessDevelopment@urac.org](mailto:BusinessDevelopment@urac.org) or at (202) 216-9010 to answer questions, provide pricing information and help organizations decide the best course of action for them.



## Compliance with State and Federal Law

The Accreditation Guide provides information on URAC's expectations regarding compliance with each standard. Some standards require applicants to attest to compliance with specific state regulations regarding operational policy and procedure. Prior to submitting an application the applicant should conduct a review of its legal obligations, including those addressed in the standards. Although it is not indicated for each standard, URAC expects that the applicant will be in compliance with all applicable state and federal laws that pertain to relevant operations. State and federal laws supersede URAC Standards if the laws or regulations are more rigorous than URAC Standards. Conversely, an applicant must comply with URAC Standards if the standards are more stringent. If an applicant is required by law to carry out its business in a manner not consistent with URAC Standards, then the applicant may request a variance from a URAC Standard. A copy of the relevant statute or regulation must accompany the request submitted for that standard in the application.

## Standards and Interpretation

The standards are grouped together into modules, with each module representing various health care functions. Individually, the standards address the structures and processes that need to be in place for performing the function to be accredited according to national standards. For the most part, the applicant is expected to be in compliance with all applicable standards at the time of application for accreditation.

In the *Accreditation Standards*, you will find:

**Definitions.** All italicized terms found in the standards are defined in this section.

**Standards.** Standards include the weight assigned to an element. In the *Accreditation Guide*, you will find:

**Definitions.** All italicized terms found in the standards are defined in this section.

**Standards, Element Weights and Interpretive Information** for each Standard.

**Points to Remember, Scope and Relevant Standards.** These bullet points identify important issues and related standards to consider when documenting your organization's compliance with the

**standard. In some cases, additional details are provided that will help your compliance efforts and in other cases, these details will alert you to potential pitfalls.**

**Evidence for Meeting the Standards: Desktop Materials and Onsite Review Materials and Activities.**

**Bright Ideas. These are common industry practices that may be helpful to the applicant organization. (Note: adoption of a “bright idea” is not required for compliance with a standard, nor does adoption of the “bright idea” guarantee compliance with that standard.)**





## Pharmacy Glossary

### DEFINITIONS

In the standards, defined terms are *italicized*. The terms are used throughout the Pharmacy Quality Management® Products. 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.

Term	Definition
<b>Access</b>	<b>Access:</b> The <i>consumer's</i> ability to obtain services in a timely manner. The ease of <i>access</i> is determined by components such as the <i>availability</i> of services, their acceptability to the <i>consumer</i> , <i>consumer</i> wait time, and the hours of operation.  <b>Note:</b> <i>Consumers</i> should not be denied <i>access</i> to treatment due to lack of coverage.
<b>Adverse Event</b>	A clinical occurrence that is inconsistent with or contrary to the expected outcomes.
<b>Advisory Board of Osteopathic Specialists (ABOS)</b>	American Osteopathic Association (AOA) certification agent organized in 1939 for the purpose of establishing and maintaining standards of osteopathic specialization and pattern of training.
<b>American Board of Medical Specialties (ABMS)</b>	Organized originally in 1933 as the Advisory Board of Medical Specialties, the <i>ABMS</i> (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.
<b>Appeal</b>	A written or verbal request by a <i>prescriber</i> , ordering provider, or <i>consumer</i> to

contest an organizational determination, such as, services have been denied, reduced, etc.

**Appeals Consideration** **Note:** Specific terms used to describe *appeals* vary, and are often determined by law or regulation. URAC's *drug management* standards apply to first-level *appeal*. 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*.

**Automated Review** A computerized process whereby a validated algorithm is used for *drug management*.

**Availability** Meeting the needs of *consumers* according to the *criteria* posed to the *organization* by its *clients*.

**Barrier Analysis** 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.

**Benefit** The description of coverage including but not limited to: *formulary* drugs, participating networks, payment structures, authorization for *drug management* programs, and *drug therapy management* programs as selected by the purchaser. The *formulary* is a subsidiary of the *benefits* plan.

**Board-Certified** 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.  
**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-* of 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 10, which relates to the clinical qualifications of senior *clinical staff* people who are physicians.

**Case**

A specific request for medical or clinical services referred to an *organization* 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.

**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** An approval of a *prescription* drug claim based on the clinical requirements for medical necessity, appropriateness, level of care, or effectiveness.

**Claimant** A party that makes a *benefit* claim.  
**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*.

**Clinical Decision Support Tools** Protocols, guidelines, or algorithms that assist in the clinical decision-making process.

**Clinical Director** A *health professional* who: (1) is duly *licensed* or *certified*; (2) is an employee of, or party to a contract with, an *organization*; and (3) who is responsible for clinical oversight including the credentialing of professional *staff* and quality assessment and improvement functions.

**Clinical Oversight** Monitoring and evaluation of the clinical integrity of program processes and decisions affecting consumers.

**Clinical Oversight Body** A body comprised of discipline specific experts such as physicians, pharmacists, *providers*, and content experts who may include non-physician *providers* such as certified health educators, respiratory therapists, nutritionists, nurses, mental *health*

*professionals* or other specialists.

<b>Clinical Peer</b>	A physician or other <i>health professional</i> who holds an unrestricted <i>license</i> and is in the same or similar specialty as typically manages the medical <i>condition</i> , procedures, or treatment under review.
<b>Clinical Rationale</b>	A statement that provides additional clarification of the clinical basis for a <i>non-certification</i> determination. The <i>clinical rationale</i> should relate the <i>non-certification</i> determination to the <i>consumer's condition</i> or treatment plan, and should supply sufficient information for a decision to pursue an <i>appeal</i> .
<b>Clinical Review Criteria</b>	The written screens, decision rules, medical protocols, or drug treatment guidelines used by the <i>organization</i> as an element in the evaluation of medical necessity and appropriateness of services under the auspices of the applicable <i>prescription benefits</i> plan.
<b>Clinical Staff</b>	Employees or contracted consultants of the health care <i>organization</i> who are clinically qualified to perform <i>clinical triage</i> and provide <i>health education</i> services.
<b>Comparable</b>	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.
<b>Compensable Complaint</b>	Being such as to entitle or warrant compensation. An expression of dissatisfaction regarding the <i>organization's</i> products or services.

**Note:** This definition does not include *appeals*.

<b>Concurrent Review</b>	<i>Drug management</i> conducted during a <i>consumer's</i> ongoing drug <i>benefit</i> use.
<b>Condition</b>	A diagnosis, clinical problem or set of indicators such as signs and symptoms a <i>consumer</i> may have that define him/her as eligible and appropriate to participate in a clinical program.
<b>Conflict of Interest</b>	<p>Any relationship or affiliation on the part of the <i>organization</i> or a <i>reviewer</i> that could compromise the independence or objectivity of the independent review process. <i>Conflict of interest</i> includes, but is not limited to:</p> <ul style="list-style-type: none"> <li>· An ownership interest of greater than 5% between any affected parties;</li> <li>· A material professional or business relationship;</li> <li>· A direct or indirect financial incentive for a particular determination;</li> <li>· Incentives to promote the use of a certain product or service;</li> <li>· A known familial relationship;</li> <li>· Any prior involvement in the specific <i>case</i> under review.</li> </ul>
<b>Consumer</b>	<p>An individual person who is the direct or indirect recipient of the services of the <i>organization</i>. Depending on the context, <i>consumers</i> may be identified by different names, such as “member,” enrollee,” “beneficiary,” “<i>patient</i>,” “injured worker,” “claimant,” etc.</p> <p><b>Note:</b> A <i>consumer</i> relationship may exist even in cases where there is not a direct relationship between the <i>consumer</i> and the <i>organization</i>. For example, if an individual is a member of a health plan that relies on the services of a <i>utilization management organization</i>, then the individual is a <i>consumer</i> of the <i>utilization management organization</i>.</p>

In the *case* of a *consumer* who is unable to participate in the decision-making process, a family member or other individual legally authorized to make health care decisions on the *consumer* behalf may be a *consumer* for the purposes of these standards.

**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*.”

**Coverage Decision** A determination of whether a service is a covered benefit based on *benefit* design and/or on clinical coverage *criteria*.

**Criteria** **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, at a minimum annually.

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.

**Delegation**

The process by which the *organization* contracts with or otherwise arranges for another entity to perform functions and to assume responsibilities covered under these standards on behalf of the *organization*, and the *organization* retains final authority to provide oversight to the delegate

**Drug Management**

Evaluation of patients’ drug profiles related to covered benefits, clinical appropriateness and safety for patients’ use of medications.

**Drug Therapy Management**

A distinct service or group of services that optimize therapeutic *outcomes* for individual *consumers* as a result of appropriate drug therapy. (Adapted from Academy of Managed Care Pharmacy’s (AMCP) Principles of a Sound Drug Formulary System, 2000.)

**Drug Utilization Management**

Evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, products, and *facilities* under the provisions of the applicable health *benefits* plan; sometimes called “drug review.”

**Eligibility Determination**

*Criteria* to determine if a consumer is entitled or qualified to receive an insurance *benefit*.

**e-prescribing**

Prescription information that is created, stored and transmitted via electronic means, (e.g., by computer or hand held device). The process is more than the capability to

transmit new prescriptions from prescribers to a pharmacy. Among other things it includes allowing pharmacies to transmit refill requests to the prescriber and prescribers to respond with their authorization, denial, or changes. The term electronic prescriptions would not apply to prescriptions communicated either by facsimile ("Fax") or verbally in a telephone conversation. Electronic transmission offers benefits over written and oral prescription transmission in terms of accuracy, storage capacity, accessibility, security, productivity and minimizing the potential for adverse drug events. Additional benefits of electronic prescriptions are:

- Reduction of errors due to
  - o Illegible handwriting
  - o Confusing similarly-sounding drug names with oral prescription orders and
  - o Order-entry errors
- Provide prescribers with information about
  - o Appropriateness of their prescriptions
  - o Other drugs the patient is taking prescribed by the same or other doctors which may result in
    - Serious drug interactions
    - Dangers with drug allergies
    - Duplicate drugs or overlapping drug classes
  - o Other diseases and medical record information, including
    - Diseases where certain drugs can cause harm
    - Correct dosing (age, weight, gender)
  - o Drug coverage by health plan such as:

- Formulary status
- Preferred drugs
- Step therapy

*Adapted from 2002 Academy of Managed Care Pharmacy (AMCP) Policy Statement*

**e-Prescribing Network**

A secure electronic network that allows pharmacy systems and payer/PBM systems to connect in real-time to provide patient eligibility, medication history and formulary and benefit information to prescribers at the point of care, and then route the prescription to the pharmacy of the patient’s choice, either retail or mail service.

Examples of e-Prescribing Networks are Networks **operated by SureScriptsRxHub.**

**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.

**Exception**

A mechanism for additional coverage determination review as described in the *benefits*. *Exceptions* take place prior to initiating the formal *appeals* process.

**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 Academy of Managed Care Pharmacy's (AMCP) Principles of a Sound Drug Formulary System, 2000.)

## 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 Academy of Managed Care Pharmacy's (AMCP) Principles of a Sound Drug Formulary System, 2000.)

## 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 Academy of Managed Care Pharmacy's (AMCP) Principles of a Sound Drug Formulary System, 2000.)

**Health Literacy**

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions regarding their health.

**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 *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.

<b>Injured Worker</b>	A <i>consumer/claimant</i> who becomes ill or injured within the scope of their employment.
<b>Injury</b>	Damage or harm caused to the structure or function of the body caused by an outside force, which may be physical or chemical and can include: a disease which is contracted by a worker in the course of employment and to which the employment was a contributing factor, and/or the aggravation, acceleration, exacerbation or deterioration of any disease, where the employment was a contributing factor to the aggravation, acceleration, exacerbation or deterioration.
<b>License</b>	A <i>license</i> 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 U.S.; and (2) required for the performance of job functions.
	<b>Note:</b> In this definition, the word “equivalent” includes <i>certifications</i> , registrations, permits, etc. Specific terms will vary by state and health profession.
<b>Medical Director</b>	A doctor of medicine or doctor of osteopathic medicine who is duly <i>licensed</i> to practice medicine and who is an employee of, or party to a contract with, an <i>organization</i> , and who has responsibility for clinical oversight of the <i>organization’s utilization management</i> , credentialing, quality management, and other clinical functions.
<b>Non-Certification</b>	A determination by an <i>organization</i> that a <i>prescription</i> , service or course of treatment has been reviewed and, based on the information provided does not meet the clinical requirements for medical necessity, appropriateness, or effectiveness and/or is not a covered benefit under the applicable <i>benefits</i> plan.
<b>Opt-In</b>	Affirmative consent actively provided by a <i>consumer</i> to participate in an activity or function of the <i>drug therapy management program</i> , provided after the <i>drug therapy management program</i> has fully disclosed the terms and conditions of participation to

the *consumer*, including:

- The duration of the *opt-in*;
- 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.

**Opt-Out**

A process by which a *consumer* declines to participate in an activity or function of the *drug therapy management program*.

**Note:** Many states mandate a workers' participation in a payer's workers' compensation pharmacy program; therefore they cannot opt out.

**Organization**

A business entity that seeks accreditation under these standards.

**Outcome**

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).

**Participant (participating)**

An eligible *consumer* that has not *opted out* of the program that has had one or more inbound or outbound contacts with the *drug therapy management program*.

**Participating Pharmacies**

A pharmacy that has entered into an agreement with the *organization* to be part of a *pharmacy network*.

**Participating Provider**

A *provider* that has entered into an agreement with the *organization* to be part of a *provider network*.

<b>Patient</b>	Refer to the definition of consumer.
<b>Patient Care</b>	The prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical and allied health.
<b>Patient Management</b>	A collaborative process that assesses, plans, implements, coordinates, monitors, and/or evaluates options and/or services to meet a <i>consumer's</i> health needs through communication and available resources to promote quality, cost-effective <i>outcomes</i> . <i>Patient management</i> may include the <i>patient/consumer</i> and/or the care giver, agent or representative authorized to act on the <i>patient's</i> behalf.
<b>Payer</b>	Provides payment for medications. <i>Payers</i> may include the health plan, the employer, or a pharmacy benefit management company acting on behalf of the health plan or employer.
<b>Personal Health Information</b>	<p>Any <i>personally-identifiable information</i>, whether oral or recorded in any form or medium, that:</p> <ul style="list-style-type: none"><li>· Is created or received by a user, owner, health care <i>provider</i>, health plan, public health authority, employer, insurer, school or university, or health care clearinghouse; and</li><li>· Relates to the past, present, or future physical or mental health or <i>condition</i> of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.</li></ul>
<b>Personally-identifiable Information</b>	Any information that can be tied to an individual identifier.
<b>Pharmaceutical Care</b>	A dynamic component of the health care system that seeks to ensure medications is used appropriately to improve a <i>patient's</i> health status. Working directly with <i>patients</i> , this essential activity is coordinated through the collaborative efforts of a team of pharmacists, physicians, nurses and other health care <i>providers</i> . The team

collaborates through a health care plan that promotes health, prevents disease; and assesses, monitors, initiates, and modifies medication use. By incorporating *Pharmaceutical Care* into the *patient's* health care plan the health care team assumes responsibility for ensuring that therapeutic and quality of life outcomes are achieved within realistic economic constraints.

**Pharmacist  
Pharmacy Distribution  
Channels**

A licensed health professional whom practices the art and science of pharmacy.

A group of pharmacy entities with which the *organization* provides pharmacy services to *consumers* (e.g. *pharmacy network*, mail service pharmacy, and *specialty pharmacy*).

**Pharmacy Network**

A group of pharmacies with which the *organization* provides pharmacy services to *consumers*.

**Pharmacy & Therapeutics  
(P&T) Committee**

An advisory committee that is responsible for developing, managing, updating, and administering the drug *formulary* system. (Adapted from Academy of Managed Care Pharmacy's (AMCP) Principles of a Sound Drug Formulary System, 2000.)

**Pharmacy Technician**

An individual who is either certified/*licensed* or has been adequately trained to prepare and dispense pharmaceuticals and related products under the direct supervision of a licensed pharmacist.

**Physician**

A licensed health professional, medical practitioner or medical doctor who practices medicine, such as M.D. or D.O.

**Plain Language**

Communication that uses short words and sentences, common terms instead of (medical) jargon, and focuses on the essential information recipients need to

understand.

**Population** *Consumers* identified to the *drug therapy management* program by *client* referral or another mechanism.

**Note:** In some instances the *drug 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.

**Preferred Drug List (PDL)** A list of preferred pharmaceutical products for selected prevalent pharmacologic or therapeutic classes; designed to maximize clinical and economic benefits and used exclusively in support of the pharmacy benefit. *Preferred Drug List* Development is part of the *Formulary System*.

**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 Academy of Managed 2000.)

**Professional Competency** The ability to perform assigned professional responsibilities.

<b>Prospective Review</b>	<i>Drug management</i> conducted prior to a <i>prescription</i> , service or course of treatment. Sometimes it can be called “pre-certification review,” “pre-service”, or “prior authorization.”
<b>Provider</b>	Any person or entity that provides health care services. Includes both <i>practitioners</i> and <i>facilities</i> .
<b>Quality Improvement Project</b>	A process that documents the variation of performance or variance from baseline standards in order to achieve a better outcome for the <i>organization’s consumers</i> .
<b>Quality Management Program</b>	A systematic data-driven effort to measure and improve <i>consumer</i> and <i>client</i> services and/or health care services including <i>consumer safety</i> .
<b>Rationale</b>	The reason(s) or justification(s) – commonly based on <i>criteria</i> – for a specific action or recommendation.
<b>Retrospective Review</b>	Review conducted after <i>prescription</i> services have been provided to the <i>patient</i> .
	<b>Note:</b> Retrospective medical necessity determinations are considered <i>drug management</i> (and subject to these standards).
<b>Reviewer(s)</b>	The individual (or individuals) selected by the <i>organization</i> to consider a <i>case</i> . All <i>reviewer(s)</i> who are health care <i>practitioners</i> must have the following qualifications: <ul style="list-style-type: none"> <li>· Active licensure;</li> <li>· Recent experience or familiarity with current body of knowledge and medical practice;</li> </ul>

- At least 5 years experience providing health care;
- o If the *reviewer* is a pharmacist;
- o 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.
- o If the *reviewer* is a D.P.M., *board certification* by the American Board of Podiatric Surgery.

**Note:** “*Reviewer*” in this context refers to peer-clinical review.

### **Specialty Drugs**

*Specialty drugs* or pharmaceuticals usually require special handling, administration, unique inventory management, a high level of patient monitoring and more intense support than conventional therapies. They could include all routes of administration.

### **Specialty Pharmacy**

*Specialty pharmacy* offers a high touch, comprehensive care system of pharmacological care wherein patients with chronic illnesses and complex disease states receive expert therapy management and support tailored to their individual needs. Medications that health plans and other *payers* classify as specialty pharmaceuticals may vary and evolve over time.

*Specialty pharmacy* incorporates synergistic core elements including:

- **Delivery Channel:** Designed to efficiently support the delivery of specialty medications direct to *patient* or physician;
- **Business Model:** Structured to support expert prescription fulfillment coupled with integrated services within a framework of rigid quality standards;

- Service Model: Crafted to achieve measurable improvements in clinical and financial *outcomes* through tailored patient-centric processes and activities; and
- Patient Satisfaction: By meeting/exceeding the clinical and administrative needs of high acuity patients in an environment of continuous quality improvement.

The *specialty pharmacy* is a *provider* of care and an agent of the *patient*. The *specialty pharmacy* is not the *payer* nor do they define the *benefit*. The *payer* may include a third party *payer* or a *patient*.

**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*.

**Note:** In most *cases*, *standard appeals* will not relate to *cases involving urgent care*. However, *standard appeals* may also include secondary *appeals* of *expedited appeals*.

**Subcontractor** A business entity that performs delegated functions on behalf of a contractor.

**Therapeutic Interchange** Authorized exchange of therapeutic alternatives. (Adapted from Academy of Managed Care Pharmacy's (AMCP) Principles of a Sound Drug Formulary System, 2000.)

**Transitional Situation** A change in drug coverage for an individual *patient*.

**Treating Provider** The individual or *provider* group who is primarily managing the treatment for a *consumer participant* in the *drug therapy management program*.

**Note:** The *treating provider* is not necessarily the *consumers' primary physician*. The *consumer* may have a different *treating provider* for different *conditions*.

<b>Valid</b>	Based on accepted principles of study design, research methodology, and statistical analysis.
<b>Workers' Compensation</b>	A state-governed system that addresses work-related injuries where employers (directly or indirectly) assume the cost of medical treatment and wage losses stemming from a worker's job-related <i>injury</i> .
<b>Written Agreement</b>	A document – including an electronic document – that specifies the terms of a relationship between the <i>organization</i> and a <i>client, consumer, or contractor</i> . This term may include a contract and any attachments or addenda.
<b>Written Notification</b>	Correspondence transmitted by mail, facsimile, or electronic medium.





## Pharmacy Core, Version 1.0

### Chapter One

#### PC - 1 - Pharm Core 1 - Organizational Structure

The *organization* has a clearly defined *organizational* structure outlining direct and indirect oversight responsibility throughout the *organization*. (2)

#### PC - 2 - Pharm Core 2 - Organization Documents

*Organization's* documents address: (No Weight)

- (a) Mission statement; (2)
- (b) *Organizational* framework for program; (2)
- (c) A description of the services delivered by the *organization* and how those services are delivered; (2)
- (d) The population served; **and** (2)
- (e) *Organizational* oversight and reporting requirements of the program. (2)

#### PC - 3 - Pharm Core 3 - Policy and Procedure Maintenance, Review, and Approval

The *organization*: (No Weight)

- (a) Maintains and complies with written policies and procedures that govern core business processes of its operations related to the scope of the accreditation; (Mandatory)
- (b) Maintains a master list of all such policies and procedures; (2)

(c) Reviews clinical policies and procedures no less than annually and non-clinical at least once every three years, and revises as necessary; and (3)

(d) Includes the following on all policies and procedures: (2)

(i) Effective dates, review dates, including the date of the most recent revision; **and** (2)

(ii) Identification of approval authority. (2)

#### **PC - 4 - Pharm Core 4 - Job Descriptions**

The *organization* has written job descriptions for *staff* that address: (No Weight)

(a) Required education, training, and/or professional experience; (2)

(b) Expected *professional competencies* (2)

(c) Appropriate *licensure/certification* requirements **and** (2)

(d) Scope of role and responsibilities. (2)

#### **PC - 5 - Pharm Core 5 - Staff Qualifications**

*Staff* meets qualifications as outlined in written job descriptions. (Mandatory)

#### **PC - 6 - Pharm Core 6 - Credentialing**

The *organization* implements a policy to: (No Weight)

(a) Verify the current *licensure* and credentials of *licensed* or certified personnel/consultants upon hire, and thereafter no less than every 3 years; (Mandatory)

(b) Require staff to notify *organization* in a timely manner of an adverse change in *licensure* or *certification* status; **and** (Mandatory)

(c) Implement corrective action in response to adverse changes in *licensure* or *certification* status. (Mandatory)

## **PC - 7 - Pharm Core 7 - Staff Training Program**

The *organization* has a training program that includes: (No Weight)

- (a) Initial orientation and/or training for all *staff* before assuming assigned roles and responsibilities; (2)
- (b) Ongoing training, at a minimum annually, to maintain *professional competency*; (2)
- (c) Training in URAC Standards as appropriate to job functions; (2)
- (d) Training in state and regulatory requirements as related to job functions; (Mandatory)
- (e) *Conflict of interest*; (Mandatory)
- (f) Confidentiality; (Mandatory)
- (g) Preventing fraud, waste and abuse; (3)
- (h) *Delegation* oversight, if necessary; **and** (3)
- (i) Documentation of all training provided for *staff*. (2)

## **PC - 8 - Pharm Core 8 - Staff Operational Tools and Support**

The *organization* provides *staff* with: (No Weight)

- (a) Written operational policies and procedures appropriate to their jobs; **and** (2)
- (b) *Clinical decision support tools* as appropriate. (2)

## **PC - 9 - Pharm Core 9 - Staff Assessment Program**

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. (3)

## **PC - 10 - Pharm Core 10 - Senior Clinical Staff Requirements**

The *organization* designates at least one senior *clinical staff* person who has: (No Weight)

- (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); (Mandatory)
- (b) Qualifications to perform clinical oversight for the services provided **and** (Mandatory)
- (c) Post-graduate experience in *patient care*; and (Mandatory)
- (d) *Board certification* (if the senior *clinical staff* person is an M.D. or D.O.). (3)

## **PC - 11 - Pharm Core 11 - Senior Clinical Staff Responsibilities**

The senior *clinical staff* person: (No Weight)

- (a) Provides guidance for all clinical aspects of program; (2)
- (b) Is responsible for clinical aspects of program; **and** (Mandatory)
- (c) Has periodic consultation with *practitioners* in the field. (3)

## **PC - 12 - Pharm Core 12 - Inter-departmental Coordination**

The *organization* establishes and implements mechanisms to promote collaboration, coordination and communication across disciplines and departments within the *organization*, with emphasis on integrating administrative activities, quality improvement, and where present, clinical operations. (3)

## **PC - 13 - Pharm Core 13 - Information Management**

The *organization* implements information system(s) (electronic, paper or both) to collect, maintain, and analyze information necessary for organizational management that: (No Weight)

- (a) Provides for data integrity; (Mandatory)
- (b) Provides for data confidentiality and security; (Mandatory)
- (c) Includes a disaster recovery plan that; (3)
  - (i) Is tested at least every two years; **and** (3)
  - (ii) Addresses identified areas for improvement; **and** (3)
- (d) Includes a plan for storage, maintenance, and destruction. (2)

## **PC - 14 - Pharm Core 14 - Business Relationships**

The *organization* maintains signed *written agreements* with all *clients* describing the scope of the business arrangement. (4)

## **PC - 15 - Pharm Core 15 - Delegation Review Criteria**

The *organization* establishes and implements criteria and processes for an assessment prior to the *delegation* of functions. (3)

## **PC - 16 - Pharm Core 16 - Delegation Review**

Prior to *delegating* functions to another entity, the *organization*: (No Weight)

- (a) Conducts a review of the potential *contractor's* policies and procedures and capacity to perform *delegated* functions; **and** (3)
- (b) Outlines and follows criteria and processes for approving *contractors*. (3)

## PC - 17 - Pharm Core 17 - Delegation Contracts

The *organization* enters into *written agreements* with *contractors* that: (No Weight)

- (a) Specify those responsibilities *delegated* to the *contractor* and those retained by the *organization*; (2)
- (b) Require that services be performed in accordance with the *organization's* requirements and URAC standards; (Mandatory)
- (c) Require notification to the *organization* of any material change in the *contractor's* performance of *delegated* functions; (4)
- (d) Specify that the *organization* may conduct surveys of the *contractor*, as needed; (4)
- (e) Require that the *contractor* submit periodic reports to the *organization* regarding the performance of its *delegated* responsibilities; (3)
- (f) Specify recourse and/or sanctions if the *contractor* does not make corrections to identified problems within a specified period; (4)
- (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** (4)
- (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. (Mandatory)

## PC - 18 - Pharm Core 18 - Delegation Oversight

The *organization* implements an oversight mechanism for delegated functions within the scope of accreditation that includes: (No Weight)

- (a) A periodic review (no less than annually) of the *contractor's* policies and procedures and documentation of quality activities for related delegated functions; (3)

(b) A process to verify (no less than annually) the *contractor's* compliance with contractual requirements and policies and procedures; **and** (3)

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

## **PC - 19 - Pharm Core 19 - Regulatory Compliance**

The *organization* implements a regulatory compliance program that: (No Weight)

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

(b) Promote the *organization's* compliance with applicable laws and regulations. (Mandatory)

## **PC - 20 - Pharm Core 20 - Financial Incentive Policy**

If the *organization* has a system for reimbursement, bonuses, or incentives to *staff* or *prescribers* 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. (Mandatory)

## **PC - 21 - Pharm Core 21 - Communication Practices**

The *organization* follows marketing and communication practices that include: (No Weight)

(a) Mechanisms to clearly and accurately communicate information about services to *consumer* and *clients*; (2)

(b) Safeguards against misrepresentations about the *organization's* services; (Mandatory)

(c) A formal process of inter-departmental review of marketing materials before dissemination;  
(3)

(d) Monitoring of existing materials for accuracy; and (3)

(e) Timely and complete correction notices to *consumers* and *clients* if any material misrepresentations are found. (Mandatory)

## **PC - 22 - Pharm Core 22 - Consumer Communication Plan**

The *organization* documents and has a mechanism for informing *consumers* and *clients* of their rights and responsibilities, including: (No Weight)

- (a) How to obtain services; **and** (4)
- (b) How to submit a *complaint* or *appeal*. (4)

## **PC - 23 - Pharm Core 23 - Consumer Safety Mechanism**

The *organization* has a mechanism to respond on an urgent basis to situations that pose an immediate threat to the health and safety of *consumers*. (Mandatory)

## **PC - 24 - Pharm 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: (No Weight)

- (a) Identifies how *individually-identifiable health information* will be used; (Mandatory)
- (b) Specifies that *individually-identifiable health information* is used only for purposes necessary for conducting the business of the organization, including evaluation activities; (Mandatory)
- (c) Addresses who will have access to *individually-identifiable health information* collected by the *organization*; (Mandatory)
- (d) Addresses oral, written, or *electronic* communication and records that are transmitted or stored; (Mandatory)

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

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

### **PC - 25 - Pharm Core 25 - Consumer Satisfaction**

The *organization* implements a mechanism to collect or obtain information about *consumer* satisfaction with services provided by the *organization*. (3)

### **PC - 26 - Pharm Core 26 - Access to and Monitoring of Services**

The *organization*: (No Weight)

(a) Establishes standards to assure that *consumers* or *clients* have *access* to services: **and** (4)

(b) Defines and monitors its performance with respect to the access standards. (3)

### **PC - 27 - Pharm Core 27 - Complaint and Appeal System**

The *organization* maintains system(s) to receive and respond in a timely manner to *complaints* and, when appropriate, inform *consumers* of their rights and avenues to submit an *appeal*. (4)

### **PC - 28 - Pharm Core 28 - Appeal Process**

The *organization* maintains a formal *appeal* resolution process that includes: (No Weight)

(a) Written notice of final determination with an explanation of the reason for the determination; (2)

(b) Notification of the process for seeking further review, if available; **and** (4)

(c) A reasonable, specified time frame for resolution and response. (2)

## **PC - 29 - Pharm Core 29 - Complaint and Appeal Reporting**

The *organization* reports analysis of the *complaints* and *appeals* to the quality management committee (refer to Standard Pharm Core 33). (3)

## **PC - 30 - Pharm Core 30 - Quality Management Program**

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. (3)

## **PC - 31 - Pharm Core 31 - Quality Management Program Resources**

The *organization* provides *staff* and/or provides resources necessary to support the day-to-day operations of the *quality management program*. (2)

## **PC - 32 - Pharm Core 32 - Quality Management Program Requirements**

The *organization* has a written description for its *quality management program* that: (No Weight)

- (a) Is approved by the *organization's* governing body; (2)
- (b) Defines the scope, objectives, activities, and structure of the *quality management program*; (2)
- (c) Is reviewed and updated by the quality management committee at least annually; (2)
- (d) Defines the roles and responsibilities of the quality management committee; **and** (2)
- (e) Designates a member of senior management with the authority and responsibility for the overall operation of the *quality management program* and who serves on the quality management committee. (3)

## PC - 33 - Pharm Core 33 - Quality Management Committee

The *organization* has a quality management committee that: (No Weight)

- (a) Is granted authority for quality management by the *organization's* governing body; (3)
- (b) Provides on-going reporting to the *organization's* governing body; (2)
- (c) Meets at least quarterly; (2)
- (d) Maintains approved minutes of all committee meetings; (2)
- (e) If applicable, includes at least one *participating provider* or a mechanism to receive input from *participating providers*; (2)
- (f) Provides guidance to *staff* on quality management priorities and projects; (3)
- (g) Approves the *quality improvement projects* to undertake; (3)
- (h) Monitors progress in meeting quality improvement goals; **and** (3)
- (i) Evaluates the effectiveness of the *quality management program* at least annually. (3)

## PC - 34 - Pharm Core 34 - Quality Management Documentation

The *organization*, as part of its *quality management program*, provides written documentation of: (No Weight)

- (a) Ongoing monitoring for compliance with URAC Standards; (Mandatory)
- (b) Objectives and approaches utilized in the monitoring and evaluation of activities; (Mandatory)
- (c) Identification and tracking and trending of key indicators relevant to the scope of the entire *organization* and related to: (3)

- (i) Consumer and health care services; **or** (3)
- (ii) For *organizations* who do not interact with *consumers, client* services; (3)
- (d) The implementation of action plans to improve or correct identified problems; (3)
- (e) The mechanisms to communicate the results of such activities to *staff*; and (2)
- (f) The mechanisms to communicate the results of such activities to the quality management committee. (2)

### **PC - 35 - Pharm Core 35 - Quality Improvement Project Requirements**

For each *quality improvement project*, the *organization* utilizes *valid techniques comparable* over time to: (No Weight)

- (a) Develop quantifiable measures; (3)
- (b) Measure baseline level of performance; **and** re-measure level of performance at least annually; **and** (3)
- (c) Establish measureable goals for quality improvement. (3)

### **PC - 36 - Pharm Core 36 - Quality Improvement Project Goals and Measurement**

For each *quality improvement project*, the *organization*: (No Weight)

- (a) Designs and implements strategies to improve performance; (3)
- (b) Establishes projected time frames for meeting goals for quality improvement; (3)
- (c) Documents changes or improvements relative to the baseline measurement; (3)
- (d) Conducts at least one remeasurement prior to re-accreditation; **and** (3)

(e) Conducts a *barrier analysis*, if the performance goals are not met. (3)

## **PC - 37 - Pharm Core 37 - Clinical, Error Reduction, and Consumer Safety Requirements**

At any given time, the *organization* maintains no less than two *quality improvement projects*. (3)

(a) At least one *quality improvement project* that: (3)

(i) Focuses on *consumers*; **or** for *organizations* who do not interact with *consumers, client services*; (3)

(ii) Relates to key indicators of quality as described in 34(c); **and** (3)

(iii) Involves a senior *clinical staff* person in judgments about clinical aspects of performance, if the *quality improvement project* is clinical in nature; **and** (3)

(b) At least one *quality improvement project* focuses on *error reduction* and/or *consumer safety*. (3)

(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. (3)

(ii) *Error reduction* QIPs are required of all accreditation programs that do not conduct *consumer safety* QIPs. (3)



## Pharmacy Benefit Management, Version 1.0

### Customer Service, Communications, and Disclosure

#### 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: (4)

- (a) A mechanism to *access* an up-to-date pharmacy directory; (4)
- (b) Covered *benefits* and general coverage guidelines; (4)
- (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; (4)
- (d) Options and implications of prescription *benefits* decision-making for *consumers*; (4)
- (e) *Evidence-based* health information and content for common *conditions*, diagnoses, and the treatment diagnostics and interventions; (4)
- (f) Information and tips to assist in interactions, such as “Financial decision-making for pharmacy benefits”; and (4)
- (g) Instructions on how to receive assistance via e-mail, telephone, or in person. (4)

#### CSCD 2 - On-going Communication Practices

The *organization* follows on-going communications practices (required under Core 21) that monitor existing materials for accuracy, and updates them as changes are made to clearly and accurately communicate information about: (No Weight)

- (a) Currently *participating pharmacies*; (4)
- (b) *Formulary* design, *formulary* changes, and their financial implications; and (4)

(c) *Benefit* design, *benefit* changes, and their financial implications. (4)

### **CSCD 3 - Communication Safeguards**

The *organization* implements safeguards for any communication with potential *consumers* and *clients* to ensure that marketing and sales activities performed by the *organization* do not misrepresent: (No Weight)

- (a) Products and services, and (Mandatory)
- (b) The *organization's* ownership. (Mandatory)

### **CSCD 4 - Disclosure**

If included in the *client* contract, the *organization* discloses to *clients* the following financial model information upon request: (No Weight)

- (a) Existence of organizational arrangements that could potentially create a *conflict of interest* that affects clinical or financial decisions; (4)
- (b) Sources of revenue; and, (4)
- (c) Pricing structure for pharmacy benefit management services, such as: (4)
  - (i) Rebate structure; and (4)
  - (ii) Administration fees. (4)

### **CSCD 5 - Disclosure Verification**

The *organization* has a mechanism to allow its *clients* to verify the *organization's* records to ensure that the disclosures in CSCD 4 (c) are comprehensive and accurate, per the terms of the *client* contract. (4)

## **CSCD 6 - Program Representative Availability**

The *organization* operates a call center during the following hours in the time zones in its service area: (No Weight)

- (a) For enrolled *consumers*, 7 days a week, from 8 am to 8 pm; (4)
- (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 (4)
- (c) For physicians and other prescribers, not less than 8 am to 6 pm. (4)

## **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*: (No Weight)

- (a) Incoming calls must have an average speed of answer within 30 seconds, and (4)
- (b) Average abandonment rate of all incoming calls cannot exceed 5 percent (4)

## **CSCD 8 - Scope of Telephonic Services**

At a minimum, available telephonic services under CSCD 6 include: (No Weight)

- (a) For enrolled *consumers*, information about *benefits*, including co-payments, deductibles, network pharmacies; (4)
- (b) For pharmacies, information on claims processing, *benefit* coverage, claims submission and claims payment; (4)
- (c) For physicians and other *prescribers*, information about the *appeals* process; and (4)
- (d) The acceptance of *complaints* for issues related to (a-c) consistent with Standard Core 27. (4)

## **CSCD 9 - Multiple Format Communications 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). (4)

## **CSCD 10 - Health Literacy Communication Requirement**

The *organization* has a process to provide information that: (No Weight)

- (a) Lowers to the extent practicable the cognitive effort required to use the information; (2)
- (b) Helps *consumers* understand what effect a health care decision may have for their daily lives; and (4)
- (c) Displays the information in a way that highlights information important to the *consumer*. (2)

## **CSCD 11- Cultural Sensitivity Communication Requirement**

Information is presented and delivered in ways that are sensitive to the diversity of the *organization's* enrollment, including: (No Weight)

- (a) Literacy levels; (4)
- (b) Language differences; (4)
- (c) Cultural differences; and (4)
- (d) Cognitive and/or physical impairment. (4)

## **CSCD 12 - Generic and Mail Order Educational Information**

Mandatory generic and mandatory mail order programs must offer educational information for the consumer. (Mandatory)

## Pharmacy Distribution Channel Standards

### PHARM-DC 1 Scope of Services

The *organization* defines the scope of its services with respect to: (No Weight)

- (a) The distribution channels offered (e.g. *pharmacy network*, mail order pharmacies, or specialty pharmacies); (2)
- (b) The types of pharmacy services offered within each distribution channel; **and** (2)
- (c) The geographic area served by each distribution channel. (2)

### PHARM-DC 2 Access and Availability

With respect to *access* and *availability* of *pharmacies* to provide access to medications to *consumers*, for each distribution channel, the *organization*: (No Weight)

- (a) Establishes criteria; (4)
- (b) Measures actual performance in comparison to those criteria: **and** (4)
- (c) Makes improvements where necessary to maintain the *pharmacy network* and meet contractual requirements. (4)

### PHARM-DC 3 Quality and Safety Criteria

For each distribution channel, the *organization* maintains a mechanism to identify and address concerns related to: (No Weight)

- (a) Quality and safety of drug distribution; **and** (Mandatory)
- (b) Quality of service. (Mandatory)

## PHARM-DC 4 Out of Network Services

The *organization* has a mechanism to refer *consumers* and *prescriber* inquiries regarding methods to obtain covered medication from a participating pharmacy. (Mandatory)

## PHARM-DC 5 Participating Pharmacy Relations Program

The *organization* implements a *participating pharmacy relations* program to include: (No Weight)

- (a) Implementation of a *participating pharmacy* communications plan, to address at least:  
(4)
  - (i) Orientation of new *participating pharmacies*; (4)
  - (ii) Updates of network activities; (4)
  - (iii) Changes in fee schedules or contracting provisions; (4)
  - (iv) Informing *participating pharmacies* how to obtain *benefit*, eligibility, *formulary*, and *appeals* information; **and** (4)
  - (v) Mechanisms for the *availability* and distribution of current *participating pharmacy* manuals (or other documents describing the relationship between the *organization* and *participating pharmacies*). (4)
- (b) Assistance for *participating pharmacies* and their *staff* regarding *pharmacy* network issues; **and** (4)
- (c) Mechanism(s) to receive suggestions and guidance from *participating pharmacies* about how the *pharmacy network* can best serve *consumers*. (3)

## PHARM-DC 6 Participating Pharmacy Written Agreements

The *organization* has *written agreements* with *participating pharmacies*. (Mandatory)

## PHARM-DC 7 Written Agreement Inclusions

All new and revised *written agreements* (consistent with PHARM-DC 6) executed by the *organization* include the following elements: (No Weight)

- (a) A description of entities that are party to the *written agreement*; (4)
- (b) Licensure and other conditions for participation as a *participating pharmacy*; (4)
- (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; (4)
- (d) Events that may result in the reduction, suspension, or termination of network participation privileges; (4)
- (e) Term of the contract and procedures for terminating the contract; (4)
- (f) Terms and conditions for pharmacy audits; (4)
- (g) The specific circumstances under which the *organization* may require *access* to applicable *consumers'* records; (4)
- (h) Pharmacy services to be provided and any related restrictions; (4)
- (i) Requirements for claims submission and any restrictions on billing of *consumers*; (4)
- (j) *Participating pharmacy* payment methodology and fees; (4)
- (k) Mechanisms for dispute resolution by *participating pharmacies*; and (4)
- (l) Requirements with respect to preserving the confidentiality of *personal health information*. (4)

## **PHARM-DC 8 Written Agreement Subcontracting**

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 PHARM-DC 7. (Mandatory)

## **PHARM-DC 9 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*: (No Weight)

- (a) Address the items listed in PHARM-DC 7 that are not addressed in the *written agreement*; **or** (4)
- (b) Provide instructions on how to obtain the items listed in PHARM-DC 7 and not addressed in the *written agreement*. (4)

## **PHARM-DC 10 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: (No Weight)

- (a) A *participating pharmacy's* status within the *pharmacy network*; **or** (4)
- (b) Any action by the *organization* related to a *pharmacy's* competency or conduct; **or** (4)
- (c) Any contractual issues related to the distribution channel. (4)

## **PHARM-DC 11 Participating Pharmacy Suspension Mechanism**

The *organization* implements a mechanism, consistent with *written agreements*: (No Weight)

- (a) to change the participation status of a *participating pharmacy* which is engaged in behavior or who is practicing in a manner that: (Mandatory)

- (i) Poses a significant risk to the health, welfare, or safety of *consumers* or (Mandatory)
  - (ii) Promotes fraud and abuse. (Mandatory)
- (b) Investigates such instances on an expedited basis; **and** (Mandatory)
- (c) Makes the dispute resolution process available to any *participating pharmacy* subject to change of participation status. (4)

## PHARM-DC 12 Claims Processing

The *organization's* electronic 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, where applicable. (Mandatory)

## PHARM-DC 13 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. (Mandatory)

# Drug Utilization Management Standards

## DrUM 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: (No Weight)

- (a) Identifying the optimal drug use; (Mandatory)
- (b) Evaluating the available drug submission data: (Mandatory)
  - (i) Comparing between optimal (based on best available science)/appropriate and actual use in order to address discrepancies; (Mandatory)

(ii) Coordinating intervention when treatment alternatives are warranted; and (Mandatory)

(iii) Evaluating the effectiveness of *the drug utilization management* program; and (Mandatory)

(c) Timeliness of the reviews. (Mandatory)

## **DrUM 2 - Coverage Decisions Based on Clinical Information**

Coverage decisions based on clinical information include (No Weight)

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

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

(c) Comparing the efficacy as well as the type and frequency of side effects and potential drug interactions among alternative drug products; or (No Weight)

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

(e) Basing *formulary system* decisions on a thorough evaluation of the benefits, risks and potential *outcomes* for *consumers*. (Mandatory)

## **DrUM 3 - Review Criteria Requirements**

The *organization* utilizes explicit *clinical review criteria* that are: (No Weight)

(a) Developed with involvement from appropriate *prescribers* with current knowledge relevant to the *criteria*; (Mandatory)

(b) Based on current clinical principles and processes; (Mandatory)

(c) Evaluated at least annually and updated if necessary by: (Mandatory)

(i) the *organization* itself; and (4)

(ii) appropriate, actively practicing physicians and pharmacists, with current knowledge relevant to the *criteria*, and; (Mandatory)

(d) Approved by either the *medical director*, senior *clinical staff* person, *P & T Committee* or other equivalent *clinical oversight body*. (Mandatory)

## **DrUM 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: (No Weight)

(a) Therapeutic appropriateness; (Mandatory)

(b) Over and underutilization; (Mandatory)

(c) Generic Use; (Mandatory)

(d) *Therapeutic interchange*; (Mandatory)

(e) Duplication; (Mandatory)

(f) Drug-disease contraindications; (No Weight)

(g) Drug-drug or drug-allergy interactions; (Mandatory)

(h) Drug dosage; (Mandatory)

(i) Duration of treatment; (Mandatory)

(j) Clinical abuse or misuse; (Mandatory)

(k) Drug-age precautions; (Mandatory)

(l) Drug-gender precautions; (Mandatory)

(m) Drug-pregnancy precautions; and (Mandatory)

(n) Regulatory and *benefit* design limitations. (Mandatory)

## **DrUM 5 - Consumer Safety**

The *organization's drug utilization management, formulary* process and procedures have distinct systems for identifying and rectifying *consumer safety* issues including: (No Weight)

(a) A system for identifying and communicating drug-drug *consumer* safety issues at point-of service; and (Mandatory)

(b) A system of *drug utilization management* tools, such as prospective and concurrent DrUM that identifies situations which may compromise the safety of the *consumer*. (Mandatory)

## **DrUM 6 - General Transition Process Requirements**

The *organization* demonstrates evidence of a process for *formulary* management in *transitional situations*, such that the drug classes included cover common diseases and *conditions*. (3)

## **DrUM 7 - Review Service Disclosures**

The *organization* requires staff that provides *drug utilization* management information to identify themselves by first name, title, and *organization* name upon request. (2)

## **DrUM 8- Prospective Reviewer Qualifications**

Individuals who conduct prospective review: (No Weight)

(a) Are appropriate *health professionals* (including pharmacists); or (Mandatory)

(b) Are *pharmacy technicians* who follow DrUM 1 established *criteria*; and (Mandatory)

(c) If required by state law, possess an active professional relevant *license* in good standing. (Mandatory)

## **DrUM 9 - Rendering of Non-Certifications**

*Non-certifications* will be rendered by a pharmacist or physician. (Mandatory)

## **DrUM 10 - Automated Review**

*Organizations* with an *automated review* process must: (No Weight)

(a) Define the guideline-based algorithmic protocol being used; and (Mandatory)

(b) Validate the initial automated algorithm. (Mandatory)

## **DrUM 11 - Oversight of Automated Review Non-Certifications**

*Organizations* must have policies and procedures in place to provide oversight of the *automated review* process and its linkage to the *appeals* process by a: (No Weight)

(a) *Health professional*; (Mandatory)

(b) Senior *clinical staff* person; (Mandatory)

(c) *P & T Committee*; or (Mandatory)

(d) Other equivalent *clinical oversight body*. (Mandatory)

## **DrUM 12 - Exceptions**

The *organization* provides a process that allows *consumers* to request coverage of a *prescription drug* if the drug is not covered. (4)

## **DrUM 13 - Policies and Procedures for Excluded Drugs**

The *organization* will develop policies and procedures to define how it will handle excluded drugs. (2)

## **DrUM 14 - 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: (No Weight)

- (a) The *principal reasons* for the determination not to certify; (4)
- (b) A statement that the *clinical rationale* used in making the *non-certification* decision will be provided, in writing, upon request; **and**  
(4)
- (c) Instructions for: (4)
  - (i) Initiating an *appeal* of the *non-certification*; and (4)
  - (ii) Requesting a *clinical rationale* for the *non-certification*. (4)

## **DrUM 15 - 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*. (4)

## **DrUM 16 - Scope of Review Information**

The *organization*, when conducting *drug utilization management*: (No Weight)

- (a) Accepts information from an *evidence-based* process that will assist in the *certification* process; (3)
- (b) Collects only the information necessary to certify the *prescription*; and (2)

(c) Requires only the section(s) of the medical record necessary in that specific case to certify medical necessity or appropriateness of the *prescription*. (4)

## **DrUM 17 - Prospective and Concurrent Review Determination**

For *prospective review* and *concurrent review*, the *organization* bases review determinations solely on the clinical information available to the *organization* at the time of the review determination. (3)

## **DrUM 18 - Retrospective Review Determinations**

For *retrospective review*, the *organization* bases review determinations solely on the clinical information available to the *prescriber* or the *organization* at the time the medical care was provided. (3)

## **DrUM 19 - Lack of information Policy and Procedure**

The *organization* implements policies and procedures to address situations in which it has insufficient information to conduct a review. Such policies and procedures provide for: (No Weight)

(a) Procedural time frames that are appropriate to the clinical circumstances of the review (i.e., *prospective, concurrent, retrospective reviews*); and (2)

(b) Resolution of *cases* in which the necessary information is not provided to the *organization* within specified time frames. (2)

## **DrUM 20 - Appeals**

The *organization* should provides *access* to a formal *appeal* process which may include a mechanism to refer *appeal* inquiries to the plan administrator. (Mandatory)

## **DrUM 21 - Appeals Process Consumer Rights**

The *organization* must provide information to the *consumer* on how to request an *exception* and *appeal*. (Mandatory)

## DrUM 22 - Non-Certification Appeals Process

The *organization* maintains a formal process to consider *appeals* of *non-certifications* that includes: (No Weight)

- (a) The *availability* of *standard appeal* for non-urgent *cases* and *expedited appeal* for *cases involving urgent care*; and (Mandatory)
- (b) Written *appeals* policies and procedures that: (Mandatory)
  - (i) Clearly describe the *appeal* process, including the right to *appeal* of the *consumer* or *prescriber*; (Mandatory)
  - (ii) Provide for explicit time frames for each stage of the *appeal* resolution process; **and** (Mandatory)
  - (iii) Are available, upon request, to any *consumer* or *prescriber*. (Mandatory)

## DrUM 23 - Appeals Process

As part of the appeals process: (No Weight)

- (a) The *organization* provides the *prescriber*, *consumer* or *provider* (on behalf of the *consumer*) the opportunity to submit written comments, documents, records, and other information relating to the *case*; (Mandatory)
- (b) Takes all such information into account, in a timely manner, during the *appeals* process without regard to whether such information was submitted or considered in the initial consideration of the *case*; (Mandatory)
- (c) Ensures the *appeal* is reviewed by a *clinical peer*; and (Mandatory)
- (d) In instance of a first level *appeal*, the *organization* implements the decision of the first level clinical *appeal* if it overturns the initial *non-certification*. (Mandatory)

## DrUM 24 - Appeal Peer Reviewer Qualifications

*Appeals considerations* are conducted by *health professionals* who: (No Weight)

(a) Are *physicians, pharmacists, as permitted by state appeal laws, or clinical peers*; (Mandatory)

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

(c) Are *board-certified* (if applicable) by: (3)

(i) A specialty board approved by the *American Board of Medical Specialties* (doctors of medicine); **or**  
(3)

(ii) The *Advisory Board of Osteopathic Specialists* from the major areas of clinical services (doctors of osteopathic medicine); (3)

(d) Are in a similar specialty that typically manages the medical *condition*, procedure, or treatment; **and** (Mandatory)

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

## DrUM 25 - Expedited Appeals Process Timeline

*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. (Mandatory)

## DrUM 26 - 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*. (Mandatory)

## DrUM 27 - Written Notification of Upheld Non-Certifications

For *appeals* determinations, the *organization* issues *written notification* of the adverse *appeal* decision to the consumer and *prescriber* that includes: (No Weight)

- (a) The *principal reasons* for the determination to uphold the *non-certification*; (4)
- (b) A statement that the *clinical rationale* used in making the *appeal* decision will be provided, in writing, upon request; **and** (4)
- (c) Information about additional *appeal* mechanisms available, if any. (4)

## DrUM 28 - Appeal Record Documentation

The *organization* maintains records for each *appeal* that includes: (No Weight)

- (a) The name of the *consumer*, or *prescriber*; (4)
- (b) Copies of all correspondence from the *consumer* and the *organization* regarding the *appeal*; (4)
- (c) Dates of *appeal* reviews, documentation of actions taken, and final resolution; (4)
- (d) Minutes or transcripts of *appeal* proceedings (if any); (4)
- (e) Name and credentials of the *clinical peer*, and (4)
- (f) Specific *clinical review criteria* upon which the *non-certification* was based. (4)

## P & T Standards / Formulary Development

### PTFD 1 - P & T / Formulary Development

The *organization* has a process to ensure that it promotes clinically appropriate, safe, and cost-effective drug therapy which shall include a: (No Weight)

- (a) *Pharmacy & Therapeutics(P & T) Committee*; (Mandatory)
- (b) *Formulary* management decision-making process; and a (Mandatory)
- (c) Process for regular evaluation and review. (Mandatory)

## **PTFD 2 - Formulary Management Decision Making**

The *organization* has a clearly defined *formulary* management process that includes the following: (No Weight)

- (a) Drugs' therapeutic advantages (safety and efficacy) must be considered when selecting *formulary* drugs. (Mandatory)
- (b) Established and documented procedures to assure appropriate drug review and inclusion. (Mandatory)

## **PTFD 3 - Economic Formulary Considerations**

Economic considerations include (when available), but are not limited, to the following: (No Weight)

- (a) Basing *formulary* system decisions on cost factors only after the safety, efficacy and therapeutic need have been established. (Mandatory)
- (b) Evaluating equivalent alternative drug products and therapies in terms of their impact on health care costs. (4)

## **PTFD 4 - Organizational Specifications**

The *organization* must: (No Weight)

- (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. (3)

(b) Provide *consumer* education that explains how *formulary* decisions are made and the roles and responsibilities of the consumer. (4)

(c) Disclose the existence of formularies and have copies of the *formulary* readily available and *accessible*. (4)

## **PTFD 5 - P & T Committee Membership**

Members of the *Pharmacy and Therapeutics Committee* include: (No Weight)

(a) Various clinical specialties that represent the needs of the plans beneficiaries; (3)

(b) Representation of or consultation with appropriate specialists; (3)

(c) A majority must be practicing physicians, practicing pharmacists or both; (3)

(d) At least one practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons; and (3)

(e) At least one practicing pharmacist and one practicing physician independent and free of conflict (health plan & pharmaceutical manufacturers). (3)

## **PTFD 6 - P&T Committee Conflict of Interest**

Members of the *Pharmacy and Therapeutics Committee* must sign a *conflict of interest* statement, updated annually, revealing economic interests or relationships that could influence committee decisions. (No Weight)

## **PTFD 7 - P & T Committee Policies and Procedures**

*Formulary system* policies: (No Weight)

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

(b) Require *P & T Committee* members to adhere to the *formulary system's* policy on disclosure and participation in discussion as it relates to *conflict of interest*.  
(Mandatory)

## **PTFD 8 - 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. (2)

## **PTFD 9 - P & T Committee**

The *Pharmacy and Therapeutics Committee*: (No Weight)

- (a) Objectively appraises, evaluates, and selects drugs for the *formulary*. (2)
- (b) Evaluates, analyzes, and reviews policies and procedures to educate and inform health care *providers* about drug products, usage, and committee decisions. (2)
- (c) Evaluates, analyzes, and reviews protocols and procedures for the use of and *access* to non-*formulary* drug products. (2)

## **PTFD 10 - Interface with Quality Improvement & DrUM Programs**

The *organization* must have a policy and procedure to define how the *P & T Committee* interfaces with the quality improvement and *drug utilization management* programs. (2)

## **PTFD 11 - Timely Consideration of New Drugs**

The *Pharmacy and Therapeutics Committee* will establish a policy and procedure that addresses timely consideration of new chemical entities covered under the pharmacy *benefit* once released onto the market. (2)

## **PTFD 12 - 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: (No Weight)

- (a) A policy for use and access of drug products prior to *formulary* review; and (Mandatory)
  
- (b) *Formulary* management activities, such as prior authorizations, step therapies, quantity limits, *generic substitutions*, drug utilization and related activities that affect *access*. (Mandatory)