



## **ASHP ACCREDITATION STANDARD FOR COMMUNITY AND OUTPATIENT PHARMACY PRACTICE**

### **Introduction**

The ASHP Accreditation Standard for Community and Outpatient Pharmacy Practice reflects contemporary best practice for community and outpatient pharmacy. The accreditation process is designed to be easy to understand, flexible, and consultative in nature and can be tailored to different models of care.

The accreditation focuses on optimal care delivery through evaluation of:

- Organizational structure
- Professional and support staff requirements
- Environment to deliver quality services
- Patient care services
- Patient counseling and education
- Documentation of patient management activities
- Quality improvement program
- Ongoing quality training and education for pharmacy staff

This standard combines the Center for Pharmacy Practice Accreditation (CPPA) standards<sup>1</sup> with the support of ASHP's pharmacy expertise and accreditation history. Successful accreditation signifies to payers, patients, and other healthcare providers that the pharmacy provides an advanced level of high-quality, safe, and efficient patient care in a predictable and measurable way.

### **Purpose of the Standard for Community and Outpatient Pharmacy Practice**

Pharmacy practice in all sectors is evolving rapidly. The development of a standards-based accreditation process promotes continuous quality improvement, consistency, and "to ensure medication safety and

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<sup>1</sup> Version II, December 20, 2016; Standards used with permission of Center for Pharmacy Practice Accreditation (CPPA)

effectiveness and quality of medication use for desired health outcomes.”<sup>2</sup> Established standards help to guide, describe and gain recognition for innovative, high quality, safe and effective practices.

Scope of Standard: The Standard for Community and Outpatient Pharmacy Practice addresses three primary areas, which encompass the overall provision of patient care in the community and outpatient pharmacy setting. These areas of focus include the organizational infrastructure, or practice management, to support the provision of community and outpatient pharmacy care, clinical management of the patient, and quality.

Specifically, the standard are organized under the following Standard Domains:

- 1.0 Practice Management
- 2.0 Patient Care Services
- 3.0 Quality Improvement

Within each Standard Domain are key elements that demonstrate competency in the identified area of community and outpatient pharmacy practice. The accompanying narrative for each standard element describes the specific criteria for evaluation of the community and outpatient pharmacy practice to determine consistency with the standard for accreditation.

It is expected for accreditation that patient care and support services provided by the community and outpatient pharmacy practice and as described in their Scope of Services demonstrate compliance with applicable state and national regulatory requirements and/or standards established by a recognized organization appropriate for the services provided.

All standard elements are required for accreditation except those designated as “Goal.” Accredited practices will be expected to be working toward these “Goals.” As practices evolve, “Goals” will eventually be required for accreditation.

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<sup>2</sup> Nahata M, et al. The academy’s agenda for improving the safety use: report of the 2006–2007 Argus Commission. Am J Pharm Ed. 2007;71(6) Article S18.

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## STANDARD DOMAIN 1.0: Practice Management

**1.0 The pharmacy practice is appropriately managed to allow for safe and effective delivery of services.**

**1.1 The pharmacy practice has a well-defined organizational structure that supports the safe and effective provision of services.**

**NARRATIVE:**

The practice has structural components to evidence a well-defined organizational structure:

1. A patient-centered mission statement that reflects the services provided. The mission statement is posted in the practice setting to serve as a reminder to the staff of the focus of the practice and is reviewed by leadership and staff regularly.
2. A description of each patient service, including the dispensing services. Descriptions of such services are provided in a manner that allows staff to understand what is expected of them and so they may convey information about these services to patients. Descriptions include the name of the service, the population(s) served, the intended goal of the service, additional costs to the patient and other information as appropriate.
3. Organizational goals for each patient care service. Pharmacy practices evaluate their patient population and establish clinical practice goals and other metrics, such as enrollment rate goals and patient satisfaction goals, tailored to the specific needs of their patients. For example, if a pharmacy's highest risk population is composed of elderly patients, establish a clinical practice goal that promotes influenza vaccination for those patients.
4. A well-defined organizational structure that supports the safe and effective provision of services. The pharmacy practice has a clearly defined organizational leadership structure which encourages the reporting of safety risks and demonstrates the value of doing so. The practice establishes a process appropriate to the size of the organization for escalating safety concerns or information that warrants management's attention. The practice may include, as part of the escalation plan, access to a means of anonymous reporting, such as the use of a compliance hotline.
5. Current policies and procedures that are readily available and followed by appropriate pharmacy staff in everyday practice. Pharmacy practices have a standardized, documented process to maintain, review, and update, policy and procedure documents regularly. This process also occurs when circumstances require, such as the enactment of a new regulation or a change in practice. New or revised policies and procedures are provided to the pharmacy staff in a readily-retrievable format, such as online or an easily accessed binder in each facility, and when necessary, staff is provided training and education.

**1.1.1 The pharmacy practice has a written code of conduct demonstrating the practice's commitment to provision of ethical care and services.**

**NARRATIVE:**

- The community and outpatient pharmacy practice has a written code of conduct that articulates the practice's commitment to the provision of ethical care and services. The written code of conduct articulates the practice's commitment to comply with all applicable statutory and regulatory requirements and includes expectations of its staff and

professional pharmacy partners to act in an ethical and compliant manner and ramifications of failure to comply with these expectations i.e. disciplinary actions.

- The code of conduct should encourage employees, management, and board members or other governing body members to report violations of law and policy to the community and outpatient pharmacy practice and/or to the board of pharmacy of the state and/or to law enforcement.
- The code of conduct is approved and reviewed periodically by the community and outpatient pharmacy practice board of directors and senior management.

## **1.2 The pharmacy practice has appropriate professional and support staff to deliver quality services.**

### **NARRATIVE:**

The practice has structural components which evidence compliance with this standard:

1. Job descriptions for each category of staff. These descriptions evidence clear separation of duties, so each person, according to his or her category, understands precisely and in sufficient detail the duties and activities that are expected and permitted in the course of performing his or her job. The usual categories for job descriptions include the roles and responsibilities of the pharmacist-in-charge, the pharmacy manager, the staff pharmacist, the pharmacy graduate intern, the student pharmacist, the pharmacy technician, ancillary pharmacy staff, and other health care providers<sup>3</sup> where applicable. The practice ensures that all employees, even the newest or least experienced, are vigilant about performing only those tasks permitted by their category, understand the practice's policies and procedures, and know who to contact with concerns about their scope of practice.
2. Current policies and procedures for hiring and credentialing personnel. Hiring and credentialing practices are standardized and documented in order to review and maintain competent staff. Such practices include those related to ensuring all staff complies with continuing education requirements of the relevant licensing or credentialing board.
3. A performance appraisal system that includes an annual performance review aligned to the duties, responsibilities, and roles required for each staff member and defined measures of success. Pharmacy practices recognize the power of performance evaluations, and they ensure that these evaluations are crafted to incentivize staff to support and promote positive patient outcomes and compliance with policy and rules, rather than primarily focusing on volume or financials.
4. A process to collect, evaluates, and document pharmacy workload and performance data, and utilizes these data to improve patient safety. The pharmacy annually establishes metrics to measure the effectiveness of the staffing model, taking into account the appropriate workload or financial expectations of the pharmacy staff without compromising patient safety. The pharmacy practice has a mechanism to gather staff input on staffing effectiveness and validate and address any concerns.
5. Sufficient professional, technical, and support staff resources to fulfill the mission of the practice, deliver patient care services, and ensure quality and patient safety. The practice evaluates staffing ratios and mix based on quality and safety factors.

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<sup>3</sup> A health care provider refers to any health care professional, health care organization and its staff. Examples of health care providers involved in the collaborative care of telehealth pharmacy practice patients may include pharmacists, nurses, physicians, physician assistants and other healthcare practitioners, community pharmacies, home health agencies, inpatient and outpatient facilities, and clinical laboratories.

**GOAL:**

The practice promotes Continuing Professional Development as a model for ensuring pharmacist competence, including personal self-appraisal, educational plan development, documentation, and evaluation.<sup>4</sup>

**1.3 The pharmacy practice has an appropriate environment to deliver quality services.****1.3.1 Pharmacy practice provides patient care services in a setting that maintains privacy and confidentiality.****NARRATIVE:**

1. Pharmacy staff members are aware of privacy requirements and take measures to secure patient information and protect patient privacy and confidentiality.
2. The practice ensures that patients receive services in a space that provides the level of privacy required by state and federal law.
3. Additional privacy accommodations are considered in response to patient requests and feedback received by patients (see Standard 4.3).

**1.3.2 Pharmacy practice environment provides appropriate capabilities to provide quality services.****NARRATIVE:**

Pharmacy practice has adequate space to conduct its operations. Staff implements workflow designs that provide for safe dispensing practices and delivery of patient care services. Environments have been created to minimize interruptions and allow staff to concentrate on their assigned duties. Practice site is neat, clean, and organized to maintain and project a professional appearance. Patient care services, such as comprehensive medication reviews, are delivered in an environment that provides comfort to the patient. Where appropriate, the environment allows for conducting point-of-care testing and immunization services.

**1.4 The pharmacy practice uses information systems and technology to support quality service delivery.****1.4.1 Pharmacy practice information systems allow for documentation into a patient record of appropriate medical/health information including but not limited to prescription medications, over-the-counter medications, dietary supplements, immunizations, allergies, laboratory values, diagnoses, and other information required to deliver available patient care services.****NARRATIVE:**

The pharmacy practice ensures that pharmacy information systems are utilized to ensure patient identity and document all clinically relevant patient information in one location at the point of care. The practice includes all clinically relevant patient information in the pharmacy

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<sup>4</sup> The Council on Credentialing in Pharmacy Resource Document Continuing Professional Development in Pharmacy © Copyright 2004, <http://www.pharmacycredentialing.org/Files/cpdprimer.pdf>.

information system, including patient demographics, patient allergies, over-the-counter medications, dietary habits and supplements, clinically relevant laboratory values when available, and patient diagnosis information when available. Patient information is obtained from a reliable source such as the patient's physician, patient care discharge documentation, or by patient self-reporting and documented as such. All information is stored and made accessible in a manner that facilitates effective pharmacist communications with other pharmacists in the practice, patients, caregivers, prescribers, other appropriate health care providers, or organizations. Pharmacy information systems may be electronic or paper-based systems.

**GOAL:**

The pharmacy practice implements an electronic pharmacy information system that facilitates access to clinically relevant patient information.

**1.4.2 Pharmacy practice information systems support the pharmacist performing effective prospective and retrospective drug utilization review.**

**NARRATIVE:**

1. Pharmacy practice information systems assist the pharmacist in checking the prescription medication order and/or patient profile prior to dispensing for: proper and/or reasonable dosage, duplicate medication therapy, drug interactions including dietary and non-prescription medications, frequency, route of administration, rational therapy contraindications, patient allergies, and/or potential or actual adverse drug reactions.
2. The pharmacy practice information system provides integrated clinical decision support that informs the pharmacist about interactions, therapeutic duplications, and timeliness of fill prior to final verification or dispensing. Updated clinical decision support modules are part of the pharmacy information system and provide some automated review of patient profile information and clinical alerts to the pharmacist.
3. The pharmacy practice has a system that reduces alert fatigue and provides the most clinically relevant information to the pharmacist regarding the patient's medication therapy. In addition, the pharmacy practice ensures that this clinical information is available at the point of care, at the location where counseling occurs, and to the pharmacist who is performing the counseling.

**1.4.3 Pharmacy practice information systems provide access to appropriate evidence-based references and clinical decision support programs that facilitate the delivery of patient care services.**

**NARRATIVE:**

Pharmacy information systems provide access to clinical decision support programs that include current drug interaction and adherence screening methodologies for guidance in up-to-date clinical decision making efforts. The pharmacy practice ensures that the software is readily available and routinely updated to assist the pharmacy staff in effective clinical decision making. The pharmacy practice establishes expectations for utilization of the most current references and the primary literature in the provision of patient care services.

**GOAL:**

The pharmacy practice provides access to clinical decision support programs, as described by AHRQ, that aid in guiding evidence-based decision making.

**1.4.4 Pharmacy practice uses systems and technology that support safe medication distribution processes and facilitate patient safety.****NARRATIVE:**

The pharmacy practice has implemented technology and/or uses other tools that limit the opportunity for misfills. Examples of this technology may include, but are not limited to, bar-code verification of ordered drug and stock bottle and the presentation of an image of the intended medication for the pharmacists at verification. Other tools include biometric verification and photo image verification of tablet/capsule descriptions.

Pharmacy practice has systems, policies, and procedures in place to appropriately manage drug recalls, outdated drugs, and returned drugs. If the pharmacy practice participates in a drug take-back program, it complies with applicable regulations as well as established policy and protocol.

**1.5 The pharmacy practice supports the interoperability of information systems.****1.5.1 Pharmacy practice implements strategies to facilitate exchange of medical/health and medication information.****NARRATIVE:**

The exchange of data occurs via fax or telephone or other appropriate method.

**GOAL:**

The pharmacy practice explores strategies for and takes steps to implement technology to electronically interface with other health care entities to exchange information by means of electronic health records (EHR).

**1.5.2 Pharmacy practice supports e-prescribing transmissions.****NARRATIVE:**

The pharmacy practice systems are able to accept e-prescribing transmissions.

**1.6 The pharmacy practice implements policies and procedures to maintain the integrity, security, and privacy of patient information and other data.****NARRATIVE:**

1. The pharmacy practice has policies and procedures to ensure information systems and technology are tested, validated, and updated on a routine basis.
2. The pharmacy practice information system utilizes the most recent National Council for Prescription Drug Programs standards or other appropriate standard(s), and the practice routinely receives updates to ensure use of current standards.

3. Pharmacy practice information systems have routine maintenance, validation, update, back-up, cyber security, and data-retrieval systems.
4. Pharmacy practice has a continuity plan in the event that pharmacy practice information systems fail. The pharmacy practice has implemented a reliable disaster recovery plan that is tested periodically.
5. Pharmacy practice has quality assurance mechanisms to monitor and respond to concerns with performance of pharmacy information systems and technology.
6. Pharmacy practice data are secure and protected from unauthorized access. The practice protects and secures the integrity of patient and transactional data. Pharmacy practice has protocols to establish (provision) access to sensitive information including patient and human resource information, to revoke (deprovision) access when appropriate, and to periodically evaluate employee lists for properly continuing access at existing level. The practice ensures that the pharmacy information systems containing patient information meet or exceed security requirements of the Health Insurance Portability Accountability Act (HIPAA), the Payment Card Industry Data Security Standard, and other industry standards governing the protection of electronic protected health information. The pharmacy practice ensures the maintenance of standard operating procedures including documentation of all staff with access to patient information.

### **1.7 The pharmacy practice develops business models to support the delivery of patient care services.**

#### **GOAL:**

The pharmacy practice develops the business model(s) to support the delivery of value-added patient care services. The pharmacy practice is encouraged to take advantage of compensation opportunities for patient care services, which may include direct billing to health plans, patient self-pay, or participation in emerging health care delivery models such as accountable care organizations.

## **STANDARD DOMAIN 2.0: Patient Care Services**

### **2.0 The pharmacy practice provides patient-centered services.**

#### **2.1 The pharmacy practice develops, implements, and oversees patient-centered services focused on improving patient medication use, health, and wellness.**

##### **2.1.1 Patient care services are developed and delivered under the oversight of a pharmacy practice based on the following framework:**

###### **2.1.1.1 Established need in the practice's patient population.**

#### **NARRATIVE:**

1. The pharmacy practice provides evidence-based, patient focused care that targets the pharmacy practice's patient population. The pharmacy practice conducts evaluations of patient populations utilizing information such as demographics and/or patient-focused surveys to identify opportunities to develop and improve services.

2. While executive leadership within an organization may establish patient care initiatives that apply to all pharmacies, the individual pharmacy practice also evaluates their patient populations and designs initiatives that target clinical care specific to their needs.

#### **2.1.1.2 Evidence-based guidelines and best practices, when available.**

##### **NARRATIVE:**

Examples of evidence-based guidelines and sources for outcomes measures include:

- Adherence and other measures
  - Pharmacy Quality Alliance (PQA) Measures
- Asthma
  - National Asthma Education and Prevention Program Guidelines for the Diagnosis and Treatment of Asthma
- Anticoagulation services
  - Chest – Antithrombotic and Thrombolytic Therapy 8th Edition – American College of Chest Physicians Guidelines
- Cholesterol management
  - Guidelines National Cholesterol Education Program (NCEP) Guidelines
- Chronic kidney disease
  - National Kidney Foundation KDOQI Clinical Practice Guideline for Diabetes and Chronic Kidney Disease
- Chronic obstructive pulmonary disease
  - GOLD Standard for Chronic Obstructive Pulmonary Disease
- Diabetes care
  - American Diabetes Association Standards of Medical Care in Diabetes
  - American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan
- Drug shortages
  - American Society of Health-System Pharmacists Drug Shortages
- Heart failure
  - American Heart Association Get With the Guidelines-Heart Failure
- Hepatitis C
  - Department of Veteran’s Affairs and National Hepatitis C Program
- HIV/AIDS
  - Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents
- Hypertension
  - Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- Immunization services
  - American Pharmacists Association Immunization Guidelines;
  - Centers for Disease Control Immunizations Recommendations and Guidelines
- Medication reconciliation across transitions of care

- Agency for Healthcare Research and Quality (AHRQ) Medication at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation
- Medication therapy management (MTM) services
  - Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model
  - The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes (Patient-Centered Primary Care Collaborative)
- Non-sterile and sterile compounding
  - U.S. Pharmacopeia Chapters <795> and <797>
- Outcome measures
  - PQA Measures
  - National Committee for Quality Assurance (NCQA Measures)

#### **2.1.1.3 Efforts to collaborate with physicians and other health care providers.**

##### **GOAL:**

1. Pharmacists have a relationship with the prescribers caring for their patients. The pharmacy practice demonstrates efforts towards a coordinated, team-based approach to patient care whereby patient clinical goals are shared between the patient's physician and pharmacist. The pharmacy practice fosters collaborative relationships that may include activities such as educational sessions on medication therapy updates, provision of drug information, team meetings/visits, etc. A team based approach to patient care, which includes referrals to or from physicians and other providers and entities such as hospitals, nursing homes, assisted living facilities, and wellness centers, is evidenced by referral forms and documentation of communications with such providers and entities.
2. Pharmacy practice supports collaborative practice agreements with physicians and other health care providers, in accordance with state practice acts and where feasible.

#### **2.1.1.4 Needs of individual patients.**

##### **NARRATIVE:**

The pharmacy practice has systems in place to evaluate the individual needs of patients, and patient care services are delivered with a focus on addressing the patient's medication, therapeutic, and consultation needs.

#### **2.1.1.5 Appropriate documentation and communication of patient care to physicians and other health care providers by pharmacists and other staff to enhance continuity of care among health care providers.**

##### **NARRATIVE:**

The pharmacy practice documents and communicates appropriate information to prescribers and other health care providers, including consultation on the selection of medications, patient care plan that incorporates recommendations to address identified medication and other

health-related problems, services provided, updates on the patient's progress, and recommended follow-up.

**GOAL:**

Pharmacy practice is exploring strategies to implement electronic systems that can generate and receive structured documents using the Systemized Nomenclature of Medicine–Clinical Terms (SNOMED CT) MTM Value Set and other applicable codes for documenting patient care services.

**2.1.2 Pharmacists deliver medication therapy management services.**

**NARRATIVE:**

1. The pharmacy practice offers medication therapy management (MTM) services delivered by a pharmacist focused on improving patients' therapeutic outcomes.<sup>5</sup> The MTM services are patient-centered, based on individual patient need, and use a standard patient care process. Delivery of MTM services includes a comprehensive approach to identifying and resolving medication therapy problems in collaboration with other health care providers during the time period the patient is under the pharmacist's care. The service design empowers patients to take an active role in managing their medications.
2. MTM services may be targeted to specific patients. The practice conducts evaluations of patient populations utilizing information such as number of prescriptions/patient, patient-focused surveys, or health plan initiatives, to identify those patients in need of MTM services.

The MTM service design follows the model, Medication Therapy Management In Pharmacy Practice: Core Elements of an MTM Service Model<sup>6</sup>. More complex MTM services, including initiating or modifying medication therapy and ordering laboratory tests pursuant to collaborative practice agreements with prescribers are highly encouraged, but not required. The Core Elements service model includes:

- **Medication Therapy Reviews**, both comprehensive and targeted, whereby the pharmacist identifies and resolves the patient's medication therapy problems
- **Personal Medication List** for the patient that includes an accurate list of all of the patient's prescription and nonprescription medications, herbals and other dietary supplements. The patient shares this list with other health care providers to improve continuity of care and prevent adverse events due to medications. The list is updated during follow-up monitoring.
- **Medication Action Plan** for the patient that includes action items for the patient to improve medication therapy outcomes. The plan is updated during follow-up monitoring.
- **Intervention/Referral** whereby the pharmacist intervenes with the patient, prescriber, or appropriate provider to address potential problems/issues identified during medication reviews. As appropriate, the pharmacist refers the patient to other providers/services based on information discussed in the medication therapy review.

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<sup>5</sup> Bluml BM. Definition of medication therapy management: development of profession-wide consensus. *J Am Pharm Assoc.* 2005; 45:566–72.

<sup>6</sup> American Pharmacists Association; National Association of Chain Drug Stores Foundation. *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model.* Version 2.0. March 2008. Available at: <http://www.pharmacist.com/MTM/CoreElements2>.

- **Documentation/Follow-up** whereby pharmacist documents the MTM visit in the patient's chart, including the patient's goals of therapy, care plan, interventions and referrals made, communication with the prescriber, etc. The pharmacist will document this episode in a retrievable format that is accessible to all pharmacy staff, real time, at the point of care. A follow-up visit is scheduled for the patient for ongoing monitoring as appropriate. (See the Core Elements service model for more information.)

**2.1.2.1 Comprehensive medication reviews are conducted to obtain a complete medication history, assess the appropriateness of medication therapy, and create a reconciled medication list and a care plan for the patient.**

**NARRATIVE:**

1. The pharmacist collects necessary subjective and objective information about the patient including a complete medication history (prescription and nonprescription medications, herbals and other dietary supplements) to understand the relevant medical/medication history and clinical status of the patient.
2. The pharmacist comprehensively assesses the patient's medical history, medications, laboratory results, socio-economic factors, health literacy, cultural issues, and other relevant data and the clinical effects of the patient's therapy, including medication adherence, to identify and resolve problems.
3. The pharmacist develops patient-centered goals and a care plan in collaboration with the patient and other health care providers.
4. The pharmacist implements the care plan, including providing patient education and training to improve the patient's self-management of this or her medications.
5. The pharmacist monitors the outcomes of the patient's therapy and/or transitions the patient to the appropriate health care provider as necessary.

**2.1.2.2 Targeted medication reviews are conducted for ongoing monitoring of medications and interventions to address specific medication-related problems.**

**NARRATIVE:**

Targeted medication reviews are conducted by the pharmacist when:

- Follow-up monitoring is needed to address problems identified during a comprehensive medication review. For example, targeted medication reviews to address medication adherence issues, high risk medications, or ongoing monitoring of cholesterol medications
- The patient experiences a new medication-related problem that needs to be addressed.

The pharmacist assesses the new therapy problem or reassesses the problem needing monitoring, intervenes where necessary, and provides education and information to the patient, the prescriber, or both, as appropriate. Ideally, targeted medication reviews are performed for patients who have received a comprehensive medication review within the past year.

**2.1.3 The pharmacy practice provides additional patient care services, such as the following health-related services:**

- **Health and wellness services (e.g., blood pressure screenings, cholesterol screenings, osteoporosis screenings, smoking cessation programs, weight loss programs)**
- **Immunization services**
- **Programs to monitor and improve patients' medication adherence**
- **Care transitions services**
- **Chronic disease education services**
- **Chronic disease management services**

**NARRATIVE:**

1. The pharmacy practice delivers value-added patient care services that improve the quality of patient care and overall patient health. The pharmacy practice implements patient care services that target their unique patient population. Patient care services chosen are:
  - Focused on the pharmacy's patient populations and potential patient volume to receive such services.
  - Implemented with adequate training, education, or certification of pharmacy staff to manage and deliver these services.
2. The pharmacy practice has policies and procedures for all patient care services in the practice. The policies and procedures include the responsibilities of pharmacy staff, patient management procedures, clinical documentation, laboratory testing procedures where appropriate, communication with primary care physicians or others involved in patient's care and other relevant areas where appropriate.
3. The practice offers two or more patient care services. Adherence programs in this standard are based on patient-specific needs and comprise services beyond refill reminders.
4. Services may be provided by the pharmacy staff or by contracted health care providers whose activities are under the control of the pharmacy practice. The services, delivered by contracted health care providers, comply with these standards, and the pharmacy practice receives documentation of patient care delivered by the contracted health care providers and integrates the documentation into the patient record.

**2.2 The pharmacy practice proactively provides counseling to patients regarding medications and related products.**

**2.2.1 The pharmacy practice has a defined process for patient counseling.**

**NARRATIVE:**

1. The pharmacy practice obtains, records, and maintains at least the following information required by OBRA 90<sup>7</sup> before a prescription is filled and delivered to a patient.
  - Name address, telephone number, date of birth (or age) and gender
  - Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
  - Pharmacist comments relevant to the individual's drug therapy.

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<sup>7</sup>Source: Omnibus Budget Reconciliation Act of 1990. Public Law 101-508, S4401, 1927(g). November 5, 1990. Available at <http://thomas.loc.gov/>. Accessed February 14, 2013.

2. The pharmacy practice follows OBRA 90 in conducting prospective Drug Utilization Review (DUR) before a prescription is filled and delivered to a patient. DUR includes screening for potential drug therapy problems due to
  - Therapeutic duplication
  - Drug-disease contraindications
  - Drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs)
  - Incorrect drug dosage or duration of drug treatment
  - Drug-allergy interactions
  - Clinical abuse/misuse.
3. The pharmacy practice follows OBRA 90 requirements when conducting patient counseling pursuant to a prescription order including:
  - Name and description of the medication.
  - Route, dosage form, dosage, route of administration, and duration of drug therapy.
  - Special directions and precautions for preparation, administration and use by the patient.
  - Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
  - Techniques for self-monitoring drug therapy.
  - Proper storage.
  - Prescription refill information
  - Action to be taken in the event of a missed dose.

**2.2.2 Pharmacists ascertain the patient’s understanding of medication therapy and provide counseling based on need determined by the pharmacist and/or when requested by the patient; minimally, counseling occurs upon medication initiation, with any change to medication therapy, for high-risk medications, and for high-risk patients.**

**NARRATIVE:**

1. The pharmacist assesses patient understanding and counsels the patient upon the first fill of any new medication, with the first fill of any change to a medication therapy regimen, when the pharmacist, in his or her professional judgment, determines that counseling is required, or any time the patient requests. The pharmacy practice prioritizes this activity and establishes workflows that provide adequate staffing and availability to ensure that this patient interaction occurs. Pharmacy staff are able to describe the patient counseling process and surveyors are able to observe it in practice
2. The pharmacy practice identifies high-risk medications, high-risk patient populations, or other evidence-based factors that require pharmacist counseling.
3. Pharmacists take the initiative to counsel (an “offer to counsel” by a clerk or pharmacy technician does not meet this standard). If the patient refuses counseling, then such refusal must be documented in the patient’s record.

**2.2.3 Pharmacy practice encourages patient-initiated questions using a variety of methods and materials.****NARRATIVE:**

1. The pharmacy practice provides resources and information to encourage patient-initiated questions, which may include, but is not limited to, phone numbers, e-mail addresses, or Web sites, that connect the patient with a pharmacist to receive patient counseling. The pharmacy practice utilizes practice resources that facilitate patient-pharmacist interaction and education.
2. Pharmacy staff prioritizes and makes sufficient time for opportunities to education patients about their medication regimens, and leadership designs adequate time and resources into workflow to allow and encourage such counseling. In addition, staff are evaluated based on their proficiency in this skill.

**2.2.4 Pharmacy practice uses tools and resources that supplement and support patient counseling.****NARRATIVE:**

The pharmacy practice utilizes delivery formats to provide additional sources of information that may supplement and support patient counseling for the purpose of increasing patient understanding and improving adherence. Such delivery formats may include but are not limited to printed patient information, e-mail and telephone communication, reliable and accurate Web sites, text messages, real-time Internet communication, or other means of communication.

**2.2.5 Pharmacists use a variety of communication mechanisms for providing patient counseling tailored to the needs of the patient.****NARRATIVE:**

1. Pharmacists provide counseling using various communication mechanisms, the selection of which is based on the individual needs of the patient. These mechanisms may include face-to-face conversations, e-mail, telephone communication, video conferencing, or other means as appropriate for the patient.
2. Pharmacy staff address any special communication needs of the patient, including but not limited to low health literacy, cultural influences relevant to medication therapy, or language barriers.

**2.2.6 Pharmacy practice has policies and procedures for documenting pertinent patient counseling that facilitate continuity of care.****GOAL:**

Pharmacy practice implements policies and procedures that define the information for documentation related to patient counseling. The important and pertinent information from the patient counseling session is documented in the patient record (patient profile and/or electronic medical record), This information is available and communicated as appropriate to other

pharmacists in the practice, health care providers, and caregivers in order to improve continuity of care and overall patient care.

**2.3 The pharmacy practice evaluates competency and facilitates continuing professional development of staff involved in patient care service delivery based on the complexity of services and needs of patients.**

**NARRATIVE:**

The pharmacy practice has implemented clear program requirements for evaluating the competency and educating staff involved in patient care delivery. The pharmacy practice has a process to evaluate pharmacy staff for areas of aptitude, and will provide or facilitate opportunities for continuing professional development of skills and competencies required to provide safe, high quality patient care. The specific competencies are based on factors such as patient population needs and the patient care services provided.

**2.4 The pharmacy practice has a process for evaluating the effectiveness of patient care services.**

**NARRATIVE:**

The pharmacy practice provides resources necessary to ensure pharmacists provide high quality patient care services. The pharmacy practice collects data for analysis and uses the analysis and other recognized quality measures to monitor and improve patient care outcomes. The pharmacist or appropriate pharmacy staff establishes meaningful metrics to monitor the outcome of care activities. Such metrics may include:

- Adherence metrics (30-, 60-, 90-day evaluation points)
- Improved therapeutic outcomes
- Reduction in adverse drug events
- Patient satisfaction

Meaningful metrics are designed to monitor the effectiveness of patient care activities.

Some organizations, such as PQA and the NCQA, have established peer-reviewed metrics that can be adopted and implemented by the pharmacy leadership to drive improved patient care outcomes. The pharmacy practice incorporates information about its specific patient population into design or selection of meaningful metrics. Where data analysis identifies opportunities for improvement in patient care services, the pharmacy practice incorporates such improvements into development plans

## **STANDARD DOMAIN 3.0: Quality Improvement**

**3.0 The pharmacy practice operates a continuous quality improvement (CQI) program to enhance patient safety.**

**3.1 The pharmacy practice operates a CQI program.**

### **3.1.1 Pharmacy practice staff documents quality-related event<sup>8</sup> (QREs) and conducts periodic audits of medication errors and QREs.**

#### **NARRATIVE:**

The pharmacy practice has policies and procedures that describe how the CQI program is operated, including documenting QREs and auditing medication errors and QREs.

### **3.1.2 QREs are communicated to appropriate persons internally and externally, as appropriate or required.**

#### **NARRATIVE:**

The pharmacy practice has a protocol for reporting QREs to appropriate national databases, for example MedWatch, peer review committees, or patient safety organizations.

### **3.1.3 QRE analysis by pharmacist and pharmacy staff lead to appropriate actions such as modification of workflows or procedures for the purpose of preventing similar QREs in the future.**

#### **NARRATIVE:**

The pharmacy practice demonstrates ongoing improvement of patient safety via the systematic review and enhancement of the practice's quality of care and continuous improvement over time<sup>9</sup>.

#### **GOAL:**

Pharmacy practice implements root cause analysis processes.

### **3.1.4 Quality self-audits or peer-review staff meetings are held to review pharmacy workflows and systems to support clinical pharmacy services and safe medication distribution processes.**

#### **NARRATIVE:**

Pharmacy practice conducts quality self-audits and holds peer-review meetings on quarterly

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<sup>8</sup>The NABP Model State Pharmacy Act and Model Rules define "Quality-Related Event" as any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication. The term "Quality-Related Event" includes:

- (1) a variation from the prescriber's prescription drug order, including, but not limited to:
  - (i) incorrect Drug;
  - (ii) incorrect Drug strength;
  - (iii) incorrect dosage form;
  - (iv) incorrect patient; or
  - (v) inadequate or incorrect packaging, labeling, or directions;
- (2) a failure to identify and manage:
  - (i) over-utilization or under-utilization;
  - (ii) therapeutic duplication;
  - (iii) drug-disease contraindications;
  - (iv) drug-drug interactions;
  - (v) incorrect drug dosage or duration of drug treatment;
  - (vi) drug-allergy interactions; or
  - (vii) clinical abuse/misuse.
- (3) The term also includes packaging or warnings that fail to meet recognized standards, the Delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

<sup>9</sup> Pharmacy practice is encouraged to incorporate the CQI provisions contained in the NABP Model State Pharmacy Act and Model Rules (see Model Rules for the Practice of Pharmacy, Section 3, Subsection "j") and the Community Pharmacy QRE Data Collection Form and Community Pharmacy Quality Self-Audit (see Model Rules for the Practice of Pharmacy, Appendix F) unless the pharmacy practice must comply with specific state laws or regulations.

basis.

Peer review as part of a CQI program includes:

- the collection of data necessary to identify when standards are not being met and data necessary to evaluate the reason(s) the deficiency occurred
- an objective review of the data to make recommendations for quality improvement
- an appropriate feedback mechanism to ensure that the process is operating in a manner that continually improves the quality of care provided to patients.

Peer review is not a punitive activity or a performance evaluation.

### **3.1.5 Pharmacy practice staff acts on identified trends in QREs.**

#### **NARRATIVE:**

1. Pharmacy staff are actively engaged in improvement initiatives derived from QRE activities and participate in identifying opportunities for improvement and in driving positive patient safety outcomes.
2. The pharmacy practice has a process in place that translates analysis to initiative, and subsequently initiative to measured and improved outcomes, using appropriate tools. The practice uses available internal and/or external (national) benchmark information to evaluate the effectiveness of these efforts.

### **3.2 The pharmacy practice conducts and encourages routine training and education of pharmacy staff on quality improvement initiatives.**

#### **NARRATIVE:**

Pharmacy practice makes staff training and educational materials available and removes barriers for such training, allowing open participation. The practice documents staff training received as part of the CQI program.

### **3.3 The pharmacy practice uses consumer feedback regarding pharmacy staff and patient care services with the intent of improving patient satisfaction and outcomes of care.**

#### **NARRATIVE:**

The pharmacy practice conducts patient or consumer satisfaction surveys and incorporates the findings and observations into improvement initiatives. The pharmacy practice seeks patient and consumer input via ongoing surveys. Survey topics may include items related to patient satisfaction, patient engagement, and specific care needs, as well as patient perceptions about the privacy and confidentiality of their patient information and the services the patient receives. The pharmacy practice uses this information to drive improvements in care provision, patient safety, and patient privacy protection. A few examples of improvements driven by survey include increasing mandatory counseling for medication therapies that are determined to be not well understood by patients, increasing flu

vaccinations by understanding barriers from the patient perspective, and increasing offerings of diabetic-friendly products.

## Glossary

### Access to medication; Access to care

**Definition:** Specialty pharmacy services and support activities which result in the ability of the patient/consumer to obtain the specialty medications necessary to meet the therapeutic goals. These include:

- Comprehensive benefits investigation, prior authorization assistance, and benefits coordination on behalf of the patients served, which also includes coordination and communication with the prescriber(s).
- Support for patient safety and compliance with manufacturer and payer requirements, clinical data, and other reporting specific to the medication(s) provided.
- Transparent provision of financial information to the patient and prescriber.

Note that these services and activities can also include options for use of alternate medication distribution channels (e.g., different benefits-preferred pharmacies), and any manufacturer-imposed pharmacy requirements that are tied to patient financial support and/or clinical data participation.

**Cited in Standards:** SPP Domain 2.0, Standards 2.1, 2.2, 2.3

### Assess

**Definition:** The process by which the pharmacist reviews the relevant subjective and objective medical/medication history and clinical status information collected about the patient and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

**Cited in Standards:** Used throughout CPP and SPP Standards

**Reference:** Adapted from Joint Commission of Pharmacy Practitioners (JCCP). Pharmacists' Patient Care Process. May 29, 2014.

### Benefit Coordination

**Definition:** The service conducted by the specialty pharmacy practice providing benefits investigation and prior authorization assistance, by coordinating information and involvement of the prescriber, other health care providers, and other sources of assistance, whenever possible.

A common specialty pharmacy practice example includes identifying sources of financial assistance (e.g. manufacturer-sponsored co-pay cards, manufacturer product assistance, and foundational assistance) and enrolling authorized patients.

**Cited in Standards:** SPP Standard 2.1

### Benefits investigation (BI); comprehensive benefits investigation; benefits assistance; benefits validation

**Definition:** BI services may include complete insurance review (medical and/or pharmacy benefit), formulary status assessment, financial assistance enrollment, payment clearance, selection of appropriate specialty pharmacy practice, selection of appropriate route of delivery of the specialty pharmaceutical medication, and patient advisement related to all of these services.

See also 'benefits coordination', and 'access to medications/access to care'.

**Cited in Standards:** SPP Standard 2.1 Narrative

### Case management; pharmacy patient case management; specialty pharmacy practice patient case management

**Definition:** (CMSA definition) Case management is a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an

individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes.

Pharmacy patient case management requires a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services for patients, and should include coordination and collaboration with other pharmacy providers and other healthcare providers.

Pharmacy patient case management includes the following activities:

1. A comprehensive review of the patient's medication history
2. The use and maintenance of a patient's personal medication list
3. A care plan or action plan that includes all action items for the patient to achieve the desired medication therapy outcomes
4. Pharmacist interventions as needed to address potential problems or issues
5. Referrals to other health care providers and services
6. Ongoing patient monitoring, including lab results when available, and follow-up
7. Documentation of all pharmacy case management activities
8. Transfer and discharge coordination when applicable.

Specialty pharmacy practice patient case management (and/or care coordination) can involve directly coordinating on behalf of or working with the patient to communicate with any or all of the following: the prescriber, any additional caregivers, the payer, and the pharmaceutical company--to establish a care plan, gain access to limited or restricted supply medications, and/or facilitate compliance with outcome reporting requirements. These services align as appropriate with patient-centered medication therapy management services, and are conducted using disease-specific patient-case management protocols. The delivery of medication therapy management services by the specialty pharmacy practices falls within the pharmacy case management services and includes a comprehensive approach to identifying and resolving medication therapy problems.

**Cited in Standards:** SPP Purpose, Standard 1.3, Domain 3.0, Standards 3.1, 3.4, 3.5, 3.6, 3.7, 4.1, Appendix A

**Reference:** CMSA Available at:

<http://www.cmsa.org/Home/CMSA/WhatisaCaseManager/tabid/224/Default.aspx>. Accessed on June 8, 2015.

### **Clinical decision support (CDS)**

**Definition:** "CDS is broadly defined as: a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. CDS should be intelligently-filtered and presented at the appropriate times to the appropriate people. With the growing use of technology in healthcare, CDS tools are often included within the electronic health record. These tools include alerts, reminders and documentation templates aimed improve clinical processes and outcomes."

Examples of CDS in community and outpatient pharmacy practice include, but are not limited to information technology and other tools which facilitate systematic and automated screening/identification/documentation of drug interactions, therapeutic duplications, patient adherence, utilization, and therapy-specific protocols. Some automated CDS programs include prompting and alert systems which clinicians and other staff use in the care process.

Examples of CDS in specialty pharmacy practice include, but are not limited to information technology and/or non-automated tools which facilitate systematic and timely screening/identification/documentation of drug interactions, therapeutic duplications, patient adherence, utilization, and therapy-specific protocols. Some automated CDS programs include prompting and alert systems which clinicians and other staff use in the care process, and for tailoring,

monitoring and documenting patient progress in a uniform, standardized method specific to an evidence-based therapy protocol, standardized order set, and/or a patient treatment plan.

**Cited in Standards:** CPP Standards 1.4.2, 1.4.3; SPP Standards 1.10, 1.11

**References:**

- HealthIT.gov. Available at: <http://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds>. Accessed on June 8, 2015.
- <http://healthit.gov/sites/default/files/del-3-7-starter-kit-intro.pdf>. Accessed on June 8, 2015.

### **Collaborative pharmacy practice; collaborative approach; collaboration; care coordination**

**Definition:** (NABP) “Collaborative Pharmacy Practice” is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

As a team-oriented approach to the patient care process, collaboration or a collaborative approach implies dynamic, interactive, interdisciplinary communication focused on common or mutually supporting goals centered on the patient. The collaboration occurs between staff, with delegated services, and with other providers and prescribers involved in patient care and support relative to the scope of services provided.

**Cited in Standards:** CPP Standard 2.1.2; SPP Standards 2.1, 2.3, 3.3, 3.6, 3.7, 4.1

**Reference:** NABP Model Act. Available at: [www.nabp.net/publications/assets/ModelAct.doc](http://www.nabp.net/publications/assets/ModelAct.doc). Accessed on June 8, 2015.

### **Collaborative practice agreement (CPA)**

**Definitions:** (CDC) A formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.

(APhA Foundation) CPAs are used to create formal relationships between pharmacists and physicians or other providers that allow for expanded services the pharmacist can provide to patients and the healthcare team. CPAs define certain patient care functions that a pharmacist can autonomously provide under specified situations and conditions. Of important note, CPAs are not required for pharmacists to perform many patient care services (e.g., medication reviews, patient education and counseling, disease screening, referral).

(NABP Model Act) “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by the law and the Rules of the Board.

*Note that CPA requirements are not consistent across all states; the pharmacy practice and pharmacists must comply with all applicable state-specific CPA regulations.*

**Cited in Standards:** CPP Standard 2.1.1, 2.1.2; SPP Standard 3.2

**References:**

- Centers for Disease Control and Prevention. Collaborative Practice Agreements and Pharmacists’ Patient Care Services: A Resource for Pharmacists. Atlanta, GA: US Dept. of Health and Human Services, Centers for Disease Control and Prevention; 2013. Available at: [http://www.cdc.gov/dhdsdp/pubs/docs/Translational\\_Tools\\_Pharmacists.pdf](http://www.cdc.gov/dhdsdp/pubs/docs/Translational_Tools_Pharmacists.pdf). Accessed on June 8, 2015.
- Collaborative Practice Agreements and Pharmacists’ Patient Care Services. Available at: <http://www.aphafoundation.org/collaborative-practice-agreements>. Accessed on June 8, 2015.
- NABP Model Act. Available at: [www.nabp.net/publications/assets/ModelAct.doc](http://www.nabp.net/publications/assets/ModelAct.doc). Accessed on June 8, 2015.

### Compliance Program, Corporate Compliance Program

**Definition:** a compliance program is a voluntary formal program that specifies an organization's policies, procedures and actions to prevent and detect violations of laws and regulations. The U.S. Department of Health and Human Services' Office of the Inspector General has developed a series of voluntary compliance program guidelines for several segments of the health care industry.

#### References:

- Compliance Resources, US DHHS, OIG. Available at: <https://oig.hhs.gov/compliance/101/index.asp>. Accessed 5/6/2018.
- Compliance Guidance, US DHHS, OIG. Available at: <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>. Accessed 5/6/2018.

### Continuous quality improvement (CQI)

**Definition:** CQI is a systematic, data-driven approach to monitoring, evaluating, and improving the processes and outcomes of care and services provided consistent with internal/company quality standards, external service benchmarks (including regulatory and payer expectations), and clinical standards of practice. The IOM suggests efforts for CQI should focus on the core areas for health care services: safety, effectiveness, personalized/patient-centered, timely, efficient, and equitable. (NABP Model Act) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use.

Specific areas for CQI monitoring and efforts in specialty pharmacy practice are listed in the narrative and description of SP Standard 4.1.

*See also "Metrics."*

**Cited in Standards:** CPP Domain 3.0, Standards 3.1.1, 3.1.4, 3.2; SPP Domain 4.0, Standards 4.1, 4.2, 4.3

#### References:

- IOM. Crossing the Quality Chasm. Institute of Medicine. March 2001. Available at: <http://www.iom.edu/reports/2001/crossing-the-quality-chasm-a-new-health-system-for-the-21st-century.aspx>. Accessed on June 8, 2015.
- NABP Model Act. Available at: [www.nabp.net/publications/assets/ModelAct.doc](http://www.nabp.net/publications/assets/ModelAct.doc). Accessed on June 8, 2015.

### Continuing Professional Development

**Definition:** (ACPE) Continuing Professional Development, commonly referred to as CPD, is a self-directed ongoing, systematic and outcomes-focused approach to lifelong learning that is applied to practice. It involves the process of active participation in formal and informal learning activities that assists individuals in developing and maintaining continuing competence, enhancing their professional practice, and supporting achievement of their career goals.

**Cited in Standards:** CPP Standard 2.3; SPP Standard 3.8

**Reference:** CPD – Accreditation Council for Pharmacy Education. Available at: <https://www.acpe-accredit.org/ceproviders/CPD.asp>. Accessed on June 8, 2015.

### Contract; contracted service; contractual agreement; service agreement

**Definition:** Any formalized arrangement, documented in writing, which specifies the scope, service performance expectations and monitoring methods, as well as the business and financial arrangement for the provision of delegated services on behalf of the specialty pharmacy practice seeking accreditation under these standards.

*See also delegated service.*

Cited in Standards: SPP Standards 1.1, 1.2, 1.4, 1.15, 4.1

### Contracted health care providers

**Definition:** A health care provider who is contracted through a formalized arrangement to deliver health care services on behalf of the community and outpatient pharmacy practice. The formalized arrangement, documented in writing, specifies the scope of services, service performance expectations and monitoring methods, as well as the business and financial arrangement for the provision of delegated services on behalf of the community and outpatient pharmacy practice.

Cited in Standards: CPP Standard 2.1.3

### Delegated service (see also contract)

**Definition:** Any components of the scope of services subject to this accreditation which are outsourced either externally or to another division of the company. Examples of delegated services for specialty pharmacy practice include, but are not limited to: benefits coordination, clinical and/or financial case management support, call center management, billing/insurance processing, data tracking and reporting, and information systems management.

Cited in Standards: SPP Standards 1.2, 1.4, 1.15, 2.1

### Delegation of authority; delegation of organizational oversight and leadership; organizational structure

**Definition:** The official legal structure as well as the chain of command of the specialty pharmacy practice under which the scope of services subject to this accreditation are managed. Per the standard, this must be in writing, and must clearly delineate the management and staff responsible for scope of services, including any which are supported as delegated services.

Cited in Standards: SP Standard 1.2

### Direct patient care

**Definition:** (CDC) Hands on, face-to-face contact with patients for the purpose of diagnosis, treatment and monitoring.

Examples of direct patient care may include patient education/counseling for a new device (e.g., blood glucose monitor), vaccine administration, point-of-care testing.

**Reference:** The National Healthcare Safety Network (NHSN) Manual. Available at:

[http://www.cdc.gov/nhsn/PDFs/HPS-manual/HPS\\_Manual-exp-plus-flu-portfolio.pdf](http://www.cdc.gov/nhsn/PDFs/HPS-manual/HPS_Manual-exp-plus-flu-portfolio.pdf). Accessed on June 8, 2015.

### HUB services

**Definition:** Programs with centralized (or regionalized) operations which register potential patients and enroll patients to facilitate patient access to medication financial assistance programs when required, and in certain cases, provide product access for medications in limited supply or with contractual data reporting requirements (e.g. REMS, safety, clinical outcomes.)

Cited in Standards: SPP Standard 2.2

### Information system

**Definition:** The electronic and/or paper driven systems and resources available to the pharmacist at the point of care which support the applicable scope of services, including, but not limited to:

- the documentation of all clinically relevant patient information necessary for the scope and size of the practice
- effective prospective and retrospective Drug Utilization Review (DUR);
- relevant clinical decision support;

- safety and efficiency in the care process;
- sharing of relevant patient information among the patient care providers;
- ensuring the integrity, security, and privacy of patient information and other data;
- timely and accurate data reporting requirements; and
- accurate, timely, and complete billing, reimbursement, and fiscal management.

**Cited in Standards:** CPP Standards 1.4, 1.5, 1.6; SPP Standards 1.10, 1.11, 1.12, 1.13, 1.15, 2.2

### Interoperability

**Definition:** The ability of health information systems to work together within and across organizational boundaries by exchanging and making use of information in order to advance the effective delivery of healthcare for individuals and communities.

**Cited in Standards:** CPP 1.5; SPP 1.12; TPP 1.5.

#### References:

- Oxford Dictionary. Available at: <https://en.oxforddictionaries.com/definition/interoperability>. Accessed 3/27/2018.
- HIMSS. What is Interoperability? Available at: <http://www.himss.org/library/interoperability-standards/what-is>. Accessed 3/27/2018.

### Intervention; Pharmacist intervention

**Definition:** An action or measure recommended and/or undertaken for the purpose of changing the course of events for a patient; an intercession made by a pharmacist with the goal of improving the patient's care and/or preventing an adverse outcome.

Interventions in pharmacy practice may be globally divided into patient education, drug interaction intervention, medication side effect mitigation, adherence intervention, vaccination and vaccination screening, laboratory monitoring recommendation, and other interventions that benefit patient medication therapy, improve clinical outcomes, and/or avoid costs through the prevention of potentially unfavorable

**Cited in Standards:** CPP Standard 2.1.2; SPP Standards 2.1, 2.2, 3.4, 3.6, 3.9, 4.1

**References:** Available at: <http://medical-dictionary.thefreedictionary.com/intervention>. Accessed on June 8, 2015.

### Manufacturer, Pharmaceutical manufacturer

**Definition:** The developers, producers, and marketers of drugs and pharmaceuticals that are licensed by the U.S. Food and Drug Administration for use as medications. In some cases these companies directly distribute their products to pharmacies; they typically work with drug wholesalers or other licensed distributors to bring these products securely and safely through the supply chain to authorized inpatient and outpatient providers.

**Cited in Standards:** SPP Purpose, Standards 1.6, 1.7, 1.14, 2.1, 2.2, 2.3, 3.5, 4.1, 4.3

**Reference:** Available at: <http://www.phrma.org/about>. Accessed on June 8, 2015.

### Medication Management Services (MMS)

**Definition:** (JCPP) A spectrum of patient-centered, pharmacist-provided, collaborative services that focus on medication appropriateness, effectiveness, safety, and adherence with the goal of improving health outcomes. This is revised and expanded definition and term for the pharmacy profession's original Medication Therapy Management Services definition to better align with contemporary pharmacy practice. Various terms have been codified in federal and state laws and regulations, such as Part D Medication Therapy Management and Comprehensive Medication Management as well as those used in private sector programs, and these terms are likely to remain in use.

**Reference:** JCPP Approves New Medication Management Services Definition. Available at: <https://www.prnewswire.com/news-releases/jcpp-approves-new-medication-management-services-definition-300615345.html>. Accessed 3/28/2018.

### Medication therapy management (MTM)

**Definition:** (APhA/NACDSF) Medication therapy management (MTM) services are patient-centered, based on individual patient need, and use a standard patient care process. MTM services are delivered by a pharmacist and focused on improving a patient's therapeutic outcomes. Delivery of MTM services includes a comprehensive approach to identifying and resolving medication therapy problems in collaboration with other health care providers during the time period the patient is under the pharmacist's care. The service design empowers patients to take an active role in managing their medications.

The MTM service design follows the model, Medication Therapy Management In Pharmacy Practice: Core Elements of an MTM Service Model.

The Core Elements service model includes:

- Medication Therapy Reviews, both comprehensive and targeted, whereby the pharmacist identifies and resolves the patient's medication therapy problems
- Personal Medication List for the patient that includes an accurate list of all of the patient's prescription and nonprescription medications, herbals and other dietary supplements. The patient shares this list with other health care providers to improve continuity of care and prevent adverse events due to medications. The list is updated during follow-up monitoring.
- Medication Action Plan for the patient that includes action items for the patient to improve medication therapy outcomes. The plan is updated during follow-up monitoring.
- Intervention/Referral whereby the pharmacist intervenes with the patient, prescriber, or appropriate provider to address potential problems/issues identified during medication reviews. As appropriate, the pharmacist refers the patient to other providers/services based on information discussed in the medication therapy review.
- Documentation/Follow-up whereby pharmacist documents the MTM visit in the patient's chart, including the patient's goals of therapy, care plan, interventions and referrals made, communication with the prescriber, etc. The pharmacist will document this episode in a retrievable format that is accessible to all pharmacy staff, real time, at the point of care. A follow-up visit is scheduled for the patient for ongoing monitoring as appropriate. In specialty pharmacy practices, the delivery of medication therapy management services falls within pharmacy case management services and includes a comprehensive approach to identifying and resolving medication therapy problems.

*See "case management; pharmacy patient case*

**Cited in Standards:** CPP Standards 1.2, 2.1.1.2, 2.1.2; SPP Purpose, Standards 1.5, 3.6, 3.10

**Reference:** American Pharmacists Association; National Association of Chain Drug Stores Foundation. Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model. Version 2.0. March 2008. Available at: <http://www.pharmacist.com/MTM/CoreElements2>. Accessed on June 8, 2015.

### Metrics

**Definition:** Metrics are standardized measures (quantitative) or performance thresholds used to monitor quality, efficiency, outcomes, and other key parameters of a pharmacy practice and its operation.

Specialty pharmacy metrics include, but are not limited to, tracking, compilation, analysis, and reporting of standardized/accepted measures for service volumes, dispensing, pharmacist interventions, adherence and persistence, call center performance, satisfaction and complaints, quality related events, adverse drug events, cost avoidance, and external audit findings.

**Cited in Standards:** CPP Standard 1.1, 2.4 (goal); SPP Purpose, 2.2, 3.7, 4.1

### **Organizational structure, organizational infrastructure**

**Definition:** This is the official legal structure, and the chain of command of the pharmacy practice under which the scope of services subject to this accreditation are managed. This must be spelled out in writing, and must clearly delineate the management and staff responsible for the scope of services. A specialty pharmacy infrastructure also includes any delegated services.

**Cited in Standards:** CPP Standard 1.1, 1.1.4; SPP Domain 1.0, 1.2

### **Patient care process, Patient management, Clinical management**

**Definition:** (JCCP) “The pharmacist patient care process is a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.”

Using principles of evidence-based practice, pharmacists:

- Collect the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient
- Assess the information collected and analyze the clinical effects of the patient’s therapy in the context of the patient’s overall health goals in order to identify and prioritize problems and achieve optimal care
- Develop an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective
- Implement the care plan in collaboration with other health care professionals and the patient or caregiver
- Monitor and evaluate the effectiveness of the care plan and modify the plan in collaboration with other health care professionals and the patient or caregiver as needed.”

*See “Case management; pharmacy patient case management”*

**Cited in Standards:** CPP Standard 2.1.2; SPP Purpose, Domain 3.0, Standards 3.1, 3.2, 3.7, 4.1 and throughout the SPP standards

**Reference:** Joint Commission of Pharmacy Practitioners (JCCP). Pharmacists’ Patient Care Process. May 29, 2014.

### **Point of care**

**Definition:** The location and timing in the care process where the pharmacy practice interacts directly with the patient or caregiver.

Examples for pharmacy practice include patient counseling, dispensing and/or administration of the medication. This interaction may be face to face or via another communication method.

**Cited in Standards:** CPP Standards 1.4.1, 1.4.2, 2.1.2; SPP Standard 1.10

### **Prescriber**

**Definition:** A provider legally authorized to prescribe a medication, treatment, protocol, and/or care monitoring plan.

**Cited in Standards:** CPP Standards 1.4.1, 2.1.1.3, 2.1.1.5, 2.1.2, 2.1.2.2; Appears throughout the SPP Standards

### Provider

**Definition:** A health care provider refers to any health care professional, health care organization and its staff. Examples of health care providers may include pharmacists, nurses, physicians, physician assistants and other healthcare practitioners, community and outpatient pharmacies, home health agencies, inpatient and outpatient facilities, and clinical laboratories.

**Cited in Standards:** Appears throughout the CPP and SPP standards; used in the overall general sense.

### Quality related events (QRE)

**Definition:** (NABP) Any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication. The term Quality-Related Event includes the following:

- (1) A variation from the prescriber's prescription drug order, including, but not limited to
  - (i) Incorrect drug;
  - (ii) Incorrect drug strength;
  - (iii) Incorrect dosage form;
  - (iv) Incorrect patient; or
  - (v) Inadequate or incorrect packaging, labeling, or directions.
- (2) A failure to identify and manage
  - (i) Over-utilization or under-utilization;
  - (ii) Therapeutic duplication;
  - (iii) Drug-disease contraindications;
  - (iv) Drug-drug interactions;
  - (v) Incorrect drug dosage or duration of drug treatment;
  - (vi) Drug-allergy interactions; or
  - (vii) Clinical abuse/misuse.

The term also includes packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

**Cited in Standards:** CPP Standard 3.1.1, 3.1.2, 3.1.3, 3.1.5; SPP Standard 4.1

**Reference:** NABP Model Act. Available at: [www.nabp.net/publications/assets/ModelAct.doc](http://www.nabp.net/publications/assets/ModelAct.doc).

**Accessed on June 8, 2015.**

### Referral; patient referral

**Definition:** A request for the transfer of patient care from one provider or clinical setting (e.g. clinic, hospital, prescriber) to another provider. A referral may or may not include orders or prescriptions required to initiate care or services; it initiates the process for the provider(s) and prescriber(s) to confer, transfer information, and take the required steps to provide care and services requested. In specialty pharmacy practice, the referral is typically a request to the specialty provider to initiate a therapy for a patient with a chronic disease; the pharmacy then follows established procedures to review the referral, obtain all necessary information including specific medication and therapy orders, and verify/facilitate steps for reimbursement. The referral then converts to an active case once therapy is initiated.

**Cited in Standards:** CPP Standard 2.1.1.3 (goal) Standard 2.1.2; SPP Standard 1.3. 2.1, 3.6

### Root cause analysis

**Definition:** (AHRQ) Root cause analysis (RCA) is a structured method used to analyze serious adverse events. RCA uses the systems approach to identify both active errors (errors occurring at the point of

interface between humans and a complex system) and latent errors (the hidden problems within health care systems that contribute to adverse events).

**Cited in Standards:** CPP Standard 3.1.3 (goal); SPP Standard 4.1

**References:**

- AHRQ. Available at: <http://www.psnet.ahrq.gov/primer.aspx?primerID=10>. Accessed on June 8, 2015.
- ISMP Resource. Root Cause Analysis Workbook for Community/Ambulatory Pharmacy. Available at: <http://www.ismp.org/tools/rca/RCA-Complete.pdf>. Accessed on June 8, 2015.

### **Safety Data Sheet – SDS (formerly Material Safety Data Sheet)**

**Definition:** (OSHA) The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) (formerly MSDs or Material Safety Data Sheets) for each hazardous chemical to downstream users to communicate information on these hazards. The SDS includes information such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical.

**Reference:** OSHA. Available at: <https://www.osha.gov/Publications/OSHA3514.html>. Accessed on June 8, 2015.

### **Scope of practice document**

**Definition:** A written description of all the services provided by the specialty pharmacy practice, including population served, specialty medications dispensed, clinical management and patient care services (including methodology or evidence-based guidelines used), therapeutic goals, and patient support services, communications with patients and providers, and related patient record and other documentation.

**Cited in Standards:** SPP Standard 1.3

### **Specialty pharmaceuticals**

**Definition:** Medications with at least four of the following characteristics:

- Typically high in cost (\$600 or more per month)
- Involve complex treatment regimens that require ongoing clinical monitoring and patient education
- Have special handling, storage, or delivery requirements
- Are generally biologically derived and available in injectable, infusible, or oral form
- Are dispensed to treat individuals with chronic and/or rare diseases
- Frequently have limited or exclusive product availability and distribution
- Treat therapeutic categories such as oncology, autoimmune/immune, or inflammatory conditions marked by long-term or severe symptoms, side effects, or increased fatality

**Cited in Standards:** SPP Purpose, Standard 1.3, 1.7, 2.1, 2.2

**Reference:** Distribution Management Association’s Center for Healthcare Supply Chain Research. Specialty Pharmaceuticals Facts, Figures and Trends in Healthcare. 2012. Available at: <http://www.hcsupplychainresearch.org/projects/pdfs/2012-SpecPharm-ExecSummary.pdf>. Accessed on June 8, 2015.

### **Specialty pharmacy practice (referred to as “the practice”)**

**Definition:** A pharmacy practice created:

1. To manage the medication access and handling requirements of specialty pharmaceuticals, including dispensing and distribution, and

2. To provide clinical management services for patients with chronic, serious, life-threatening and/or rare disease or conditions receiving specialty medications aimed toward achieving the desired patient therapeutic and economic outcomes.

**Cited in Standards:** SPP Purpose, used throughout the standards

**Reference:** Health Policy Brief: Specialty Pharmaceuticals. Health Affairs, November 25, 2013.

Available at: <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief%20id=103>. Accessed on June 8, 2015.

### **Specialty pharmacy services; specialty pharmacy programs**

**Definition:** Specialty pharmacy services and programs involve the provision of 1) high cost medications with 2) special handling procedures and 3) requiring complex patient care.

The term 'specialty pharmacy' is clarified in the Purpose section of the SP standards and includes additional criteria for the characteristics of these services.

**Cited in Standards:** SPP Purpose, used throughout the standards

### **Telehealth**

**Definition:** Telehealth is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.

**Reference:** HRSA. Available at: <http://www.hrsa.gov/ruralhealth/about/telehealth/>. Accessed on June 8, 2015.

### **Transition**

**Definition:** The point in the patient care process that involves hand-off of responsibility for the continuation of patient services to another provider.

**Cited in Standards:** CPP Standard 2.1.3; SPP Standard 3.3