



ASHP ACCREDITATION STANDARD FOR SPECIALTY PHARMACY PRACTICE

Introduction

The ASHP Accreditation Standard for Specialty Pharmacy Practice reflects contemporary best practice for specialty 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:

- Effective patient care plans to achieve desired medication therapy outcomes
- Patient-specific assessments and optimal collection, use, and documentation of information
- Inclusion of specialty drug-specific assessment and disease state-specific assessment requirements
- Comprehensive review of the patient's medication history and medication list prior to each fill
- Documentation of all pharmacy case management activities
- Patient consultation and education
- Quality metrics and quality improvement plans

This standard combines the Center for Pharmacy Practice Accreditation (CPPA) standards¹ 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 Specialty Pharmacy Practice

Specialty pharmacy generally revolves around the provision of 1) high cost medications with 2) special handling procedures and 3) requiring complex patient care.² Specialty pharmaceuticals have at least four of the following characteristics:³

- Typically high in cost (\$600 or more per month)

¹ Version III, February 27, 2019; Standards used with permission of Center for Pharmacy Practice Accreditation (CPPA)

² Blaser DA, Lewtas AJ, et al. How to define specialty pharmaceuticals—a systematic review. *Am J Pharm Benefits*. 2010;2(6):371-380.

³ Distribution Management Association's Center for Healthcare Supply Chain Research. Specialty Pharmaceuticals Facts, Figures and Trends in Healthcare. 2012. <http://www.hcsupplychainresearch.org/projects/pdfs/2012-SpecPharm-ExecSummary.pdf>. Accessed December 31, 2012.

- 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

Prescription medications continue to be among the fastest growing elements of healthcare spending,⁴ and the growth of the specialty medication spend continues to outpace traditional medication growth. In 2017 the specialty medication spend was 43.4% of the total non-discounted spend in the US. The majority of new active substances launched in 2017 were considered orphan.⁵ By 2022 the spending on specialty medications, including orphan and precision, is expected to reach nearly \$450B.⁶ Under the pharmacy and medical benefits, the members who use specialty medications account for a much greater percentage of healthcare costs. Given these factors, it is imperative that pharmacy practices help optimize the clinically appropriate use of specialty medications.

The ASHP Standard for Specialty Pharmacy Practice is designed to create a consensus around the practice of specialty pharmacy and guide the accreditation process. Specialty pharmacy practice is defined as 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 diseases or conditions⁷ receiving specialty medications aimed toward achieving the desired patient therapeutic and economic outcomes.

While specialty pharmacy practice continues to evolve, best practices inclusive of patient management and support, product management, medication therapy management, healthcare provider relationships, manufacturer relationships, and continuous quality improvement should remain contiguous and be readily supported by its practitioners. Established standards help to guide, describe, and gain recognition for innovative, high quality, safe and effective specialty pharmacy practices.

The development of a standards-based accreditation process is critical for continuous quality improvement, consistency, and “to ensure medication safety and effectiveness, and quality of medication use for desired health outcomes.”⁸ This standard seeks to provide clarity to the key metrics

⁴ Kacik A. Drug prices rise as pharma profit soars. www.modernhealth-care.com/article/20171228/NEWS/171229930 (accessed 2019 Feb 13).

⁵ Medication use and spending in the US: A review of 2017 and outlook for 2022. April 2018. Accessed February 13, 2019.

⁶ BFG Analysis on IMS 2016 Rx Sales, CMS Office of the Actuary. Accessed February 13, 2019.

⁷ <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief%20id=103>

⁸ 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.

that effectively support patients, healthcare providers, manufacturers, payers, and peers engaged in specialty pharmacy practice.

Scope of Standard: The Standard for Specialty Pharmacy Practice addresses four primary areas, which encompass the overall provision of pharmacy care for patients receiving specialty pharmaceuticals. These areas of focus include the organizational infrastructure to support the provision of specialty pharmacy care, patient access to medications via manufacturer requirements and benefits investigation (BI), clinical management of the patient, and quality.

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

- 1.0 Organizational Infrastructure
- 2.0 Medication Access Support
- 3.0 Clinical Management Services
- 4.0 Quality Improvement

Within each Standard Domain are key elements that demonstrate competency in the identified area of specialty pharmacy practice. The accompanying narrative for each standard element describes the specific criteria for evaluation of the specialty pharmacy practice to determine consistency with the standard for accreditation within the overall management of specialty pharmaceuticals and clinical pharmacy management of patients.

It is expected for accreditation that patient care, dispensing services, and support services provided by the specialty 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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Domain 1.0: Organizational infrastructure

The specialty pharmacy practice has an organizational infrastructure to support the provision of specialty pharmacy care.

1.1 The specialty pharmacy practice has appropriate documents and current licensure required of the specialty pharmacy practice.

NARRATIVE:

It is expected for accreditation that the patient care, dispensing services, and support services provided by the specialty 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. The specialty pharmacy practice may or may not have a legal department or outside legal counsel to ensure necessary legal and regulatory compliance including resolution of conflict between state and federal laws and regulations.

In order to provide pharmacy services beyond the borders of a pharmacy's home state, out-of-state licensure and additional documentation may be applicable. Dispensing, wholesaling, infusion service provision and nursing services require individualized licensure with practice-specific oversight guiding individual practice authority.

Maintaining an adequate and well-trained workforce is essential for high quality patient care and to reduce organizational risk. Regarding the staff of the specialty pharmacy practice, all pharmacists and nurses are licensed or registered and all technicians are licensed, registered, and/or certified, as required by state regulations. The specialty pharmacy practice has mechanisms for ensuring that all pharmacists and technicians are in good standing in all states where they are licensed/registered/certified through verification of licensure, registration, certifications and continuing education requirements.

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 specialty 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 encourages employees, management, and board members or other governing body members to report violations of law and policy to the specialty 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 specialty pharmacy practice board of directors or senior management.

GOAL:

The specialty pharmacy implements sales and marketing practices, through policy implementation, orientation, and training of sales and marketing personnel, that support the practice's expectations of its staff and professional pharmacy partners to act in an ethical and compliant manner.

1.1.2 The specialty pharmacy practice has a Compliance Program.**NARRATIVE:**

The specialty pharmacy practice has a written compliance program implemented for the entire organization. The program includes the following elements:

- Written policies and procedures (SPP 1.1, SPP 1.1.1, SPP 1.1.2, SPP 1.5, SPP 1.6, SPP 1.7) address the organization's commitment to compliance, risk areas for potential fraud (i.e. claims processing) and financial relationships with prescribers.
- A compliance officer and committee (SPP 1.1.2) are charged with the operation and monitoring of the compliance program and report directly to executive management.
- Training and education (SPP 1.1.1, SPP 1.1.2, SPP 1.5) include effective corporate compliance training on hire and annually.
- Lines of communication (SPP 1.1.1, SPP 1.1.2, SPP 1.2) assure effective communication of complaints and a means to protect complainants from retaliation.
- Enforcement and disciplinary guidelines (SPP 1.1.1, SPP 1.1.2) address response to allegations of compliance program infractions and enforce disciplinary action against employees who have violated laws and regulations.
- Auditing and monitoring (SPP 4.1) are used to monitor and ensure regulatory, contractual, and procedural compliance.
- Responses to detected offences and corrective action (SPP 1.5, SPP 4.1) address investigation and remediation of systemic compliance problems.⁹

1.2 The specialty pharmacy practice has a) a clear organizational structure including a mission statement, b) a policy and procedure process, and c) a process for the delegation of organizational oversight and leadership to allow for safe and effective delivery of services.**NARRATIVE:**

Specialty pharmacy practice requires a clear understanding of business relationships, internal reporting, and documented organizational structure. This organizational structure includes the direct and indirect reporting relationships within the organization and with service providers to whom specialty pharmacy practice roles are contractually delegated. Organizational structure documentation is inclusive of pharmacy ownership, management, reporting structure, and delegated authority to outside entities.

A patient-centered mission statement that reflects the services provided to the patient is an essential guide for the specialty pharmacy practice and is posted in the practice setting to serve as a reminder to

⁹ 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.

the staff of the focus of the practice. The mission statement is reviewed by leadership and staff regularly for necessary modifications based on scope of practice and is included in the patient enrollment materials.

The specialty pharmacy practice has current policies and procedures that are readily available and followed by appropriate pharmacy staff in everyday practice. The specialty pharmacy practice has a documented process to develop, maintain, review, and update policy and procedure documents, including the documentation of ownership, leadership responsibility and formal approval of policies and procedures. This process also occurs when required, such as the enactment of a new regulation or a change in practice. Policies and procedures should be documented in a consistent format and should include dates of creation, reviews, revisions and approvals. New and revised policies and procedures are provided to the pharmacy staff on an ongoing basis in a readily-retrievable format, such as online or in an easily accessed binder in each facility and, when necessary, staff is provided training and education related to policies and procedures.

The specialty pharmacy practice has a clearly defined organizational leadership structure that encourages the reporting of safety risks. The specialty pharmacy practice establishes a process appropriate to the size of the organization for escalating safety concerns or information that warrants management's attention. The specialty pharmacy practice may include, as part of the escalation plan, access to a means of anonymous reporting of concerns, such as a compliance hotline.

1.3 The specialty pharmacy practice describes the scope of specialty pharmacy services offered.

NARRATIVE:

The scope of services provided by the specialty pharmacy practice may be determined by the specialty medication provided, the specific patient population served, disease state(s), or specialty provider referrals. The scope includes the population(s) served, the specialty medications dispensed and related protocols, the clinical management of specialty medications, and patient care services provided (including methodology and evidence-based guidelines used), patient support services (e.g., financial assistance information, patient education), the desired therapeutic goals (e.g., disease cure, quality of life, symptom reduction), and other information as appropriate. Many specialty medications have restricted distribution networks and limited patient populations, and defining the scope of specialty services at the pharmacy is important to ensure consistency and competency in the skills and ability of staff. In addition, specialty pharmaceuticals are typically ordered by medical specialists whose geographical location to the specialty pharmacy practices may be a driving force behind patient referrals to the specialty pharmacy practice. These and other considerations, such as the methodology/guidelines used for patient services, communications with patients and healthcare providers, patient records and other documentation should be factored into the description of the scope of services.

Example areas of specialty pharmacy practice or specialty pharmaceuticals/medications dispensed include:

1. Alpha-1 antitrypsin deficiency

2. Behavioral health
3. Bleeding disorders
4. Bone marrow transplantation
5. Fertility and high-risk pregnancy
6. Growth disorders
7. Hepatology
8. Hereditary angioedema (HAE)
9. HIV
10. Hypercholesterolemia
11. Immune globulin therapy (IV or subcutaneous)
12. Inflammatory conditions (includes rheumatology, dermatology, gastroenterology)
13. Infusible oncology/hematology
14. Osteoporosis
15. Multiple sclerosis
16. Oral oncology/hematology
17. Pulmonary disorders (cystic fibrosis, pulmonary arterial hypertension)
18. Renal failure
19. Restricted distribution or orphan pharmaceutical-specific support programs
20. Solid organ transplantation

1.4 The specialty pharmacy practice defines and manages internal and external delegated services.

NARRATIVE:

Delegated services may be provided by contracted internal organizational staff or by external contracted healthcare providers whose activities are under the control of the specialty pharmacy practice. These delegated roles do not supplant the requirement that specialty pharmacy practice staff be able to provide these delegated services when needed at the point of patient contact. Delegated roles are clearly defined, contractually documented, and of appropriate scope. Contracts include training and competency requirements of staff providing services. The specialty pharmacy practice is responsible for all aspects of delegated services.

Delegated services, which may be services traditionally provided by a specialty pharmacy, are documented and integrated into the specialty pharmacy practice's patient record. Contracts or service agreements for the delegated services and the performance of the delegated services are reviewed by the specialty pharmacy practice at regular intervals to ensure that services are appropriately provided and to ensure that delegation contracts and service agreements are current and accurate. Significant changes to delegated services contracts or agreements should be reported to ASHP.

1.5 The specialty pharmacy practice has appropriate professional and support staff to deliver services.

NARRATIVE:

The specialty pharmacy practice has appropriate staff management procedures to support overall operations and patient care. Effective staff management also aligns the roles of employees within the overall specialty pharmacy practice and assists in maintaining the integrity and consistency of the operations and patient care services.

The specialty pharmacy practice has the following elements for effective staff management:

1. Job descriptions for each category of staff that outline duties, functions, and responsibilities so that each employee understands precisely and in sufficient detail the tasks and functions that are expected and permitted by regulation in the course of performing his or her job or scope of service, and to whom the employee reports. The categories may include the pharmacist-in-charge, the pharmacy manager, the staff pharmacist, the pharmacy graduate intern, the pharmacy resident, the student pharmacist, the pharmacy technician, ancillary pharmacy staff, nurses, and other healthcare providers where applicable. The specialty pharmacy practice ensures that all employees are vigilant about performing only those tasks permitted by their category, are competent in their role, understand the practice's policies and procedures, and know who to contact with concerns about their scope of practice. The specialty pharmacy practice has a defined scope of practice for pharmacists. The scope defines the necessary credentials and skill level for the specialty pharmacy practice. The pharmacist scope of practice is obtained through careful review of pharmacist qualifications, training, and demonstration of skills and allows for collaborative medication management, where practice setting allows. There is a written procedure for position description approval and frequency of update.
2. Hiring procedures that include initial review of credentials. These procedures are standardized and documented in order to assess and maintain competent staff. Necessary education and training required for each position are documented and reviewed as part of the hiring process. Such practices include those related to ensuring all staff is compliant with the continuing education requirements of the relevant licensing or credentialing board. Other elements that should be included and documented as part of the hiring and ongoing process are employee background checks, review of OIG Medicare and Medicaid fraud registry, safety, infection control, HIPAA and patient privacy, malpractice insurance carriage for applicable positions, and applicable health factors for staff in direct patient contact. Specifically, the pharmacy practice has comprehensive TB screening, hepatitis B, and influenza vaccination programs for their employees who come in direct contact with patients. Other screenings and vaccinations may be applicable.
3. Staff training and skills assessment as part of initial orientation as well as ongoing training to maintain job competency. This training will vary by job or profession but should include what staff needs to know to perform job duties and to have the most current knowledge required for job competency on an ongoing basis. Training also includes confidentiality of personal health information and organizational proprietary information, conflict of interest disclosures, and code of conduct policies.
4. A performance appraisal system that includes an annual performance review aligned to the duties, responsibilities, and roles required for each staff member's specific job description and defined measures of success including performance levels related to patient care programs. The specialty pharmacy practices recognize the power of performance evaluations and 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. The procedure includes a process for corrective action plans. Job descriptions are routinely reviewed by the employee and supervisor at least yearly and preferably during annual performance reviews.

5. A written procedure to evaluate the effectiveness of the staffing model by collecting, evaluating, and documenting pharmacy workload and performance data and utilizing these data to improve operations and patient safety. The pharmacy annually establishes metrics to measure the effectiveness of the staffing model, which consider the appropriate workload or financial expectations of the pharmacy staff without compromising patient safety. The specialty pharmacy practice has a mechanism to gather staff input on staffing effectiveness and validate and address any concerns as part of an ongoing quality process.
6. Sufficient professional, technical, and support staff resources to fulfill the mission of the specialty pharmacy practice, deliver patient care services, and ensure quality and patient safety. The specialty pharmacy practice evaluates staffing model necessary for effective and safe organizational performance.

GOAL:

1. The specialty pharmacy practice has a comprehensive influenza vaccination program to offer all employees.
2. The specialty pharmacy encourages applicable pharmacist certification through the Board of Pharmacy Specialties, the Specialty Pharmacy Certification Board, the American Academy of HIV Medicine, or other similar certification body.
3. The specialty pharmacy encourages applicable pharmacy technician certification through the Pharmacy Technician Certification Board and other applicable certification programs.
4. The specialty pharmacy supports the professional, emotional, physical, and social well-being and resilience of their staff. Dedicated resources are available to help staff maintain their compassion for others and self; maintain their sense of purpose, meaning, and professional fulfillment; develop resiliency skills; and maintain or develop habits of healthy living and self-care. Clinician burnout can cause significant human suffering and can negatively impact patient safety and overall healthcare quality throughout entire organizations and systems. It is essential for the pharmacy workforce to be healthy, resilient, and functioning at the highest capacity.

1.6 The specialty pharmacy practice maintains a structure to ensure appropriate fiscal management.

NARRATIVE:

Access and timely provision of specialty medications for patients is a critical element of care entrusted to specialty pharmacy practices. The specialty pharmacy practice has a significant investment in the medication inventory required to provide specialty pharmacy services. The specialty pharmacy practice has established procedures surrounding the fiscal management of pharmacy operations and inventory. The pharmacy has procedures for management of contractual agreements with third-party payers, manufacturers, wholesalers and third party logistics vendors including record retention and data reporting pursuant to the agreements. Procedures for third party payers include plan reimbursement,

patient collections and accounting, billing units associated with specialty medications, and third-party audits to ensure financial integrity and timely access of medications for patients.

1.7 The specialty pharmacy practice has protocols for medication procurement, storage, preparation, and distribution for medication integrity and safe and timely delivery.

NARRATIVE:

Specialty pharmaceuticals routinely have specific handling requirements necessary for medication potency and integrity at the point of administration by the patient. Even in the absence of these special handling requirements, the significant costs associated with specialty medications require the specialty pharmacy practice to have the ability to reconcile delivery of medication to the patient. Because of the high percentage of specialty medication delivered via mail or courier service, diligence is exercised by the specialty pharmacy practice to protect and ensure safe delivery of medications to the patient. These policies and procedures include supply chain, storage, medication preparation, inventory control and delivery. The specific areas are the following:

Supply chain:

Due to the costs associated with specialty pharmacy therapy and the increasing risks associated with tertiary or “grey” market suppliers, specialty and non-specialty pharmaceuticals are sourced from licensed (minimum) and accredited (desired) distributors, wholesalers or manufacturers to ensure patient safety. This includes all branded and generic medications provided to patients under the care of the pharmacy provider. It is the responsibility of the applicant pharmacy to ensure that the specialty pharmacy practice stays current with established regulatory requirements governing supply chain and medication provision. The specialty pharmacy should ensure it has processes to prevent the dispensing of medications that have been adulterated, misbranded, are/or suspected of being counterfeit or fraudulent. Medication products should be visually inspected upon receipt and put into inventory. Additionally, inventory control should detect theft or diversion, and include investigating and reporting suspicious events to the appropriate agency, if warranted.

Storage:

Specialty pharmaceuticals have specific storage requirements and frequent requirements for inventory reporting. The specialty pharmacy practice ensures that medications are stored appropriately and pursuant to manufacturer requirements. The specialty pharmacy practice also demonstrates ability to identify storage temperatures, humidity conditions and have procedures for continuous temperature and humidity monitoring and detection of variances and excursions, as well as addressing ambient refrigerator or freezer storage conditions.

Storage refers to both the act of medication storage and the ability to accurately reconcile medication inventory stored within the pharmacy location. The specialty pharmacy practice has mechanisms to track inventory levels and provide reporting via a reliable inventory tracking tool for internal auditing and reporting requirements. Appropriate physical storage conditions are ensured from the point of receipt from the medication source, storage at the pharmacy level, medication preparation at the site of dispensing, and throughout the delivery process of providing medication to the patient.

Medication recalls, outdated and returned medications:

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

Medication preparation:

During the process of medication preparation, storage and labeling, refrigerated medications are at risk of exposure to excessive temperatures if preventative safeguards are not in place. Generally, refrigerated medications should be at room temperature for a limited time, consistent with good handling practices, during medication preparation and labeling procedures. Pharmacy staff is protected from exposure to hazardous medications and other materials used in the preparation of the specialty medications.

Medication delivery:

Medication delivery represents the largest threat to overall medication stability as temperatures can vary widely based on different courier options. The threat of temperature fluctuation is greater for refrigerated medications but also exists for non-refrigerated medications. The specialty pharmacy practice ensures that medications are shipped by the most appropriate method to accommodate the storage requirements of the therapeutic agent being provided to the patient. While disposable temperature sensors and non-pharmacy-based packaging suppliers exist, it is the responsibility of the pharmacy to ensure that internal procedures are developed and appropriate for medication delivery including routine and seasonal temperature monitoring. The specialty pharmacy practice has internal policies and procedures to ensure that internal packaging protocols are appropriate for temperature integrity of packaged medications. Medications are packaged and shipped by an appropriate courier to ensure that the medication is maintained within the manufacturer's or USP storage requirements while in transit through receipt of the package by the patient or patient caregiver.

Hazardous Medications:

The practice has procedures for handling, storage, preparation, and delivery of hazardous medications, including other hazardous materials and access to Safety Data Sheets.

1.8 The specialty pharmacy practice has an appropriate environment to maintain patient privacy and deliver patient care services.**NARRATIVE:**

The specialty pharmacy practice provides patient care services in a setting that maintains privacy and confidentiality and provides the pharmacy staff access to relevant patient information. The specialty pharmacy practice has a procedure to make pharmacy staff members aware of privacy requirements and takes measures to secure patient information and protect patient privacy and confidentiality. The specialty pharmacy practice ensures that patients receive services, including services delivered telephonically, in a space that provides the level of privacy which reduces noise and visibility and is

required by state and federal law. In addition, privacy accommodations are considered in response to patient requests and feedback received by patients.

The specialty pharmacy practice has adequate space and workflow design to conduct its operations and deliver patient care services and is in compliance with state and federal laws regarding access, privacy and safety. Environments have been created to minimize interruptions and allow staff to concentrate on their assigned duties. The specialty pharmacy practice site is neat, clean, and organized to maintain and project a professional appearance. Patient care services are delivered in an environment that provides comfort and privacy to the patient and protects their health information. In addition, the area is not used for storage and is accessed directly without going through storage or dispensing areas. Where appropriate, the environment allows for conducting point-of-care testing and immunization services.

1.9 The specialty pharmacy practice uses systems and technology that support safe medication distribution processes and facilitate patient safety.

NARRATIVE:

The specialty 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, barcode verification of ordered drug and stock bottle and the presentation of an image of the intended medication for the pharmacists at verification. Other tools and technology include biometric verification and photo image verification of tablet/capsule descriptions, automated counting and dispensing devices or equipment. Equipment cleaning, calibration and maintenance should also be addressed. Compounding, sterile and non-sterile, complies with state and federal regulations.

1.10 The specialty pharmacy practice uses information systems and technology for documentation and support of the delivery of patient care services.

NARRATIVE:

The specialty pharmacy practice ensures that pharmacy information systems are utilized to document all clinically relevant patient information in one location at the point of care. This documentation includes all clinically relevant patient information 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 may be obtained from the patient's physician, patient care discharge documentation, or by patient self-reporting and other sources as needed. All information is stored and accessible in a manner that facilitates effective pharmacist communication with patients, caregivers, prescribers, other appropriate healthcare providers, other pharmacists in the specialty pharmacy practice, or external care organizations. Electronic pharmacy information systems are appropriate for the scope of service and size of practice, and facilitate access to clinically relevant patient information.

The specialty pharmacy practice information systems support the pharmacist performing effective prospective and retrospective Drug Utilization Review (DUR).

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.

1.11 Specialty 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 specialty pharmacy practice ensures that the software is readily available and routinely updated to assist the pharmacy staff in effective clinical decision-making. The specialty pharmacy practice establishes expectations for utilization of the most current references and the primary literature in the provision of patient care services.

GOAL:

The specialty pharmacy practice implements clinical decision support programs, as described by the Agency for Healthcare Research and Quality (AHRQ)¹⁰, that aid in guiding evidence-based decision-making.

1.12 The specialty pharmacy practice supports the interoperability¹¹ of information systems.

NARRATIVE:

Patient care is improved through the sharing of patient information among patient care providers. The specialty pharmacy practice implements strategies to facilitate the foundational exchange of medical and medication information. The exchange or transmission of data occurs via fax or telephone or other appropriate method and the practice is able to accept e-prescribing transmissions. This exchange is primarily for the purpose of sharing information between and among appropriate healthcare providers.

GOAL:

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

1.13 The specialty pharmacy practice ensures the integrity, security, and privacy of patient information and other data.

¹⁰ References: What is Clinical Decision Support? Available at: <http://www.himss.org/library/clinical-decision-support>. Accessed 3/27/2018. Clinical Decision Support (CDS). AHRQ. Available at: <https://healthit.ahrq.gov/ahrq-funded-projects/current-health-it-priorities/clinical-decision-support-cds>. Accessed 3/27/2018. Clinical Decision Support (CDS), Chapter 1: "Approaching Decision Support in Medication Management", Section 1 – Introduction. AHRQ. Available at: <https://healthit.ahrq.gov/ahrq-funded-projects/current-health-it-priorities/clinical-decision-support-cds/chapter-1-approaching-clinical-decision/section-1-introduction>. Accessed 3/27/2018.

¹¹ Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. Reference: www.himss.org/library/interoperability-standards/what-is. Accessed 3/27/2018

NARRATIVE

1. The specialty pharmacy practice has policies and procedures to ensure information systems and technology are tested, validated, and updated on a routine basis.
2. The specialty pharmacy practice information system utilizes the most recent National Council for Prescription Drug Programs standards or other appropriate standard(s), and the specialty pharmacy practice routinely receives updates to ensure use of current standards.
3. Specialty pharmacy practice information systems have routine maintenance, validation, update, backup, cyber security, and data-retrieval systems.
4. The specialty pharmacy practice has quality assurance mechanisms to monitor and respond to concerns with performance of pharmacy information systems and technology.
5. Specialty pharmacy practice data are secure and protected from unauthorized access. The specialty pharmacy practice protects and secures the integrity and confidentiality of patient and transactional data. The specialty 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 specialty pharmacy practice ensures that the pharmacy information systems containing patient information meet or exceed security requirements of the Health Insurance Portability and Accountability Act (HIPAA), the Payment Card Industry Data Security Standard, and other industry standards governing the protection of electronic protected health information. The specialty pharmacy practice ensures the maintenance of standard operating procedures including documentation of all staff with access to patient information.

1.14 The specialty pharmacy practice maintains policies and procedures to ensure compliance with HIPAA and HITECH regulations.**NARRATIVE:**

Because data reporting and fee-for-service agreements are commonplace within the specialty pharmacy marketplace, it is imperative that specialty pharmacy practices ensure compliance with regulations protecting patient confidentiality. This preservation of patient confidentiality includes all aspects of pre-dispensing BI services, prior authorization (PA) services, dispensing services, and data reporting services. Specifically within fee-for-service data reporting (non-mandated by payer or manufacturer agreement) patients must be given the opportunity to opt-out of data reporting streams.

The specialty pharmacy has a HIPAA policy in place for employees, vendors, and contractors and the policy includes names of privacy officers, crisis plan, provision of patient documentation, and destruction of protected health information.

With any revisions to regulations governing privacy, such as the HITECH Act provisions and HIPAA requirements, specialty pharmacy practices ensure pharmacy staff is trained. Following privacy regulations, the pharmacy practice provides outbound phone calls and patient assessments to drive overall compliance rates and improve the outcomes of medication therapy.

Equivalent services are provided to all patients as a standard of care service irrespective of fee-for-service agreements tied to particular medications within a therapeutic class.

1.15 The specialty pharmacy practice has a contingency plan in order to maintain patient care services during unplanned events.**NARRATIVE:**

As a critical component of the patient's care team, 24/7 pharmacist access and timely medication delivery are integral to the successful outcome of specialty therapy. Contingency planning for interruption in operations is required in order to maintain service to patients and healthcare providers during unplanned events. Examples include power failure, telephonic failure, pharmacy software downtime, events affecting pharmacy contracts and suppliers, courier service interruption, and other system failure/event leading to operational interruption. The specialty pharmacy practice has a comprehensive contingency plan, including actions to be performed by specific pharmacy staff positions, in order to provide continuity of service in the event that information systems fail as a critical component of patient and healthcare provider support. This may include access to other healthcare providers necessary for provision of care (e.g., nursing). The contingency plan is reviewed at least annually as well as updated based on actual events.

Domain 2.0: Medication Access Support

The specialty pharmacy practice provides services that enable patient access to medications.

2.1 The specialty pharmacy practice provides comprehensive benefits investigation, prior authorization assistance, and benefits coordination on behalf of the patients it serves.**NARRATIVE:**

Specialty pharmacy practice is well-positioned to provide a variety of services that enable the patient to access specialty pharmaceuticals in an appropriate and affordable manner. The specialty pharmacy practice completely and accurately provides benefits investigation (BI), prior authorization (PA), and benefits coordination services to patients in a consistent manner. These services enable access to specialty pharmaceuticals, proper patient education, patient acceptance of medication therapy, and formulary and benefits coverage compliance.

BI services may include complete insurance review (medical and/or pharmacy benefit), formulary status assessment, HUB coordination, 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. The ability of specialty pharmacy practices to assist prescribers in the management of PA for specialty pharmaceuticals is an evolving standard of care.

The specialty pharmacy practice has a consistent process for providing PA services which may include complete insurance coverage review, clinical information assessment, and prospective reauthorization management. When this role has been delegated by the prescriber to the specialty pharmacy practice, it is supported by delegation documentation from the prescriber authorizing the practice to provide the PA service on the prescriber's behalf and is in accordance with any HIPAA/HITECH requirements. BI and PA services are provided either internally within the specialty pharmacy practice or delegated externally

to a third party. As with other delegated functions, delegation documentation is regularly reviewed for compliance and delegation relationships are fully disclosed, as needed.

The specialty pharmacy practice conducts benefits coordination when providing BI and PA assistance services by coordinating information and involvement of the prescriber, other healthcare providers, and other sources of assistance, whenever possible. A major benefits coordination service provided by the specialty pharmacy practice to patients is identifying various sources of financial assistance (manufacturer-sponsored copay cards, manufacturer product assistance, and foundational assistance) and enrolling patients on their behalf after they authorize the service.

The outcome of BI and PA services and benefits coordination (especially patient financial assistance) is communicated to the prescriber by an appropriate method of communication as a means of fostering collaborative patient management.

2.2 The specialty pharmacy practice implements mechanisms to support patient safety and compliance with manufacturer and payer requirements.

NARRATIVE:

Specialty pharmacy practice represents an area of pharmacy practice in which establishing relationships with pharmaceutical manufacturers and payers are integral for gaining/retaining access to specialty pharmaceuticals, providing care to patients, and facilitating patient safety from the time an order is initiated and for the duration of therapy. Specialty medications frequently have restricted distribution networks and require data reporting to manufacturers on dispensing volumes, inventory levels, and patient load. Payer reporting may include call center metrics, formulary and pharmacist interventions, copay compliance, patient adherence and persistence rates, plan cost avoidance, and other dispensing metrics.

Manufacturers provide patient support services through reimbursement HUBS. The registration of patients with these HUB services and the integration of specialty pharmacy practice services with existing HUB services, when appropriate, are frequently required to ensure patient access to manufacturer-sponsored medication financial assistance. In addition, Risk Evaluation and Mitigation Systems (REMS) requirements are integrated into the specialty pharmacy practice in order to support manufacturers in maximizing patient medication safety.

Data reporting is a critical component of specialty pharmacy. Data reporting is frequently required pursuant to inclusion in third-party payer contracts as a mechanism to support quality metrics, cost avoidance, and other measures to support specialty pharmacy network inclusion. Data reporting to pharmaceutical manufacturers is often required in order to gain access to limited distribution pharmaceuticals. Specialty pharmacy practices may be compensated for this and other non-dispensing-related activities as part of product/manufacturer-specific fee-for-service agreements. Specialty pharmacy practices can best meet these reporting requirements by having data/ information systems with the capabilities and capacity to generate and support such reporting.

2.3 The specialty pharmacy practice facilitates patient access to care through the transparent provision of financial information to the patient and prescriber.

NARRATIVE:

Patient acceptance of and long-term compliance with therapeutic regimens are critical for positive therapeutic outcomes from specialty medication therapies. Through a collaborative, patient-centric approach to patient enrollment and financial assessment and education, specialty pharmacists are uniquely qualified to enhance patient adherence and drive improved overall outcomes.

As in Standard 2.1, prescribers are increasingly dependent on specialty pharmacy practices to provide support for their patients through benefits investigation (BI) and prior authorization (PA) services. Through these arrangements, the prescriber is often insulated from the true cost of therapy at the patient level and may be unaware of the overall cost of therapy when alternate therapy exists. Enrollment of patients in manufacturer-sponsored copay assistance programs and the selection of a preferred pharmacy provider shields patients from the true cost of care, and patients are often undereducated about the financial implications of therapy initiation. Manufacturer-sponsored programs often reduce or eliminate deductible phases of coverage, significant coinsurance, and specialty tier copay structures. These programs also protect the patient from adverse formulary agent selection, which could potentially lead to higher out-of-pocket costs if the patient were fully responsible for the costs of therapy.

The collaborative approach to patient access to care through the transparent provision of financial information is multi-factorial and includes the following:

1. Financial assessment and patient education: Through the BI and PA process, specialty pharmacy practice staff is able to fully understand the financial implications of therapy. Staff is fully able to manage patient assistance programs. Prior to enrolling patients in these programs, pharmacy staff will provide full information to patients about the sources of funding and any long-term implications of programmatic changes which could impact the financial responsibility of the patient.
2. Manufacturer-sponsored programs: These programs provide a clear financial benefit to patients. Prior to enrolling patients in these programs, pharmacy staff will provide full information to patients about the sources of funding and any long-term implications of programmatic changes which could impact the financial responsibility of the patient. This information is also provided to prescribers as a means of keeping them abreast of patient therapy initiation and the financial responsibility of their patients when making therapy choices. Enrollment in these programs is not used as a means of shifting patients away from appropriate generic substitution without substantive reason that the generic medication cannot be used. In addition, specialty pharmacy staff ensures compliance with manufacturer-based patient financial support systems (copay cards, etc.). Acquisition cost of the pharmaceutical to the specialty pharmacy practice does not adversely influence patient utilization of nonpreferred/nonformulary options, which increase the cost of care to payers unless it can be documented that the patient has exhausted formulary options.
3. Transparency in pharmacy choice: If, during the course of BI or PA, it is determined that the patient's insurance mandates care through another pharmacy provider, it is an obligation of specialty pharmacy practice to assist the patient with navigating the care system to establish care

with the preferred pharmacy, if desired. In addition, if there is a financial disincentive to the patient for use of the specialty pharmacy providing BI service, this information is provided to the patient in a nonbiased way to avoid influencing patient pharmacy selection or restricting pharmacy choice. This process is seamless from the patient's perspective.

4. Appropriateness of route of medication administration/delivery based on patient characteristics or preference: Specialty pharmacy practices are in an ideal position to assist prescribers to identify patients who may be appropriate for transition to alternate medication/alternate route of administration based on patient characteristics. Specialty pharmacy staff is also uniquely positioned to complete a BI of the alternate therapy to assess formulary placement and streamline the conversion process. This interaction and all discussions with the patient, including financial information, are fully transparent with the intent of preserving patient choice and encouraging adherence to third-party payer formulary.

GOAL:

The specialty pharmacy practice maintains policies for disclosure of manufacturer-based financial agreements and financial assistance provided to patients. Transparency in services provided and associated patient costs are divulged such that the patient understands the current costs and future financial implications for their specialty medications. A commensurate level of service is provided to all patients, irrespective of financial remuneration to the specialty pharmacy by the manufacturer

Domain 3.0: Clinical and Patient Management Services

The specialty pharmacy practice provides clinical management services

3.1 The specialty pharmacy practice facilitates coordinated patient management through enrollment communications to patients and prescribers

NARRATIVE:

The specialty pharmacy practice provides patients with an enrollment or welcome packet inclusive of pharmacy mission statement, ownership, pharmacy location(s) and contact information, hours of operation, organizational goals, expectations of therapy and patient care goals, patient rights, and the complaint process. The patient information is written in language that is easily understood. The welcome packet includes contact information for 24-hour pharmacist support and emergency services offered by the specialty pharmacy provider if appropriate for the scope of practice. The specialty pharmacy practice provides prescribers with a copy of their welcome packet as information about the pharmacy services.

3.2 The specialty pharmacy practice communicates with healthcare providers to facilitate coordination of patient care.

NARRATIVE:

Communication between pharmacy, patient, healthcare providers, and care settings is integral to patient management. It is critical for the specialty pharmacy practice to support prescribers and other healthcare providers in timely therapy coordination, from the initiation of therapy, to the delivery dates of medications, therapy abandonment and interruptions, and through all other points along the

continuum of care. In addition, the ability to assist with the timing of refills to coordinate with key treatment intervals (provider teaching appointments, chemotherapy cycling, patient follow-up appointments, transition to alternate site of care or care provider) is essential to managing the overall patient experience and enabling patient acceptance of therapy. By virtue of their integral role in care delivery, the specialty pharmacy practice is directly involved in the timely provision of medication to avoid delays in key treatment milestones and is directly involved in the timing of therapy initiation and the continuation of therapy.

Relationships with prescribers are also important in supporting them in patient care, in general, and in complying with and maximizing patient medication safety regarding REMS requirements.

GOAL:

The specialty pharmacy practice utilizes collaborative practice agreements to facilitate patient management

3.3 The specialty pharmacy practice maintains internal policies and procedures for collaboration with other pharmacy providers included in the patient's care.

NARRATIVE:

The cornerstone of specialty pharmacy care is the patient-centric focus of the care model. Collaboration between specialty pharmacy and traditional pharmacy providers is critical to managing the overall care of the patient to decrease the fragmentation of specialty medication dispensing from non-specialty medication dispensing. Increased focus on narrow pharmacy networks and limited medication distribution raises potential challenges (e.g., increases the likelihood of polypharmacy of the most complex patients). The specialty pharmacy has policies and procedures for patient/profile/prescription transfers to other pharmacies.

Specialty pharmacy practices are uniquely positioned in the care team and have a responsibility to collaborate with providers of traditional pharmacy care (as well as prescribers and all other stakeholders of patient care). This collaboration begins at the point of patient intake, through BI, dispensing, and to the achievement of therapeutic endpoint or active transfer to the next provider of specialty pharmacy care.

3.4 The specialty pharmacy practice maintains a comprehensive patient profile for all patients.

NARRATIVE:

In order to provide comprehensive clinical management services to specialty pharmacy patients, a specialty pharmacy practice needs as much patient information as possible, and so maintains a complete patient profile inclusive of all medications (specialty and non-specialty, prescription, OTC, and herbal), social information pertinent to patient care, emergency contact information, allergies, adverse drug reactions, REMS adherence, MedGuides, health literacy, and any other information necessary to provide care. The specialty pharmacy practice collects necessary subjective and objective information about the patient including the patient's medical history, diseases states and health conditions, medications, lab results, socio-economic factors, health literacy, language, cultural issues and other

relevant patient data. Prior to each dispense and during each patient contact, staff review the information contained within this profile and make a concerted effort to update pertinent information contained herein, including information from other healthcare providers. As a provider on the healthcare team and the medication use expert, specialty pharmacists use the comprehensive patient profile to properly evaluate patients for clinical appropriateness of targeted therapies prior to therapy initiation or refill including the review of companion diagnostic and pertinent lab data results. It is important that the patient profile include documentation of patient consultations and education provided by specialty pharmacy staff.

3.5 The specialty pharmacy practice provides patient-centered consultation and education regarding expectations of therapy.

NARRATIVE:

Through the review of social and patient medical information, pharmacy staff provides medication consultation, patient education, and patient education materials in a patient-centered fashion. Information is provided at a literacy, health literacy and education level appropriate for the patient based on staff assessment, and addresses the communication needs of the patient or caregiver, including languages and cultural influences, and disabilities, such as blindness or deafness. In addition to specialty pharmacy staff, other patient education resources are available including websites (links to medication information, for example), email, print, text messaging, live web chats, etc.). References or medication information are available to the patient or caregiver during business hours and after hours (include website information or links).

Patient consultation and education is patient-centered and focuses on patient engagement and encompasses expectations of therapy which include: anticipated duration of treatment, expected outcome of treatment, anticipated time to benefit, and the importance of adherence and persistence with therapy, managing adverse events, and other therapeutic and clinical goals. Education about appropriate disposal of unneeded, unwanted, and expired products is provided. This education can be combined with first-dose patient teaching, patient therapy case management, or can be provided as a stand-alone service at patient intake. It is critical that this process establish a realistic baseline of therapy expectation in order to maximize patient adherence and persistence with therapy.

Documentation of patient consultation and education services is required as part of patient profile maintenance and is applicable based on identified specialty pharmacy practice scope of services. The specialty pharmacy practice proactively provides counseling to patients regarding medications and related products and has a defined process for patient counseling. The specialty pharmacy practice obtains, records, and maintains at least the following information required by OBRA 90¹² before a prescription is filled and delivered to a patient:

1. Name address, telephone number, date of birth (or age) and gender
2. Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices

¹²Omnibus Budget Reconciliation Act of 1990. Public Law 101-508, S4401, 1927(g). November 5, 1990. <http://thomas.loc.gov/>. Accessed February 14, 2013.

3. Pharmacist comments relevant to the individual's drug therapy

The specialty pharmacy practice follows OBRA 90 in conducting prospective DUR before a prescription is filled and delivered to a patient. DUR includes screening for potential drug therapy problems due to the following:

1. Therapeutic duplication
2. Drug-disease contraindications
3. Drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs.)
4. Incorrect drug dosage or duration of drug treatment
5. Drug-allergy interactions
6. Clinical abuse/misuse

The specialty pharmacy practice follows OBRA 90 requirements when conducting patient counseling pursuant to a specialty prescription order including the following:

1. Name and description of the medication
2. Route, dosage form, dosage, route of administration, and duration of drug therapy
3. Special directions and precautions for preparation, administration, and use by the patient
4. 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
5. Techniques for self-monitoring drug therapy
6. Proper storage
7. Prescription refill information
8. Action to be taken in the event of a missed dose
9. Education about appropriate disposal of unneeded, unwanted, and expired products

3.6 The specialty pharmacy practice provides and monitors pharmacy patient case management services.

NARRATIVE:

Given the complexity of therapy and the significant financial obligations, patient needs require that specialty pharmacy practice provides clinical management services in a consistent fashion for optimal patient care. Based on identified scope of pharmacy services, the specialty pharmacy provides pharmacy patient case management services consistent with a diagnosis, or by drug therapeutic category or specific drug. Patient-specific documentation of the elements of pharmacy patient case management is required and can be proprietary or a commercially-available documentation system.

The specialty pharmacy practice offers clinical management services, and specifically pharmacy patient case management services, that align with the Joint Commission of Pharmacy Practitioners (JCPP) definition of medication management services (MMS)¹³, and are conducted using disease-specific

¹³ <https://jcpp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf>. Accessed Oct 19, 2018.

patient-case management protocols. The delivery of MMS by the specialty pharmacy practice falls within pharmacy case management services and includes a comprehensive approach to identifying and resolving medication therapy problems. Pharmacy practice staff also evaluates gaps in care, medication history, lab results, medication adherence and other factors to identify patient medication, therapeutic and consultation needs related to patient care services. 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 and allergy 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 outcomes¹⁴
4. Pharmacist interventions as needed to address potential problems or issues, including drug-drug interactions and adverse drug reactions, and assessing barriers to adherence
5. Referrals to other healthcare providers and services, including patient assistance and/or financial assistance programs or grants
6. Ongoing patient monitoring, including lab results when available, and follow-up, and
7. Documentation of all pharmacy case management activities.

The specialty pharmacy incorporates medication therapy management into their services.

1. The pharmacy practice offers medication therapy management (MTM) services delivered by a pharmacist focused on improving patients' therapeutic outcomes. 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 per 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. 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

¹⁴ Pharmacists' Patient Care Process <https://jcpp.net/patient-care-process/>

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. (See the Core Elements service model for more information).

Pharmacy patient case management is offered to all patients, and includes the following patient-specific assessments and information which should be obtained, incorporated and documented as part of the patient case management process (See Appendices for specific protocols):

1. At initiation of specialty therapy, assessment of current and prior medication therapy
2. Pertinent vaccination status assessment at initiation and annually
3. Patient assessment, education, and documentation of all patient parameters needed to determine appropriate medication therapy including patient/caregiver ability to correctly administer medications
4. Patient-reported side effects to any medications
5. Date of previous refill and adherence assessment
6. Drug-specific assessment and/or disease state-specific assessment (inclusive of pertinent lab testing and reporting, pregnancy testing, symptom assessment)
7. REMS and MedGuide accommodation and documentation

In addition, the ability of the specialty pharmacy practice to quantify and readily identify patients with specific diagnoses or on specific therapies is important to ensure compliance with patient pharmacy case management and consistency of patient management with increasing patient volumes.

3.7 The specialty pharmacy practice modifies patient case management based on patient-specific factors when needed.

NARRATIVE:

Specialty pharmacy care is dynamic and is inclusive of patient-centric assessment. Specialty pharmacy practices have the ability to take an individualized approach to every patient and assess those patient-specific metrics which increase the likelihood of non-adherence, lack of follow-up, or drug interactions. However, pharmacy staff must be able to make modifications to the standardized patient management protocol pursuant to patient assessment. These modifications may drive more frequent follow-up or patient assessment if a reason exists to do so.

3.8 The specialty pharmacy practice evaluates and documents 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 specialty pharmacy practice has implemented clear program requirements for evaluating and documenting competency and educating staff involved in patient care delivery, initially and on an ongoing basis. The specialty 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 specialty pharmacy practice also facilitates staff development by providing access to appropriate evidence-based materials and primary literature. The specific competencies are based on factors such as patient population needs and the patient care services provided. Continuing education and professional development should also ensure compliance with appropriate licensures and other credentials.

3.9 The specialty pharmacy practice maintains consistent procedures for patient notification of delays in therapy and interventions.

NARRATIVE:

The ultimate stakeholder in the provision of specialty pharmacy care is the patient, and it is the responsibility of the specialty pharmacy provider to keep the patient informed of any situations that have the potential to delay or interrupt therapy. In addition, the specialty pharmacy notifies patients when interventions have been made on their behalf and why those interventions were made. This further supports the role of the pharmacist in the care team and reinforces the collaboration between pharmacy staff and the patient. Interventions are documented in the patient's pharmacy profile and are communicated directly to the patient and physician by appropriate medium for the clinical scenario.

3.10 The specialty pharmacy practice prohibits the use of refill protocols whereby specialty medications are filled without direct patient contact.

NARRATIVE:

A cornerstone of specialty pharmacy practice is the ability to provide patient-centered care services to ensure that patients have an appropriate response to therapy in order to guide continuation or modification to their therapeutic regimen. Refill mechanisms that bypass specialty patient care programs represent a gap in the safety and effectiveness of medication management and should not be a part of standard specialty pharmacy care protocols.

Domain 4.0: Quality Improvement

The specialty pharmacy practice implements a continuous quality improvement program

4.1 The specialty pharmacy practice reports and evaluates quality outcomes and quality metrics to assess the effectiveness of patient care services and promote continuous quality improvement.

NARRATIVE:

A key component of specialty pharmacy care is the ability to routinely intervene early and often with patients and their medications in order to ensure appropriateness of therapy and perform medication interventions. The specialty pharmacy practice maintains internal procedures for ongoing surveillance and reporting to assess overall appropriateness of therapy and implement quality improvements as needed to integrate quality and outcomes metrics to drive quality improvement and refocus efforts on areas of need. The ability to directly integrate data into practice to influence patient behaviors and drive patient outcomes is a major specialty pharmacy practice core responsibility.

Data reporting on quality metrics and quality outcomes represents a critical component of a comprehensive quality improvement program, allowing patient identification and pharmacy patient case management improvement based on established metrics. Various metrics are important for optimizing patient management and for driving improved outcomes at neutral or reduced cost.

Minimum requirements for specialty pharmacy reporting include the ability to document the following:

1. Adherence rates, Percentage of Days Covered (PDC), preferred, OR Medication Possession Ratio (MPR), based on consensus guidelines for therapeutic class
2. Persistence on therapy and persistence metrics
3. Pharmacist interventions
4. Call center performance
5. Patient and healthcare provider satisfaction
6. Procedure for patient, healthcare provider and employee complaints about any specialty pharmacy practice's services provided internally or delegated contract partner services
7. Quality-related events and medication errors
8. Active patient volume count is maintained on pharmacy patient case management protocols, by disease state
9. Effectiveness of staff resources and staffing model (Standard 1.5.5)

Outcomes measures suggestions related to specific disease states, therapeutic categories, and specific medications are included in Appendix A: Minimum Requirements for Patient Case Management Protocols.

DESCRIPTION:

Adherence metrics: The ability to influence patient behavior through patient-centered education and interventions is a critical component of patient care for specialty pharmacy practices. Adherence rates as measured by standard metrics of adherence such as PDC or MPR can be used as readily reportable benchmarks for adherence. With increasing maturity within Health Economic and Outcomes Research, this differential can also be used to estimate the medical cost savings through the incremental improvement in overall adherence rate and maintaining disease control. In order to adequately estimate compliance rates to allow for benchmarking within the industry, specialty pharmacy practices should follow a standardized approach to calculation of PDC, preferred/MPR rates and ensure that calculation procedures for any payer-based data reporting are consistent with the requirements contained within those agreements.

Patient persistence on therapy: Patient persistence is an important measure to demonstrate specialty pharmacy practice influence on patient behavior through improved patient education. The ability to maintain a patient on preferred formulary therapy and offer incidental cost avoidance related to non-formulary use further reinforces the ability of the provider to drive patient behaviors and acceptance of therapy. This measure is provided as a metric of the percentage of patients maintained on originally prescribed therapy over a defined period of time applicable to the therapy.

Pharmacist interventions: The number and type of pharmacist interventions completed by a specialty pharmacy provider represents a highly tangible metric of quality improvement. Interventions in specialty 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 and cost avoidance. Accurately quantifying the type and quality of interventions by specialty pharmacy practices supports the contribution of specialty pharmacy practice. When possible, intervention tracking is included in pharmacy patient case management in order to fully integrate data for reporting. Additionally, regarding pharmacist interventions and patient management through pharmacy patient case management, it is important for the specialty pharmacy practice to be able to identify, document and quantify the volume of active patients on patient case management protocols, by disease state.

Call center performance: Many, and in some practices most, patient and prescriber interactions with the specialty pharmacy practice are conducted telephonically. Tracking call center performance is part of the continuous quality improvement process. Call center performance tracking is conducted continually and trended and reviewed at least quarterly. Performance trends are integrated to improve the overall care of patients enrolled in the specialty pharmacy practice.

Patient and healthcare provider satisfaction: Patient and healthcare provider satisfaction surveys are a critical part of the continuous quality improvement process. Feedback from these surveys, as well as any internal staff surveys, is integrated to improve the overall care of patients enrolled in the specialty pharmacy practice. Surveys are conducted at least annually and maintained for three years. Surveys should include respondent demographics which will assist quality improvement efforts and the survey process should be continually evaluated to ensure the process gathers pertinent and sufficient feedback for pharmacy service quality improvement.

Complaints from patients, healthcare providers and internal staff regarding any of the services provided by the specialty pharmacy practice or delegated to an external entity provide important information for quality management and continuous quality improvement. The specialty pharmacy practice should have mechanisms for recording, analyzing and addressing complaints.

Quality related events: Specialty pharmacy practice staff documents quality-related events¹⁵ (QREs) and conducts periodic audits of medication errors and QREs. Quality related event monitoring incorporates clinical services, operations and technology. Prescription error rates and error tracking is a critical part of continuous quality improvement and directly drives patient and healthcare provider satisfaction. By investigating the root cause of medication errors and influencing practice to reduce the likelihood of reoccurrence, the overall specialty pharmacy practice is improved. Procedures should include detection, data collection, documentation, tracking, internal reporting and reporting to outside agencies as appropriate.

The specialty pharmacy practice has created a definition for a patient medication event that causes death or serious injury and a process to identify and immediately respond to such an event. The specialty pharmacy practice utilizes root-cause analysis to determine the cause(s), develops and implements a plan to reduce the likelihood of reoccurrence, and monitors effectiveness of the improvements.

Secondary to the role of the specialty pharmacy provider in patient adherence and persistence monitoring, pharmacy providers should also take a proactive role in assuring adherence with manufacturer, payer, and legal requirements associated with the provision of care. Core areas of pharmacy compliance should include the following:

Adverse event reporting:

Due to the complexity of therapy provided to specialty patients and the role of specialty pharmacy in post-marketing surveillance, it is imperative that the specialty pharmacy provide adverse event reporting on behalf of both the industry-based partnerships that are commonplace within the industry and to ensure patient safety. Many specialty medications are used in niche populations and do not have studies prior to approval to provide adequate vetting of side effects within a scalable population.

Procedures should include detection, data collection, documentation, tracking, and internal reporting. In addition, specialty pharmacy practices are frequently the first point of contact for patients experiencing adverse events and as such must have procedures to ensure compliance with MedWatch

¹⁵The 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 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.
- (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.

and other industry-based adverse event reporting programs, as well as reporting to other patient safety organizations as appropriate. Adverse events that potentially jeopardize patients' ability to continue therapy should be reported to the physician and be addressed in a collaborative manner.

Compliance with REMS requirements:

With the increasing implementation of REMS requirements on pharmaceutical manufacturers, REMS management responsibility is increasingly being shifted to pharmacy providers. The number and complexity of REMS programs associated with specialty medications adds to the importance of having internal procedures to ensure compliance with REMS mandates in order to ensure patient safety.

Medication cost avoidance tracking and reporting:

Medication cost avoidance tracking represents a tangible metric and provides value to the patient and the payer. Cost avoidance in specialty pharmacy practice can be globally divided into medication discontinuation (when inappropriate or in cases of lack of therapeutic response), conversion to formulary alternative, and split regimen dispensing. Patient financial assistance sourcing represents an opportunity for medication cost avoidance when it would lead to patient discontinuation or transitioning to nonformulary/nonpreferred therapy. For example, cost to the payer and the patient for a formulary medication versus cost to payer and patient for non-formulary medication represents a significant savings to the payer and patient. Whenever possible, these metrics of intervention tracking are included in pharmacy patient case management in order to integrate data reporting ability.^{16 17}

Adverse third-party audit findings:

Adverse findings of third-party audits represent a significant financial risk to specialty pharmacy practices. In order to mitigate the financial risks of audits, specialty pharmacy practices have a standardized approach to replying to third-party audits and incorporate the findings of those audits into continuous quality improvement and staff training procedures to ensure regulatory, contractual and procedural compliance.

GOAL:

1. The specialty pharmacy monitors the prescription abandonment rate.
The prescription abandonment rate is a contributor to understanding how barriers might impact early non-adherence, as well as lowering medication adherence over time after initiation of therapy. Prescription abandonment that leads to lower medication adherence negatively affects patient health and increasing financial burden on the healthcare system. Prescription abandonment is understood as a prescription written by a prescriber, but never picked up at the pharmacy or obtained by the patient. The prescription abandonment rate can be calculated retrospectively by identifying the proportion of prescriptions (as a percentage of all prescriptions that are authorized) that are initially authorized, but never come into patient possession (or the claim is reversed/credited) with no evidence of a subsequent dispensing of the medication, or a

¹⁶ Resources: <https://www.dovepress.com/role-of-the-pharmacist-in-reducing-healthcare-costs-current-insights-peer-reviewed-fulltext-article-IPRP>.
https://www.researchgate.net/publication/308738038_Impact_of_pharmacist_interventions_on_cost_avoidance_in_an_ambulatory_cancer_center.

¹⁷ J Manag Care Spec Pharm. 2016;22(5):516-23

therapeutic alternative medication, in the ensuing 30 days. “The ability to influence patient behavior and avoid prescription abandonment, through patient-centered education and interventions, as well as coordination of mechanisms to lessen financial barriers, is a critical component of patient care for specialty pharmacy practices.”

2. The specialty pharmacy monitors persistency through use of the Estimated Level of Persistence (ELPT). Both MPR and PDC calculations for persistency do not accommodate nuances, nor fully account for gap days in treatment. Use of the Estimated Level of Persistence (ELPT) or alternative analyses which include number of days to discontinuation and number of prescription refills over a period of time are recommended for persistency calculation.¹⁸
3. The specialty pharmacy monitors medication turnaround time. Medication turnaround time in the outpatient setting is understood as the interval from the time a prescription is received by the pharmacy to time it is received by the patient. Many factors in specialty pharmacy affect this turnaround time, factors such as prior authorization requirements, patient ability to pay and financial assistance, access to the medication, and delivery methodologies. Turnaround time can directly affect patient health and medication adherence as patients who start therapy earlier may be more likely to stay on therapy. Specialty pharmacies should consider national pharmacy quality measures and monitor their prescription turnaround time in order to prevent any delays in therapy which they can affect.

4.2 The specialty pharmacy practice implements continuous quality improvement projects based on quality metric reports.

NARRATIVE:

The use of data from data reporting and quality metrics to directly influence and improve overall specialty pharmacy practice is critical to improving patient care. Because continuous quality improvement is a fluid and evolving process, staff receives initial and ongoing education on the need for improvements so that a culture is established to integrate recommendations into practice. The pharmacy practice conducts quality self-audits and holds peer-review meetings on a quarterly basis. Peer review as part of a CQI program includes:

1. The collection of data necessary to identify when standards are not being met and data necessary to evaluate the reason(s) the deficiency occurred.
2. An objective review of the data to make recommendations for quality improvement.
3. 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.

Pharmacy staff is actively engaged in quality improvement projects and initiatives derived from quality reports and other data and participate in identifying opportunities for improvement and in driving positive patient outcomes.

¹⁸ Peterson, AM. Et al. A Checklist for Medication Compliance and Persistence Studies Using Retrospective Databases. *Value in Health* 2007;10;1. Dezii CM. Persistence with drug therapy: a practical approach using administrative claims data. *Managed Care* 2001;10:42-5

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.

The 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.

4.3 The specialty pharmacy practice provides accurate data reports.

NARRATIVE:

The specialty pharmacy practice ensures that data reports are reliable and accurate when provided to stakeholders. Data for required data reports may originate from several disparate systems and have variable formats. The value of data is significantly reduced with aberrations in the reliability, accuracy and timeliness of reporting, and additional scrutiny is warranted to ensure that reports are correct based on the intended audience and agreement.

Data reconciliation is completed prior to the submission of any specific data file or report, but broad-scale quality assurance is conducted to reconcile any gaps in reporting or aberrations in data. Reconciliation occurs more frequently pursuant to any changes to data agreements or with any identified inconsistencies within the specialty pharmacy reporting infrastructure. A complete review of the data management system occurs at least annually.

Appendix A: Minimum Requirements for Patient Case Management Protocols

Minimum requirements for patient case management protocols include initiation and refill requirements. Suggestions for outcomes measurements are advisory and not required.

Alpha-1 Antitrypsin Deficiency

Initiation Requirements

- AAT 1.1. Current and prior medication therapy assessment at initiation (54)
- AAT 1.2. Comprehensive drug interaction assessment (54)
- AAT 1.3. Vaccination status assessment at initiation and annual (3)

Refill Requirements

- AAT 2.1. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <80%
- AAT 2.2. Adverse reactions and their mitigation (1, 54)
- AAT 2.3. Annual influenza vaccination reminder (3)

Outcomes Suggestions

Hospitalization rate, functional status, exacerbation prevention, endurance, adherence

Behavioral Health

Initiation Requirements

- BH 1.1. Current and prior medication therapy assessment at initiation (52, 54)
- BH 1.2. Dose modification and titration recommendations for at-risk groups and those with major organ dysfunction, pre-existing neurological disease (27, 52)
- BH 1.3. Comprehensive drug interaction assessment (54)
- BH 1.4. Minimize unnecessarily high doses and polypharmacy (27, 52)
- BH 1.5. Assessing patient's cognitive state and ability to comprehend and retain information (27)
- BH 1.6. Vaccination status assessment at initiation and annual (3)

Refill Requirements

- BH 2.1. Medication changes and interaction assessment (54)
- BH 2.2. Adherence assessment (52, 54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <80%
- BH 2.3. Adverse reactions and their mitigation (1, 27, 54)
- BH 2.4. Communication with rehabilitation center, family, or support system, as appropriate (57)
- BH 2.5. Annual influenza vaccination reminder (3)
- BH 2.6. Relevant biochemical, hematological, neurological, psychological and/or other specialized monitoring (27)
- BH 2.7. Recommending strategies for managing discontinuation syndromes when psychotropic medications are discontinued (27, 57)

Outcomes Suggestions

Adverse events, drug interaction prevention, polypharmacy reduction, adherence

Bleeding DisordersInitiation Requirements

- BD 1.01. Current and prior medication therapy assessment at initiation (54)
- BD 1.02. Vaccination status assessment at initiation and annual (3, 39)
- BD 1.03. Patient education on ancillary treatments including adverse reaction medications such as diphenhydramine or epinephrine (32)
- BD 1.04. Assessment of ordered dose, product, and stocked product assay (9)
- BD 1.05. Prescription order turn-around of <48 hours (9)
- BD 1.06. Physicians and patients have access to all US FDA approved manufactured products and ancillary supplies (9)
- BD 1.07. Supplied dose is within 5-10% of ordered dose (9)
- BD 1.08. Lot number tracking (9)
- BD 1.09. Pharmacy participation in the National Patient Notification System for product recalls (9)
- BD 1.10. Minimum of 6 months expiration dating remaining on product (9)
- BD 1.11. Patient assessment for understanding of route of administration and IV access (32)
- BD 1.12. Procedure for patient referral to prescriber for bleeding disorder related emergency department visits (9)

Refill Requirements

- BD 2.01. Prescription order turn-around of <48 hours and 24-hour emergency access (9)
- BD 2.02. Patient body weight assessed at time of dispensing (32)
- BD 2.03. Supplied dose is within 5-10% of ordered dose (9)
- BD 2.04. Minimum of 6 months expiration dating remaining on product (9)
- BD 2.05. Assessment of bleed and dispensing history (32)
- BD 2.06. Procedure for patient referral to prescriber for bleeding disorder related emergency department visits (9)
- BD 2.07. Lot number tracking (9, 81)
- BD 2.08. Track patient's doses on hand before dispensing (51, 81)

Bone Marrow TransplantationInitiation Requirements

- BMT 1.01. Current and prior medication therapy assessment at initiation (54)
- BMT 1.02. Comprehensive drug interaction assessment (54)
- BMT 1.03. Vaccination status assessment at initiation and annual (3)
- BMT 1.04. Pertinent drug levels and therapeutic drug monitoring targets (18)
- BMT 1.05. Sun precaution recommendations (increased BCC risk) (26)

Refill Requirements

- BMT 2.01. Medication changes and interaction assessment (54)
- BMT 2.02. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <90% (transplant pharmacist expert opinion)
- BMT 2.03. Adverse reactions and their mitigation (1, 54)
- BMT 2.04. Screening for infection (42)
- BMT 2.05. Annual influenza vaccination reminder (3)
- BMT 2.06. Renal function assessment (26)
- BMT 2.07. Monitoring for GVH (allogeneic SCT) (42)
- BMT 2.08. Assessment of continued need for prophylactic medications at regular intervals (26)

Outcome measure suggestions

Survival rate, quality of life (106)

Fertility and High-risk PregnancyInitiation Requirements

FER 1.01. Current and prior medication therapy assessment at initiation (54, 55)

FER 1.02. Screening non-fertility medications for contraindication in pregnancy (28, 36, 55)

FER 1.03. Patient injection teaching (in person or virtual) (2, 65)

FER 1.04. Verification of patient acceptance and understanding of injection technique (for injectable meds) (65)

FER 1.05. Prenatal and vitamin D supplementation (50)

FER 1.06. Methotrexate for ectopic pregnancy: height/weight confirmation, BSA calculation to confirm dose, two-pharmacist dosing check. (33)

Refill requirements

N/A

Outcome measure suggestionsFertility: N/AHigh-risk pregnancy: starting drug on time: maintaining pregnancy with optimal adherence to medication up through 36 weeks gestation**Growth Disorders**Initiation Requirements

GD 1.01. Current and prior medication therapy assessment at initiation (54)

GD 1.02. Patient device teaching, in person or virtual, and verification of patient acceptance and understanding of injection technique, if applicable. (2, 15, 61)

GD 1.03. Patient appropriateness of indication and use of growth hormone product (4)

Refill Requirements

GD 2.01. Medication changes and interaction assessment (54)

GD 2.02. Adherence assessment (54)

a. Missed doses in the past 30 days (59)

b. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (53)

GD 2.03. Assessment of injection issues (15, 61)

GD 2.04. Adverse reactions and their mitigation (focus on headache, blurry vision, injection site reactions) (4, 15)

GD 2.05. Annual influenza vaccination reminder (3)

Outcome measure suggestions

Height progress to goal

HepatologyInitiation Requirements

HEP 1.01. Prior HCV therapy and all current medication therapy assessment at initiation (54)

HEP 1.02. Vaccination status assessment at initiation (3)

HEP 1.03. Hepatitis C genotype (89)

HEP 1.04. Hepatitis C RNA level (89)

HEP 1.05. Hepatic function panel, eGFR, hepatic fibrosis staging, treatment history (89)

- HEP 1.06. HBV co-infection screening (HBsAg, anti-HBs, anti-HBc) (89)
- HEP 1.07. Record of HIV risk assessment, status and/or screening results (89)
- HEP 1.08. Baseline drug specific resistance testing (i.e. ZEPATIER, prior DAA treatment failures.) (89)
- HEP 1.09. CBC if on ribavirin (89)
- HEP 1.10. Pregnancy testing in all women of childbearing potential prior to starting ribavirin (89)

Refill Requirements

- HEP 2.01. Concurrent medication therapy screening (i.e. acid reducing medication interactions, statin interactions, when applicable) (54)
- HEP 2.02. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <95% (99)
- HEP 2.03. Side effect and adverse reaction mitigation (1, 54)
- HEP 2.04. Hepatitis C RNA level at 12 weeks after end of therapy with additional testing as clinically indicated. (89)
- HEP 2.05. Hepatic function panel, eGFR. (89)
- HEP 2.06. CBC after 2 weeks if on ribavirin. (89)

Outcome measure suggestions

Sustained viral response at 12 weeks post-treatment (1, 54); differentiation between patients filling at this pharmacy vs. those required to transfer to another due to insurance restrictions; time to medication approval, time to start of therapy.

Hereditary Angioedema

Initiation Requirements

- HAE 1.1. Current and prior medication therapy assessment at initiation (54)
- HAE 1.2. Comprehensive drug interaction assessment (54)
- HAE 1.3. Vaccination status assessment at initiation and annual (3)

Refill Requirements

- HAE 2.1. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <90%
- HAE 2.2. Adverse reactions and their mitigation (1, 54)
- HAE 3.1. Annual influenza vaccination reminder (3)

Outcomes Suggestions

Change in symptom severity, frequency or duration; missed school/work days; emergency room visits

HIV

Initiation Requirements

- HIV 1.01. Prior and current medication therapy assessment at initiation (54)
- HIV 1.02. Comprehensive drug interaction screening for all medications (specialty and non-specialty) (69)
- HIV 1.03. Vaccination status assessment at initiation and annual (3, 69)
- HIV 1.04. Hepatitis B testing and results (102)
- HIV 1.05. Hepatitis C testing and results (69)
- HIV 1.06. HIV viral load and genotype (69)
- HIV 1.07. CD-4 count (69)

HIV 1.08. Depression screening (69)

HIV 1.09. Substance abuse screening (tobacco, alcohol, and illicit substances) (69)

HIV 1.10. Tuberculosis screening, toxoplasmosis screening, sexually transmitted infections testing, and comorbid conditions assessment (69)

Refill Requirements

HIV 2.01. Comprehensive drug interaction screening for all medications. (69)

HIV 2.02. Adherence assessment (69)

a. Missed doses in the past 30 days (8, 59)

b. Referral procedures to MD for evaluation for patients with PDC or MPR <90% (41)

HIV 2.03. Adverse reactions and their mitigation (1, 69)

HIV 2.04. HIV viral load every 3 - 6 months and as clinically indicated; CD4 count every 3 - 6 months and as clinically indicated (102)

HIV 2.05. Regular depression screening (44)

HIV 2.06. Pregnancy test and verification of contraception for women of childbearing age, if initiating efavirenz or dolutegravir (102)

HIV 2.07. HLA-B*5701 testing (under clinical evaluation, abacavir use only) (69)

HIV 2.08. Tropism testing (maraviroc use only) (102)

Outcome measure suggestions

achievement of virologic suppression within 6 months (24 weeks) of antiretroviral initiation; documentation of annual influenza vaccine (and other recommended vaccines as indicated); achieving HIV viral load of undetectable or <20.

Hypercholesterolemia

(non-statin therapies including mipomersen, lomitapide, and PCSK9 Inhibitors)

Initiation Requirements

HC 1.01. Current and prior medication therapy assessment at initiation (54)

HC 1.02. Patient injection teaching (in person or virtual) (2, 62, 65, 85)

HC 1.03. Verification of patient acceptance and understanding of injection technique (for injectable meds) (65)

HC 1.04. Baseline CMP (liver transaminases and kidney function) and Lipid Panel (67, 88)

HC 1.05. LFT assessment (mipomersen, lomitapide) at baseline (24, 79)

HC 1.06. Pregnancy test (lomitapide) at baseline (24)

HC 1.07. REMS program requirements for mipomersen and lomitapide (24, 79)

Refill Requirements

HC 2.01. Concurrent medication therapy screening (54, 67)

HC 2.02. Adherence assessment (54, 67)

c. Missed doses in the past 30 days (59, 67) and evaluation of barriers to adherence (67)

d. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (49)

HC 2.03. Assessment of injection issues, as appropriate (65, 88)

HC 2.04. Adverse reactions and their mitigation (54)

HC 2.05. LDL-C assessment at regular intervals (every 3-12 months), and 1-3 months after treatment modification. (67, 88)

HC 2.06. LFT assessment (mipomersen, lomitapide) at least ALT/AST monthly x 12 months, then every 3 months (24, 79) Liver enzymes should be 3 months after fibrate or niacin treatment and then periodically thereafter (annually or semiannually). (88)

HC 2.07. Annual influenza vaccination reminder (3)

HC 2.08. Assess creatinine kinase levels upon statin discontinuation for clinical reports of significant myalgias or rhabdomyolysis. (88)

HC 2.09. REMS program requirements for mipomersen and lomitapide (24, 79)

Outcome measure suggestions

Lifestyle modifications, hypertension management, weight loss and dietary changes, cardiovascular risk assessment (Framingham score), smoking cessation and DM management should be considered in patients with hypercholesterolemia. CKD management is necessary in patients with renal impairment because of the increased risk in developing ASCVD (CKD is considered an ASCVD equivalent). Patients who experience severe myalgias or rhabdomyolysis while on statin therapy need to be assessed for treatment with PCSK-9 inhibitor (statin re-challenge may not be tolerated in these patients) (88)

Immune Globulin Therapy

Initiation Requirements

IG 1.01. Current and prior medication therapy assessment is performed at initiation (54)

IG 1.02. Patient assessment for understanding of route of administration and plan of care (35)

IG 1.03. Patient-specific clinical considerations determine setting and supervision during infusion. (17)

Infusions

IG 1.04. Complete set of vital signs should be taken before initiation of any intravenous IG infusion (35)

IG 1.05. Initial infusion of immune globulin, as well as the first dose of a new immune globulin product, to be given in a controlled or monitored setting (35)

IG 1.06. Infusions are administered at rates following the manufacturer's recommendations, identified risk factors, and patient tolerability (35)

IG 1.07. Use of an infusion pump is recommended (35)

Subcutaneous route

IG 1.08. Patient device teaching and verification of patient acceptance and understanding for subcutaneous administration (2)

IG 1.09. Patient education regarding need for documentation log including dates, total time of infusion, lot numbers of products, location and number of sites, and reactions (35)

Refill Requirements

IG 2.01. Medication profile update and screening for changes in health status, and tolerability of product (54, 35)

IG 2.02. Assessment of infusion or subcutaneous injection issues and adjustment of administration supplies (i.e. changing needle length for subcutaneous administration) (35)

IG 2.03. Infusion rate monitoring (35)

IG 2.04. Monitoring compliance for missed doses (59)

IG 2.05. Adverse reaction monitoring and mitigation (1, 54)

IG 2.06. Referral procedures to MD for immune deficient patients with breakthrough infections (35)

Outcome measure suggestions

Decreased rate of infection (for PID); decreased neurological symptoms (for neurological indications).

Inflammatory Conditions

Including arthritis (RA AS, PsA, JIA), gastroenterology (CD, UC), and dermatology (Ps)

Initiation Requirements

IC 1.01. Current and prior medication therapy assessment, including DMARD and non-DMARD therapy, at initiation (54, 90, 100)

IC 1.02. Comprehensive drug interaction assessment (54)

- IC 1.03. Vaccination status assessment at initiation as recommended for condition(s), medication, and age (3, 100)
- IC 1.04. TB and opportunistic infection status at initiation of biologic and Janus Kinase inhibitor therapy (10, 56, 100)
- IC 1.05. Hepatitis B status at initiation of therapy with: B-cell modulators, Interleukin-6 antagonists, Janus kinase inhibitors, T-cell modulators, TNF-alpha inhibitors (10, 45, 100)
- IC 1.06. Patient device teaching, in person or virtual, and verification of patient acceptance and understanding of injection technique, if applicable. (2)
- IC 1.07. Sun precaution recommendations, as applicable in RA (increased BCC risk) (5, 80, 84)
- IC 1.08. Co-morbidity screening (i.e. heart failure, malignancy, MS, serious infection) at TNFI initiation (68, 75, 82, 100)
- IC 1.09. JC virus assessment prior to natalizumab treatment (100)
- IC 1.10. Pregnancy test and/or birth control counseling prior to TNFI and DMARD initiation (68, 100, see prescribing information)
- IC 1.11. Baseline disease severity and inflammatory markers, if available (13, 68)
- IC 1.12. REMS verification, as required (96, see prescribing information)

Refill Requirements

- IC 2.01. Concurrent medication therapy screening, including DMARD (54)
- IC 2.02. Adherence assessment (54):
 - a. Missed doses in the past 30 days (59)
 - b. Referral to MD for evaluation in patients with PDC or MPR <80% (56, 31, 77)
- IC 2.03. Adverse reaction assessment and mitigation (1, 54) including:
 - a. Injection related concerns, if applicable (22, 47, 105)
 - b. Infection screening, including annual TB assessment (56, 68, 105)
- IC 2.04. Efficacy assessment including:
 - a. Steroid courses in the past 30 days (14, potentially applicable for rheumatic and dermatologic disease)
 - b. Bowel movement changes or GI symptoms (i.e. recurrence frequency, abdominal pain, weight loss, fatigue, anemia, tolerance to medical intervention) (14, 64, 90, 100)
 - c. Arthritis disease activity (68)
 - d. Body surface area involvement (91)
 - e. Periodic review of inflammation markers, if applicable (13, 64, 68, 90, 100)
- IC 2.05. Annual vaccination status assessment as recommended for condition(s), medication, and age, including influenza vaccination reminder (3, 68)
- IC 2.05. REMS verification, depression screening, suicide screening, as required (94, 96, see prescribing information).

Outcome measure suggestions

Inflammatory Arthritis

- Decreased progression in joint degeneration (68)
- Achievement of remission based on disease activity scoring instrument (68)

Gastroenterology

- Decreased GI symptoms, increased quality of life (100)
- Decreased pain (19, 29)
- Hospitalization and/or emergency room visit rates. (104, 108)

Dermatology

- Decrease in body surface area involvement (91)

Infusible Oncology/HematologyInitiation Requirements

- IOH 1.01. Current and prior medication therapy assessment at initiation, including allergy history (54)
- IOH 1.02. Comprehensive drug interaction assessment (54)
- IOH 1.03. Vaccination status assessment at initiation and annual (3)
- IOH 1.04. Supportive care medication appropriateness based on emetogenic risk of therapy (92, 93)
- IOH 1.05. Pregnancy testing, baseline labs, obtaining med list, counseling on adverse drug reactions (see prescribing information)
- IOH 1.06. Intended chemotherapy cycling and dosing regimen (30, 87)

Refill Requirements

- IOH 2.01. Medication changes and interaction assessment (34, 54)
- IOH 2.02. Lab monitoring (i.e. CBC, Chem-7, and other labs as pertinent for therapy) (34)
- IOH 2.03. Adverse reactions and their mitigation (1, 34, 54)
- IOH 2.04. Infusion base solution appropriateness and expiration dating (34)
- IOH 2.05. Chemo cycle timing assessment (34)
- IOH 2.06. Annual influenza vaccination reminder (3)
- IOH 2.07. Referral procedures to MD for evaluation of patients inappropriate for continuation of therapy or demonstrating significant side effects (34)
- IOH 2.08. Assessment of continued need for prophylactic or additional medications for symptom mitigation (i.e. pain management, GCSF support) (34)

Outcome measure suggestions

Patients counseled by pharmacists, interventions made/documentated (expert opinion)

Multiple SclerosisInitiation Requirements

- MS 1.01. Current and prior medication therapy assessment at initiation (54)
- MS 1.02. Baseline lab assessments TFT, LFTs, CBC (45), including drug-specific assessments, as appropriate:
 - a. Teriflunomide: drug interactions (specifically warfarin), LFTs, TB test, CBC, pregnancy (70, 95)
 - b. Fingolimod: drug interactions, CBC with differential, LFTs, ECG, VZV titer, pregnancy and ophthalmologic exam (95, 103)
 - c. Interferon therapy: LFTs, CBC, thyroid function and pregnancy (63, 71, 72, 83, 95)
 - d. Dimethyl fumarate: CBC with differential, LFTs, and pregnancy (95, 97)
- MS 1.03. Patient device teaching, in person or virtual, and verification of patient acceptance and understanding of injection technique, if applicable. (2)
- MS 1.04. Vaccination status assessment at initiation (45)

Refill Requirements

- MS 2.01. Side effect and adverse reaction-mitigation (including liver injury assessment, i.e. yellowing of skin/eyes, dark urine, abdominal pain, vomiting, increased fatigue) (1, 54)
- MS 2.02. Drug-specific assessments, as appropriate:
 - a. Teriflunomide: pregnancy (category X), LFTs monthly every month for 6 months (though should not hinder refill availability), GI upset, alopecia (month 2-6) (70, 95)
 - b. Fingolimod: pregnancy, adherence (due to repeat FDO), changes in home medication list, eye changes, back pain (95, 103)

- c. Dimethyl fumarate: adherence, pregnancy, GI upset, flushing; Interferon therapy: signs/symptoms of depression, injection site reactions, flu-like side effects, pre-medication with NSAID/acetaminophen (95, 97)
- d. Glatiramer acetate: injection site reactions, hypersensitivity reactions, rotation of injection sites (95, 101)

MS 2.03. Assessment of injection issues or necrosis at injection sites (6)

MS 2.04. Screening for infection (45)

MS 2.05. Adherence assessment:

- a. Missed doses in the past 30 days (59)
- b. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (21)

MS 2.06. Report S/Sx of relapse to prescriber (45)

MS 2.07. Report S/Sx suggestive of progression to secondary progressive disease to prescriber (45)

MS 2.08. If collaborative practice agreement, assessment of disease effect on daily activities (urinary, fatigue, etc.) (45)

MS 2.09. Annual vaccination status assessment, including influenza vaccination reminder (45)

Outcome measure suggestions

Adherence; adverse effect mitigation; Injection site reaction and mitigation; improvement in drug access/affordability; collaborative management of MS symptoms

Oral Oncology/Hematology

Initiation Requirements

OOH 1.01. Current and prior medication therapy assessment at initiation (54)

OOH 1.02. Comprehensive drug interaction assessment (54)

OOH 1.03. Vaccination status assessment at initiation (3)

OOH 1.04. Swallow dosage forms whole, if applicable (see prescribing information)

OOH 1.05. Pregnancy testing, baseline labs, obtaining med list, counseling on adverse drug reactions (see prescribing information)

OOH 1.06. Intended chemotherapy cycling and dosing regimen (30, 87)

Refill Requirements

OOH 2.01. Medication changes and interaction assessment (87)

OOH 2.02. Adherence assessment: (30, 54)

- a. Missed doses in the past 30 days (59)
- b. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (86)

OOH 2.03. Adverse reactions and mitigation (1, 54)

OOH 2.04. Labs, pregnancy testing (see prescribing information)

OOH 2.05. Annual influenza vaccination reminder (3)

Outcome measure suggestions

Patients counseled by pharmacists, interventions made/documentated (expert opinion)

Osteoporosis*

Initiation Requirements

OP 1.1. Current and prior medication therapy assessment at initiation (54)

OP 1.2. Comprehensive drug interaction assessment (54)

OP 1.3. Bisphosphonate therapy should be avoided in patients who cannot swallow, sit upright or have pre-existing GI condition that will lead to GI irritation (107)

OP 1.3. Vaccination status assessment at initiation and annual (3)

- OP 1.4. Screen medications for fall risk (38, 78)
- OP 1.5. Evaluate adequate calcium and vitamin D intake (16, 66)
- OP 1.6. DEXA scan and fracture risk assessment, bone turnover markers, serum vitamin D (66)
- OP 1.7. Assessment of lifestyle: alcohol or smoking history, fall risk (66)
- OP 1.8. Orthostatic hypotension monitoring (23, 98)

Refill Requirements

- OP 2.1. Medication changes, interactions, and fall risk assessment (54, 78)
- OP 2.2. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (20)
- OP 2.3. Adverse reactions and their mitigation (1, 54)
- OP 2.4. Annual influenza vaccination reminder (3)
- OP 2.5. Monitor serial changes in bone mineral density (66)
- OP 2.6. Assess length of therapy appropriateness (66). Teriparatide therapy should be limited to 2 years. A “drug holiday” should be considered after 5 years of stability on oral bisphosphonates in moderate-risk patients and after 6-10 years of stability in higher-risk patients. A “drug holiday” should be considered after 3 annual doses of IV zoledronic acid and after 6 annual doses in higher-risk patients. A “drug holiday” is not recommended with denosumab.

Outcome measure suggestions

Prevention of fractures (no new fracture or fracture progression) (66)

- * Osteoporosis NOTES: Medications indicated for initial therapy of patients (66)
- Risedronate, risedronate, zoledronic acid, and denosumab are appropriate as initial therapy for most patients at high risk of fracture.
 - Teriparatide, denosumab, or zoledronic acid may be considered for patients unable to use oral therapy as initial therapy for patients at especially high fracture risk.
 - Raloxifene or ibandronate may be appropriate initial therapy in some patients requiring spine-specific efficacy.

Pulmonary Disorders (Cystic Fibrosis, Pulmonary Arterial Hypertension)

Initiation Requirements

- PD 1.01. Current and prior medication therapy assessment at initiation (54)
- PD 1.02. Comprehensive drug interaction assessment (54)
- PD 1.03. Vaccination status assessment at initiation and annual (3, PAH 48)
- PD 1.04. Baseline PFT assessment

Refill Requirements

- PD 2.01. Medication changes and interaction assessment (54)
- PD 2.02. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <90%
- PD 2.03. Screening for infection, worsening of symptoms (CF 40, PAH 48)
- PD 2.04. Adverse reactions and their mitigation (1, 54)
- PD 2.05. Annual influenza vaccination reminder (3)
- PD 2.06. PFT assessment at regular intervals
- PD 2.07. Changes to daily activities indexes (PAH 48)
- PD 2.08. Assessment of continued need for prophylactic medications at regular intervals (CF 40)

Outcome measure suggestions

CF: Pulmonary function, growth and weight gain (pediatrics), missed school/work days, hospitalization
PAH: Functional status, function tests, exercise capacity, endurance

Renal FailureInitiation Requirements

- RF 1.01. Current and prior medication therapy assessment at initiation (54)
- RF 1.02. Comprehensive drug interaction assessment (54)
- RF 1.03. Vaccination status assessment at initiation and annual (3)
- RF 1.04. Dosage form administration and timing of dosing (7)
- RF 1.05. Renal function and appropriateness of all medications for current renal function (7)
- RF 1.06. Pertinent lab data (CBC, electrolytes, renal function assessment) (7)
- RF 1.07. Currently receiving dialysis (dialysis type, and schedule, and drug/dose appropriateness) (7)

Refill Requirements

- RF 2.01. Medication changes and interaction assessment (54)
- RF 2.02. Adherence assessment (rate and timing of administration) (7)
 - a. Missed doses in the past 30 days (59)
 - b. SOT 3.3. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (46, 74)
- RF 2.03. Adverse reactions and their mitigation (1, 54)
- RF 2.04. Annual influenza vaccination reminder (3)
- RF 2.05. Renal function assessment (7)

Outcome measure suggestions

Functional status, adverse effects, symptom burden, hospitalization

Restricted DistributionInitiation Requirements

- RD 1.01. Current and prior medication therapy assessment at initiation (54)
- RD 1.02. Comprehensive drug interaction assessment (54)
- RD 1.03. Vaccination status assessment at initiation and annual (3)

Refill Requirements

- RD 2.01. Concurrent medication therapy screening (54)
- RD 2.02. Adherence assessment (54)
 - a. Missed doses in the past 30 days (59)
 - b. Referral procedures to MD for evaluation for patients with PDC or MPR <80%
- RD 2.03. Adverse reactions and their mitigation (1, 54)
- RD 2.04. Annual influenza vaccination reminder (3)

Outcomes Suggestions

Medication turn-around time, adherence, REMS compliance, satisfaction

Solid Organ TransplantationInitiation Requirements

- SOT 1.01. Current and prior medication therapy assessment at initiation (18, 54)
- SOT 1.02. Comprehensive drug interaction assessment (54)
- SOT 1.03. Vaccination status assessment at initiation and annual (3)

SOT 1.04. Swallow dosage forms whole, if applicable (43)

SOT 1.05. Sun precaution recommendations (increased BCC risk) (43)

SOT 1.06. Baseline CBC, CMP, renal function assessment when appropriate (11, 18)

SOT 1.07. Pregnancy consultation (particularly with MMF) when appropriate (11)

Refill Requirements

SOT 2.01. Medication changes and interaction assessment (43)

SOT 2.02. Annual influenza vaccination reminder (3, 43)

SOT 2.03. Adherence assessment (54)

a. Missed doses in the past 30 days (59)

b. Referral procedures to MD for evaluation for patients with PDC or MPR <80% (74) Expert opinion is that PCD or MPR of at least 0.9 should be targeted given the possibility of patient harm occurring after very few missed doses.

SOT 2.04. Screening for infection (18, 43)

SOT 2.05. Adverse reactions and their mitigation (1, 54)

SOT 2.06. Pertinent drug levels and therapeutic drug monitoring targets, if available (18, 11)

SOT 2.07. CBC, CMP, renal function assessment when appropriate (11, 18)

SOT 2.08. Periodic REMS for mycophenolate (11)

SOT 2.09. Assessment of continued need for prophylactic medications at regular intervals (18)

Outcome measure suggestions

Management of patient's diabetes, cardiovascular, osteoporosis, cancer, and infection risks (25)

Appendix A References

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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.
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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. 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/dhds/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. 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. 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. 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.

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 MSDSs 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