

*Advancing Quality, Safety and Patient Care*



# Center for Pharmacy Practice Accreditation

## Specialty Pharmacy Practice Standards

Version I, January 5, 2015

# CENTER FOR PHARMACY PRACTICE ACCREDITATION

## Specialty Pharmacy Standards

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# SPECIALTY PHARMACY PRACTICE STANDARDS

Version I, January 5, 2015

## Introduction

The Center for Pharmacy Practice Accreditation (CPPA) recognizes the public's need for specific predictable and measurable pharmacist's clinical services. To meet this need, CPPA gathered expert stakeholders to develop consensus-based specialty pharmacy practice standards. The resulting voluntary accreditation process is offered to those specialty pharmacy practices with an interest in improving patient care by differentiating their practices as exceptional through this formal recognition program.

CPPA creates, manages, and maintains the process that leads to the use of standards for pharmacy practice accreditation. CPPA implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. The mission of CPPA is to serve the public health by raising the level of pharmacy-delivered patient care services through accreditation of the pharmacy practice.

## Purpose of the Specialty Pharmacy Practice Standards

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

- 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

Specialty medication costs are expected to reach \$192B in 2016 and quadruple to over \$400B by 2020.<sup>3</sup> Under the pharmacy and medical benefits, the 3.6% of members who use specialty medications account for 25% of healthcare costs.<sup>4</sup> Given these factors, it is imperative that pharmacy practices help optimize the clinically appropriate use of specialty medications.

<sup>1</sup>Blaser DA, Lewtas AJ, et al. How to define specialty pharmaceuticals—a systematic review. *Am J Pharm Benefits*. 2010;2(6):371-380.

<sup>2</sup>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.

<sup>3</sup>CVS Caremark. Insights 2013. [http://info.cvscaremark.com/sites/default/files/INSIGHTS\\_Trend\\_0.pdf](http://info.cvscaremark.com/sites/default/files/INSIGHTS_Trend_0.pdf). Accessed February 21, 2014.

<sup>4</sup>Prime Therapeutics. Specialty Drug Trend Insights 2013. <https://www.primetherapeutics.com/PDF/specialtydtr2013/index.html>. Accessed February 21, 2014.

CPPA Specialty Pharmacy Practice Standards are designed to create a consensus around the practice of specialty pharmacy and guide the accreditation process. CPPA defines specialty pharmacy practice 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 disease or conditions<sup>5</sup> 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.”<sup>6</sup> These standards seek to provide clarity to the key metrics that effectively support patients, healthcare providers, manufacturers, payers, and peers engaged in the specialty pharmacy practice.

Scope of Standards: The CPPA Specialty Pharmacy Standards address four primary areas of specialty pharmacy practice, which encompass the overall provision of pharmacy care for patients receiving 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 standards are organized under the following Standard Domains:

- 1.0 Organizational Infrastructure
- 2.0 Access to Medications
- 3.0 Clinical Management Services
- 4.0 Quality Improvement

Within each Standard Domain are key standards that demonstrate competency in the identified area of specialty pharmacy practice. These standards represent the specific criteria for CPPA evaluation of the specialty pharmacy practice to determine consistency with the standards for accreditation within the overall management of specialty pharmaceuticals and clinical pharmacy management of patients.

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<sup>5</sup> <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief%20id=103>

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

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.

All standards are required for accreditation except those designated as “Goal.” Accredited practices will be expected to be working toward these “Goals.” As best practices evolve and become more prevalent, “Goal” standards will eventually be required for accreditation.

## **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, a designated compliance officer, or outside legal counsel to ensure necessary legal and regulatory compliance.

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.

Regarding the staff of the specialty pharmacy practice, all pharmacists 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.

### **1.2 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 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. Specialty pharmacy practices have 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 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 of the specialty pharmacy practices and this 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:

1. Alpha-1 antitrypsin deficiency
2. Bone marrow transplantation



3. Dermatology
4. Gastroenterology
5. Growth disorders
6. Hematology
7. Hemophilia
8. Hepatology
9. Hereditary angioedema (HAE)
10. HIV
11. Immune globulin (IV or subcutaneous)
12. Infertility
13. Infusible oncology
14. Neurology
15. Oral oncology
16. Pulmonary disorders (cystic fibrosis, pulmonary arterial hypertension)
17. Renal failure
18. Restricted distribution or orphan pharmaceutical-specific support programs
19. Rheumatology
20. Solid organ transplantation

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

**Narrative:**

- The telehealth pharmacy practice has a written code of conduct that articulates the practice's commitment to the provision of ethical care and services. The written code of conduct articulates the practice's commitment to comply with all applicable statutory and regulatory requirements and includes expectations of its staff and professional pharmacy partners to act in an ethical and compliant manner and ramifications of failure to comply with these expectations i.e. disciplinary actions.
- The code of conduct should encourage employees, management, and board members or other governing body members to report violations of law and policy to the telehealth 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 telehealth pharmacy practice board of directors and senior management.

**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. 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 on regular intervals to ensure that services are appropriately provided and to ensure that delegation contract and service agreements are current and accurate. Significant changes to delegated services contracts or agreements should be reported to CPPA.

### **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 assist 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. 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.
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 process are employee background checks, review of OIG Medicare and Medicaid fraud registry, malpractice insurance carriage for applicable positions, and applicable health factors for staff in direct patient contact (e.g., TB and other screenings; hepatitis B and other vaccinations)
3. Staff training 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 and defined measures of success. 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.
5. A process 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, taking into account 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.
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. Documentation of annual influenza vaccination requirements for employees with direct patient contact
2. The specialty pharmacy practice has a defined scope of practice for pharmacists. The pharmacist scope of practice is obtained through careful review of a pharmacist qualifications, training, and demonstration of skills and allows for collaborative medication management. The scope defines the necessary credentials and skill level for the specialty pharmacy practice.<sup>7</sup>

## **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 the 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 and has procedures for management of third-party 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) distributor, wholesaler or manufacturer in order to ensure patient safety. This includes all branded and generic medications provided to patients under the care of

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<sup>7</sup>VHA PBM Guidance—Pharmacist Scope of Practice; PBM Clinical Pharmacy Practice Office (CPPO). January 24, 2014. VHA Directive 2008-043 Scope of Practice for Pharmacists with Direct Patient Care and VHA Directive 2009-014 Establishing Medication Prescribing Authority for Clinical Pharmacy Specialists.

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 having processes to prevent the dispensing of medications that have been adulterated, misbranded, are/or suspected of being counterfeit or fraud. 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 demonstrated 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 can be exposed to excessive temperatures if safeguards are not established to prevent the risk. 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 nonpharmacy based packaging suppliers exist, it is the responsibility of the pharmacy to ensure that internal procedures are developed and appropriate for medication delivery. 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 pharmacy does not affect the overall expiration on receipt by the patient (e.g., medications with both refrigerated and room temperature stability such as insulin, NuvaRing, Genotropin, and Norditropin).

**Hazardous Medications:**

The practice has procedures for handling, storage, preparation, and delivery of hazardous medications, including other hazardous materials.

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

**NARRATIVE:**

Specialty pharmacy practice provides patient care services in a setting that maintains privacy and confidentiality. 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 in a space, including services delivered telephonically, that provides the level of privacy 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 to the patient and ensures patient health information is protected. 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.

### **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. Pharmacy information systems are appropriate for the scope of service and size of practice.

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

#### **GOAL:**

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

### **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 provides access to clinical decision support programs, as described by the Agency for Healthcare Research and Quality (AHRQ), that aid in guiding evidence-based decision-making.**

### **1.12 The specialty pharmacy practice supports the interoperability of information systems.**

#### **NARRATIVE:**

Patient care is improved through the sharing of patient information among the 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 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.**

#### **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. 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 to meet or exceed security requirements of the Health Insurance Portability Accountability Act (HIPAA), the Payment Card Industry Data Security Standard, and other industry standards governing the protection of electronic protected health information. The 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 predisposing BI services, prior authorization (PA) services, dispensing services, and data reporting services. Specifically within fee-for-service data reporting (nonmandated by payer or manufacturer agreement) patients must be given the opportunity to opt-out of data reporting streams.

With any revisions to regulations governing privacy, such as the HITECH Act provisions and HIPAA requirements, specialty pharmacy practices continue to provide 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 in 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 down-time, 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 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: Access to Medications**

**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, 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 and 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.
2. Manufacturer-sponsored programs: These programs provide a clear financial benefit to patients, but patients must be made fully aware of the true cost of therapy if the program were to change fundamentally or cease to exist. 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 internal policies to provide disclosure of manufacturer-based financial agreements and financial assistance provided to patients. Transparency in services must be provided to the patient and a commensurate level of service is provided to all patients, irrespective of financial incentives to provide differentiation.

## **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, pharmacy location(s) and contact information, hours of operation, organizational goals, expectations of therapy and patient care goals, and the complaint process. The patient information is written in language 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 in patient management. It is critical for the specialty pharmacy practice to support prescribers and other healthcare providers in therapy coordination, from the initiation of therapy, to the delivery of medications, 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, etc.) 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:**

**Identify ways the specialty pharmacy practice is utilizing 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).

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, medications, lab results, socio-economic factors, health literacy, 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 are able to 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 review of social and patient medical information, pharmacy staff provides medication consultation and patient education 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).

The patient consultation and education is patient-centered and focuses on patient engagement and encompasses expectations of therapy which includes: 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. 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 90<sup>8</sup> before a prescription is filled and delivered to a patient:

- Name address, telephone number, date of birth (or age) and gender
- Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices
- Pharmacist comments relevant to the individual's drug therapy

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:

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

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<sup>8</sup>Omnibus Budget Reconciliation Act of 1990. Public Law 101-508, S4401, 1927(g). November 5, 1990. <http://thomas.loc.gov/>. Accessed February 14, 2013.



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

- Name and description of the medication
- Route, dosage form, dosage, route of administration, and duration of drug therapy
- Special directions and precautions for preparation, administration, and use by the patient
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
- Techniques for self-monitoring drug therapy
- Proper storage
- Prescription refill information
- Action to be taken in the event of a missed dose

### **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, the 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 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. 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 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 healthcare providers and services

6. ongoing patient monitoring , including lab results when available, and follow-up
7. documentation of all pharmacy case management activities

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
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 the 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 the competency and educating staff involved in patient care delivery. 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 provided 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 interventions and delays in therapy.**

#### **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. Secondary to delays in treatment is the importance of notifying 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, 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 being maintained on pharmacy patient case management protocols, by disease state

##### **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. 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 applicant specialty pharmacy practice.

**Patient and healthcare provider satisfaction:** Patient and healthcare provider satisfaction surveys are part of the continuous quality improvement process and are conducted at least annually. Feedback from these surveys, as well as any internal staff surveys, is integrated to improve the overall care of patients enrolled in the applicant specialty pharmacy practice.

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 events<sup>9</sup> (QREs) and conducts periodic audits of medication errors and QREs. 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.

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 those 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, but also to ensure patient safety. Many specialty medications are used in highly niche populations and do not have studies prior to approval to provide adequate vetting of side effects within a scalable population. 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 and other industry-based adverse event reporting programs, as well as reporting to other patient safety organizations as appropriate. Adverse events that potentially jeopardize patient's ability to continue therapy should be reported to the physician and be address in a collaborative manner.

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<sup>9</sup>The NABP Model State Pharmacy Act and Model Rules define *Quality-Related Event* as any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication. The term *Quality-Related Event* includes 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.

**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. Cost avoidance in specialty pharmacy practice can be globally divided into medication discontinuation (when inappropriate or 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. Whenever possible, these metrics of intervention tracking is included in pharmacy patient case management in order to integrate data reporting ability.

**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 contractual and procedural compliance.

**GOAL:**

**Documentation of first fill drop-off rates and continuous quality improvement measures to ensure patient continuation with therapy.**

## **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. 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.

## **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 format. The value of data is significantly reduced with aberrations in the reliability, accuracy and timeliness of reporting, and warrants additional scrutiny 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**

### **Rheumatoid Arthritis:**

Rheumatoid arthritis is largely driven by pre-initiation screening protocols and post-initiation compliance and adverse effect monitoring.

#### Required at initiation:

Current and prior medication therapy assessment at initiation

**\*\*concurrent non-biologic DMARD with biologic DMARD is a HEDIS measure\*\***

Prior biologic DMARD therapy assessment at initiation

Vaccination status assessment at initiation and annual

TB status at initiation of therapy

Patient device teaching (in person or virtual)

Verification of patient acceptance and understanding of injection technique (for injectable meds)

#### Required with each refill:

Concurrent DMARD screening

Compliance rate assessment

Assessment of injection issues

Screening for infection

Adverse reactions and mitigation

#### Best practices:

Annual influenza vaccination reminder

COPD monitoring (Orencia)

Sun precaution recommendations (increased BCC risk)

Referral procedures to MD for evaluation for patients with MPR<80% **\*\*Goal MPR > 80%\*\***

Hepatitis screening prior to therapy initiation

Missed doses in the past 30 days

### **Multiple Sclerosis:**

Multiple Sclerosis patient management is largely driven by pre-initiation patient education, compliance management, and adverse effect mitigation.

#### Required at initiation:

Current and prior medication therapy assessment at initiation

Patient device teaching (in person or virtual)

Verification of patient acceptance and understanding of injection technique (for injectable meds)

Vaccination status assessment at initiation and annual

Baseline lab assessment: TSH, LFTs, CBC

#### Required with each refill:

Compliance rate assessment

Assessment of injection issues or necrosis at injection sites

Screening for infection

Adverse reactions and mitigation (including liver injury assessment)

Best practices:

Annual influenza vaccination reminder  
 Referral procedures to MD for evaluation for patients with MPR<80% \*\*Goal MPR > 80%\*\*\*  
 Missed doses in the past 30 days  
 S/Sx of relapse  
 S/Sx of progression to secondary progressive disease  
 Assessment of disease effect on daily activities (urinary, fatigue, etc.)

**Gastroenterology:**

Gastroenterology is largely driven by compliance rates and routine symptom assessment to determine effectiveness of treatment and the need for dose modification or therapy change.

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Prior biologic DMARD therapy assessment at initiation  
 Vaccination status assessment at initiation and annual  
 TB status at initiation of therapy  
 Patient device teaching (in person or virtual)  
 Verification of patient acceptance and understanding of injection technique (for injectable meds)

Required with each refill:

Concurrent medication therapy screening  
 Compliance rate assessment  
 Assessment of injection issues  
 Screening for infection  
 Adverse reactions and mitigation

Best practices:

Annual influenza vaccination reminder  
 Sun precaution recommendations (increased BCC risk)  
 Referral procedures to MD for evaluation for patients with MPR<80% \*\*Goal MPR > 80%\*\*\*  
 Hepatitis screening prior to therapy initiation  
 Missed doses in the past 30 days  
 Frequency of bowel movements in the past 7-10 days (assess for changes to disease activity)  
 Steroid courses and dosing in past 30 days

**Hepatology:**

With the evolution of drug therapy options for Hepatitis B and C treatment, patient management is largely passed on compliance monitoring and side effect mitigation to ensure positive overall outcomes.

Required at initiation:

Prior and current medication therapy assessment at initiation  
 Vaccination status assessment at initiation and annual  
 Patient device teaching (in person or virtual)  
 Verification of patient acceptance and understanding of injection technique (for injectable meds)  
 Hepatitis C genotype  
 Hepatitis C RNA level  
 HIV status and screening results

Required with each refill:

Concurrent medication therapy screening  
 Compliance rate assessment  
 Assessment of injection issues  
 Adverse reactions and mitigation

Best practices:

Referral procedures to MD for evaluation for patients with MPR<95% \*\*Goal MPR > 95%\*\*\*  
 Missed doses in the past 30 days  
 Q80K polymorphism (Olysio therapy)  
 Hepatitis C RNA level (week 4, 12, and 24 for Olysio, Week 12 and 24 for Sovaldi)

**HIV:**Required at initiation:

Prior and current medication therapy assessment at initiation  
 Comprehensive drug interaction screening for all medications (specialty and non-specialty)  
 Vaccination status assessment at initiation and annual  
 Hepatitis C testing and results  
 HIV viral load  
 CD-4 count  
 Depression screening

Required with each refill:

Concurrent medication therapy screening  
 Compliance rate assessment  
 Adverse reactions and mitigation

Best practices:

Referral procedures to MD for evaluation for patients with MPR<90% \*\*Goal MPR > 90%\*\*\*  
 Missed doses in the past 30 days  
 Bi-annual depression screening

**Immune Globulin Therapy:**

Immune Globulin therapy is largely driven by pre-initiation screening and patient education protocols, infusion monitoring, and adverse effect mitigation and monitoring.

Required at initiation:

Current and prior medication therapy assessment is performed at initiation  
 Patient assessment for understanding of route of administration and plan of care  
 Infusions

- Complete set of vital signs should be taken before initiation of any intravenous IG infusion
- 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.
- Infusions are administered at rates following the manufacturer's recommendations, identified risk factors, and patient tolerability
- Use of an infusion pump is recommended

### Subcutaneous route

- Patient device teaching and verification of patient acceptance and understanding for subcutaneous administration
- Patient education regarding need for documentation log including dates, total time of infusion, lot numbers of products, location and number of sites, and reactions.

#### Required with each refill:

Medication profile update and screening for changes in health status, and tolerability of product  
Assessment of infusion or subcutaneous injection issues and adjustment of administration supplies (i.e. changing needle length for subcutaneous administration)

Infusion rate monitoring

Supplied dose is within 10% of physician ordered dose

Adverse reaction monitoring and mitigation

Referral procedures to MD for immune deficient patients with breakthrough infections

#### Best practices:

Nurse present for entire duration of any intravenous immune globulin intravenous infusion

Notification to prescriber and patient when the product being administered is a different brand from previous IG medication

Monitoring compliance for missed doses

## Solid Organ Transplantation

#### Required at initiation:

Current and prior medication therapy assessment at initiation

Comprehensive drug interaction assessment

Vaccination status assessment at initiation and annual

Pertinent drug levels and therapeutic drug monitoring target

Swallow dosage forms whole

#### Required with each refill:

Compliance rate assessment

Screening for infection

Adverse reactions and mitigation

Medication changes and interaction assessment

#### Best practices:

Annual influenza vaccination reminder

Sun precaution recommendations (increased BCC risk)

Referral procedures to MD for evaluation for patients with MPR<90% \*\*Goal MPR > 90%\*\*\*

Missed doses in the past 30 days

CBC, CMP, renal function assessment

Assessment of continued need for prophylactic medications at regular intervals

## Bone Marrow Transplantation

#### Required at initiation:

Current and prior medication therapy assessment at initiation  
 Comprehensive drug interaction assessment  
 Vaccination status assessment at initiation and annual  
 Pertinent drug levels and therapeutic drug monitoring target  
 Swallow dosage forms whole

Required with each refill:

Compliance rate assessment  
 Screening for infection  
 Adverse reactions and mitigation  
 Medication changes and interaction assessment

Best practices:

Annual influenza vaccination reminder  
 Sun precaution recommendations (increased BCC risk)  
 Referral procedures to MD for evaluation for patients with MPR<90% \*\*Goal MPR > 90%\*\*\*  
 Missed doses in the past 30 days  
 CBC, CMP, renal function assessment  
 Monitoring for GVH (allogeneic SCT)  
 Assessment of continued need for prophylactic medications at regular intervals

## Growth Disorders

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Patient device teaching (in person or virtual)  
 Verification of patient acceptance and understanding of injection technique (for injectable meds)  
 Patient appropriateness of indication and use of growth hormone product

Required with each refill:

Compliance rate assessment  
 Assessment of injection issues  
 Adverse reactions and mitigation (focus on headache, blurry vision, injection site reactions)

Best practices:

Annual influenza vaccination reminder  
 Referral procedures to MD for evaluation for patients with MPR<80% \*\*Goal MPR > 80%\*\*\*  
 Missed doses in the past 30 days

## Oral Oncology/Hematology

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Comprehensive drug interaction assessment  
 Vaccination status assessment at initiation and annual  
 Swallow dosage forms whole  
 Counseling on intended outcome of therapy (palliative vs. therapeutic intent)  
 Intended chemotherapy cycling and dosing regimen

Required with each refill:

Compliance rate assessment

Screening for infection  
 Adverse reactions and mitigation  
 Medication changes and interaction assessment

Best practices:

Annual influenza vaccination reminder  
 Referral procedures to MD for evaluation for patients with MPR<95% \*\*Goal MPR > 95%\*\*\*  
 Missed doses in the past 30 days  
 Assessment of continued need for prophylactic medications at regular intervals  
 Radiology procedure timing to assess for disease progression  
 Scheduled future appointments

## Infusible Oncology/Hematology

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Comprehensive drug interaction assessment  
 Vaccination status assessment at initiation and annual  
 Supportive care medication appropriateness based on emetogenic risk of therapy  
 Counseling on intended outcome of therapy (palliative vs. therapeutic intent)  
 Intended chemotherapy cycling and dosing regimen

Required with each refill:

Lab monitoring inclusive of CBC, Chem-7, and other labs as pertinent for therapy  
 Infusion base solution appropriateness and expiration dating  
 Chemo cycle timing assessment  
 Screening for infection  
 Adverse reactions and mitigation  
 Medication changes and interaction assessment

Best practices:

Annual influenza vaccination reminder  
 Referral procedures to MD for evaluation of patients inappropriate for continuation of therapy or demonstrating significant side effects  
 Assessment of continued need for prophylactic or additional medications for symptom mitigation  
 Radiology procedure scheduling (to assess disease progression)  
 Future appointment schedules

## Bleeding Disorders:

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Patient education on ancillary treatments including adverse reaction medications such as diphenhydramine or epinephrine  
 Assessment of ordered dose, product, and stocked product assay  
 Prescription order turn-around of <48 hours  
 Supplied dose is within 5-10% of ordered dose  
 Lot number tracking  
 Pharmacy participation in the National Patient Notification System for product recalls

Minimum of 6 months expiration dating remaining on product  
 Patient assessment for understanding of route of administration and IV access  
 Procedure for patient referral to prescriber for bleeding disorder related emergency department visits

Required with each refill:

Prescription order turn-around of <48 hours  
 Patient body weight assessed at time of dispensing  
 Supplied dose is within 5-10% of ordered dose  
 Minimum of 6 months expiration dating remaining on product  
 Assessment of bleed and dispensing history  
 Procedure for patient referral to prescriber for bleeding disorder related emergency department visits  
 Lot number tracking

Best Practices:

Physicians and patients have access to all US FDA approved manufactured products  
 Track patient's doses on hand before dispensing

## Renal Failure

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Comprehensive drug interaction assessment  
 Vaccination status assessment at initiation and annual  
 Dosage form administration and timing of dosing  
 Renal function and appropriateness of all medications for current renal function  
 Pertinent lab data (CBC, electrolytes, renal function assessment)  
 Currently receiving dialysis (dialysis type and schedule)

Required with each refill:

Compliance assessment (rate and timing of administration)  
 Adverse reactions and mitigation  
 Medication changes and interaction assessment  
 Fluid retention, weight gain

Best practices:

Annual influenza vaccination reminder  
 Referral procedures to MD for evaluation for patients with MPR<90%  
 Missed doses in the past 30 days  
 Bi-annual CBC, CMP, renal function assessment

## Pulmonary Disorders (Cystic Fibrosis, Pulmonary Arterial Hypertension)

Required at initiation:

Current and prior medication therapy assessment at initiation  
 Comprehensive drug interaction assessment  
 Vaccination status assessment at initiation and annual  
 Pertinent drug levels and therapeutic drug monitoring target  
 Prophylactic therapy

Baseline symptomology assessment

Compliance assessment with all routes of therapy (nebulized, oral, inhaled, etc.)

Required with each refill:

Compliance rate assessment

Screening for infection, worsening of symptoms

Adverse reactions and mitigation

Medication changes and interaction assessment

Best practices:

Annual influenza vaccination reminder

Referral procedures to MD for evaluation for patients with MPR<90%

Missed doses in the past 30 days

PFT assessment at baseline and at regular intervals

Changes to daily activities indexes

Assessment of continued need for prophylactic medications at regular intervals