Operation and Management Considerations for Specialty Pharmacy

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2. Analyze regulatory and policy definitions of specialty pharmaceuticals; discuss pros and cons for community pharmacy practice.
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GROWTH OF SPECIALTY PHARMACEUTICAL MARKET

The term "specialty pharmacy," as it is used today when referring to drugs with the characteristics described later in this section, was probably coined 15-20 years ago to describe the growing biologic drug market. Prior to 2000, there were only a few dozen Food and Drug Administration-approved biologic drugs available. By the time Medicare Part D prescription drug benefit plans began in 2006, that number was more than 100, with hundreds more in development.

Formulary tiers and prior authorization are common tools that pharmacy benefits managers use to control costs for the plan sponsors and have been used for decades. Passage of the Medicare Modernization Act in 2003 was a turning point for the specialty market because it permitted Part D plan sponsors to create a specialty drug tier in their benefit design and put any drug costing more than $400 a month into that tier. Later, this threshold was raised to $600. Drugs that meet this cost-per-month threshold are *eligible* for a specialty tier but aren't required to be in the specialty tier. The Centers for Medicare & Medicaid Services regularly evaluates this threshold and its latest report concludes that no change was needed for the 2015 plan year, citing data that 99 percent of claims for 30-day equivalent fills fall short of $600.

To date, there are two other legislated definitions of a specialty drug and they are very similar. One comes from Texas and the other from Maryland. Unlike the Medicare Part D definition, these definitions require a drug to meet a set of criteria listed in Table 1 and Table 2. The Texas definition that went into effect in May 2012 applies to the Medicaid program, and the Texas Health and Human Services Commission is responsible for maintaining the list of specialty drugs. The Maryland definition went into effect in October 2014 but applies to the state Medicaid program and "all policies, contracts and health benefit plans issued, delivered or renewed in [Maryland] on or after Jan. 1, 2016." It also limits the copayment for a specialty drug to $150 (subject to adjustment based on a specified economic marker). The Maryland definition clarifies the phrases "complex or chronic medical condition" and "rare medical condition" listing multiple sclerosis, hepatitis C, rheumatoid arthritis, cystic fibrosis, hemophilia, and multiple myeloma as conditions that must be included when determining whether a drug meets the first criterion. Unlike the Texas law, the Maryland law does not make a state agency responsible for maintaining a specialty drug list. And unlike Medicare Part D, the copay limit seems to be an incentive *against* placing a drug in the specialty tier. The law also gives the Maryland Insurance Commissioner responsibility for handling complaints.

Table 1. Texas Health and Human Services Commission Specialty Drug Definition (Rule §354.1853)

1. The drug is used to treat and is prescribed for a person with a complex, chronic or rare medical condition that is progressive, can be debilitating or fatal if left untreated or undertreated, or for which there is no known cure. Examples of such conditions include multiple sclerosis, cystic fibrosis, hemophilia, and rheumatoid arthritis.
2. The drug is not routinely stocked at a majority of community retail pharmacies.
3. The drug has special handling, storage, inventory, or distribution requirements.
4. Patients receiving the drug require complex education and treatment maintenance, such as complex dosing, intensive monitoring or clinical oversight.

Table 2. Maryland Specialty Drugs Definition

1. Is prescribed for an individual with a complex or chronic medical condition or a rare medical condition
2. Costs $600 or more for up to a 30-day supply
3. Is not typically stocked at retail pharmacies
4. Requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; OR

   Requires enhanced patient education, management or support, beyond those required for traditional dispensing, before or after administration of the drug.

Although the Medicare Part D definition relies solely on cost, it is evident from the Texas and Maryland definitions there are other characteristics that influence whether a drug appears on a specialty drug list. Many health care stakeholders, especially patients, prescribers, and pharmacists, find a definition based solely on cost is likely to limit access to a great number of life-saving drugs. *Recent approvals for high-cost oral medications such as those for hepatitis C and HIV infections provide good examples of drugs that probably do not belong in a specialty category since they can be found in community retail pharmacies (or procured within 24 hours), do not require special handling, and do not require special training for administration.*

Two other published definitions that are important to consider come from IMS Health and from the Center for Supply Chain Research. IMS Health is a global health data services company and its definition published in a May 2014 specialty drug white paper may carry weight considering its wide range of clients. To meet the IMS Health definition a drug must meet *five* of these eight criteria: 1) biotech product, 2) injectable formulation, 3) REMS program, 4) treats a chronic condition, 5) specialist prescriber initiated,

6) requires special handling (cold-chain), 7) annual cost more than $6,000, or 8) distribution limited by manufacturer. The Center for Healthcare Supply Chain Research is the non-profit knowledge partner of the Healthcare Distribution Management Association. Importantly, their definition is referenced by the Center for Pharmacy Practice Accreditation (CPPA) in its specialty pharmacy practice standards published in January 2015. This definition requires that drugs meet *four* of the following to be considered specialty: "1) typically high in cost ($600 or more per month), 2) involve complex treatment regimens that require ongoing clinical monitoring and patient education, 3) have special handling, storage or delivery requirements, 4) are generally biologically derived and available in injectable, infusible or oral form, 5) are dispensed to treat chronic and/or rare diseases, 6) frequently have limited or exclusive product availability and distribution, or 7) treat therapeutic categories such as oncology, autoimmune/immune, or inflammatory conditions marked by long-term or severe symptoms, side effects, or increased fatality."

While patients, prescribers, pharmacists, payers, manufacturers, distributors, and policy makers will all find a standard definition useful, it may also prove to be quite limiting. Analysis of select pharmacy benefits manager formularies reveals a fair amount of agreement about which drugs belong in the specialty tier [ex; Aralast® (alpha-1 protease inhibitor) and Soliris® (eculizumab)], but some also include widely different products [ex. CellCept® (mycophenolate) and Hepsera® (adefovir dipivoxil)].

Some of the overlap from formulary-to-formulary carves out high-cost biologic drugs for infusion or injection—drugs that until recently were covered exclusively in the medical benefit and billed by the prescriber or a home infusion pharmacy. Prescribers and infusion centers generally oppose this practice that takes drugs out of the health care supply chain and makes patients responsible for proper handling and storage prior to administration. Liability for drug integrity administered under their supervision and conflict with facility accreditation standards cause the loudest objection.

RATIONALE FOR DEFINING (OR NOT DEFINING)

The absence of a standard definition of a specialty drug is not necessarily a bad thing. A very clear, broad definition may result in drug therapies that have been dispensed and managed by community pharmacies for decades being put into a new formulary tier. For example, if no exceptions were made, probably the most widely used biologic—insulin—would be a specialty drug due to its route of administration, use for a chronic disease, storage requirements, and extensive monitoring requirements. Forcing patients to pay much higher copays or coinsurance negatively affects patients, but the potential of specialty products being on exclusion lists for non-specialty pharmacies negatively affects accessibility and retail pharmacy. Conversely, with a narrow definition entrepreneurs and larger companies that have invested time and resources to build specialty pharmacy practices, become accredited specialty pharmacies, and secure contracts with health plans or third party payers may not meet their business goals if drugs such as Qsymia® (phentermine—topiramate) and somatropin are available at the corner drugstore. The breadth of stakeholders in the specialty marketplace, from pharmacy—both specialty and traditional, to providers, distributors, payers, manufacturers, and patients makes the question of a definition a challenging one. Regardless, both the current lack of clarity and the potential clarity of a new standard definition affects stakeholders from across the industry. There are arguments on both sides of the question and there are even those who would argue against categorizing drugs in this way, suggesting that "specialty pharmacy is really a set of services, not a distinct industry." With or without an industry-wide definition of a specialty medication, the specifications of a specialty pharmacy are becoming ever more clear with the development of multiple accrediting bodies.

ACCREDITATION PROGRAMS

If we accept the point of view that "specialty" should describe pharmacy practice rather than prescription products, there are several options available to pharmacies to become accredited specialty pharmacies. Most community pharmacy owners found a better understanding of accreditation programs in general when suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare Part B beneficiaries were required to be accredited beginning in 2010.

In general, accreditation programs exist to certify that an organization meets the minimum standards to be deemed accredited. As pharmacies and other Part B suppliers have learned, these standards cover all aspects of business from establishing chain of command (illustrated in an organizational chart), to normal operations (as described in the policies and procedures manual) to resuming operations when normal business is interrupted (as described in a disaster recovery plan). Most health care consumers do not scrutinize companies with which they do business in this manner, and it could be argued that neither do their health plans. Instead, the market relies on professional licensure, contracts, and accreditation programs to provide assurance that providers will meet service and quality expectations.

Accrediting organizations that offer specialty pharmacy accreditation programs are listed in Table 3. A review of the summary of standards between these programs reveals similar but not identical standards. Broadly, the categories cover the pharmacy organizational structure and administration, operations, clinical management and quality improvement (Table 4).

Table 3. Specialty Pharmacy Accreditation Programs
Accreditation Commission for Health Care (ACHC)
Center for Pharmacy Practice Accreditation (CPPA)
URAC

Additionally, the Specialty Pharmacy Certification Board (SPCB) offers a Certified Specialty Pharmacist program. Instead of publishing yet another definition of a specialty drug, SPCB defines the role of a specialty pharmacist as having "…an increased emphasis on patient management, medication adherence, collaboration with other members of the health care team, an ability to use metrics to optimize patient care and an ability to assist the patient to access additional supportive resources." The exam measures competency in four major categories of specialty pharmacist tasks (intake, clinical management, fulfillment and outcomes) plus knowledge of inflammatory diseases, oncology, infectious diseases, multiple sclerosis, and other diseases commonly treated with specialty drugs.

As most community pharmacies have cold storage, inventory management, and record-keeping capabilities, pharmacists who practice in this setting have the tools and possess the skills to be successful in the specialty arena. However, the driving force behind accreditation is access to payer contracts and manufacturer distribution channels.

THIRD PARTY PAYERS AND MANUFACTURER DISTRIBUTION

Health plans, pharmacy benefits managers, and pharmaceutical manufacturers may all use accreditation as part of their due diligence process though for different reasons and to varying degrees.

Payers may use accreditation as a requirement for being in-network or for access to reimbursement for patient management services. Health plans are accustomed to contracting with hospitals and other facilities that are accredited by an appropriate accrediting organization, such as ACHC, the Joint Commission, or URAC. Relying on accreditation as a mark of excellence to narrow the field of pharmacies qualified to dispense drugs and provide specialty pharmacy services shouldn't be unexpected. Other payers may also use accreditation as a minimum qualification for participation. They may also choose to deal with a select number of specialty pharmacy companies to minimize administrative burden and maximize profit.

Manufacturers that desire tight control of distribution channels may find it appealing to limit distribution to select specialty pharmacies. While many drugs that are on specialty formularies are widely available through national and regional drug wholesalers, some are not. The reasons a drug may have limited distribution include a risk evaluation and mitigation strategy (REMS) that requires limited distribution; the drug is an orphan drug or treats a rare disease; the drug has a very high cost; or the manufacturer collects postmarketing surveillance data. Two examples of drugs that have a REMS with limited distribution are Sabril® (vigabatrin) and Tracleer® (bosentan). Both of these drugs are available as twice daily tablets with no special storage or handling. However, because severe adverse effects are associated with both of these drugs, the approved REMS requires the respective manufacturers to certify pharmacies that are capable of thoroughly screening and managing patients.

Manufacturers are the driving force behind documentation and adherence data reporting requirements. They have a particular interest in seeing their product dispensed to the indicated patient population, having patients achieve high rates of adherence, and collecting reports of adverse effects. In the same way that appointment-based refill programs help community retail pharmacies manage workflow and inventory, distribution of specialty products to pharmacies that report high rates of adherences helps the manufacturer understand demand for the product, optimize production and manage distribution. Manufacturers may have other data and reporting needs, but adherence appears to carry a lot of weight.

MISCELLANEOUS BUSINESS CONSIDERATIONS

Pharmacy entrepreneurs interested in specialty pharmacy have business considerations to evaluate before reaching the point of seeking payer contracts or specialty pharmacy

Table 4. Categories of Accreditation Program Standards			
Organizational & Administration	Pharmacy Operations	Clinical Management	Quality Reporting & Improvement
• Org Chart • Staffing; staff credentials • Regulatory compliance • Contingency Plan/Disaster Recovery Plan	• Patient Intake • Dispensing procedures • Storage & handling • REMS	• Coordination of care • Patient rights and responsibilities • Adverse event reporting	• Satisfaction survey • Complaint handling • Quality measurement • Error reporting (NABP publishes a "quality-related event" definition in the Model State Pharmacy Act)

accreditation. While there are barriers to entry that are more complicated than conventional community pharmacy practice, the logistics of startup are also more complicated for startup specialty pharmacies.

Some existing pharmacy owners see specialty pharmacy as an opportunity to grow prescription volume and increase gross sales. Others see that they have a population of patients for whom they dispense biologics or other self-injectable drugs and seek to build a reputation with prescribers, patients, and caregivers as an expert. Finally, pharmacy owners may seek to diversify their business and increase professional satisfaction by entering a segment of the market where competition is keen and where high-touch, coordinated patient care is standard operating procedure.

INCORPORATION

Specialty pharmacy entrepreneurs should give special consideration to incorporation of the business as a separate entity from the community retail pharmacy. Separating the two businesses gives the owner flexibility to take on or buy out investors, accept or decline contracts, manage staff, and limit liability. Separate drug wholesaler and other supplier accounts protect the pharmacy from cash flow challenges with the specialty pharmacy business and vice versa. The benefits of common ownership might include cross-trained staff, purchasing power from drug wholesalers and other suppliers, and billing under existing contracts with payers. Owners should meet with legal counsel and/or an accountant to discuss the best corporate structure for their given situation.

CASH FLOW

Specialty pharmacies need access to a substantial amount of working capital. This may come from private investors or be financed by a bank. A pharmacy (specialty or otherwise) must cover day-to-day expenses while waiting on reimbursement from third party payers. Just-in-time inventory fulfillment by full-service wholesalers allows community retail pharmacies to keep just a few days' worth on inventory on the shelf. Most receive the wholesaler invoice two weeks after the drug was ordered, regardless of whether the prescription was dispensed. Even though they are on a two-week payment cycle, they may wait two to eight weeks or more for full reimbursement after submitting a claim and the patient has paid a co-pay and left with the medication. The accounts receivable balance of a specialty pharmacy could easily run in to the tens and hundreds of thousands of dollars with the accounts payable not far behind; cost of goods sold in community retail pharmacy are approximately 77 percent of sales. Even startups that get off the ground with private funds will probably need access to a line of credit from a bank. Careful cash flow projections will help keep a new specialty pharmacy in good standing with its drug wholesaler, other vendors, and employees.

STAFFING

Carefully written job descriptions will facilitate hiring and retaining the right staff to provide the high-touch, patient-centered care necessary to meet quality measurement goals, patient expectations, and payer terms. Consideration should be given to which credentials are needed for the job. Pharmacist credentials might include a pharmacist license, residency training, board certification, other certification related to specialty pharmacy, and/or statements of credit from continuing education programs. Technician credentials might include technical license, certified pharmacy technician (CPhT) designation, certification related to specialty pharmacy (such as sterile compounding), and/or statements of credit from continuing education programs. The pharmacy will obviously need to hire a pharmacist-in-charge to obtain a pharmacy permit from the state board of pharmacy, but other positions might include staff pharmacists, pharmacy technicians, delivery drivers, and billing specialists. Another staffing issue is having an after-hours or on-call point of contact. In many cases, the nature of the specialty products dispensed make day-or-night access to support a logical component of the services offered to patient but accreditation programs require that a pharmacist be available 24 hours a day and medication delivery as quick as possible. A toll-free number and call forwarding to the after-hours pharmacist are additional operational costs to factor.

BILLING

Any pharmacy that dispenses biologics and drugs that fit one of many "specialty" definitions could call itself a specialty pharmacy or advertise specialty pharmacy services. In fact, many pharmacies currently dispense these products and provide specialty pharmacy services. Examples include temperature-controlled storage, medication management, compliance with REMS, review of laboratory test results, and point-of-care testing. Though not insurmountable, a barrier perceived by some current pharmacy owners is writing or rephrasing parts of existing policies and procedures to mirror the language used in the standards. For example, where an accreditation program standard might call for a cold storage protocol, a pharmacy can adapt the procedure for receiving, storing, and dispensing products that must be kept refrigerated or frozen and include a plan for power interruptions to preserve the integrity of expensive inventory.

Although many community retail pharmacies dispense specialty prescription products, there may be benefits to contracting as a specialty pharmacy. Pharmacy benefit tiers are set up to encourage patients to look for

"specialty pharmacies" and some plans limit the network where patients can use their benefit. Network specialty pharmacies can accept referrals and help patients on the spot. These contracts may or may not have different reimbursement rates and dispensing fees from retail contracts, but extra care should go into verifying patient eligibility, obtaining prior authorization, and reconciling claims. The pharmacy has more to lose with high-cost inventory if it is dispensed before payment is certain or documentation that guards against audits and recoupment is complete.

CONCLUSION

Specialty pharmacy, however it is defined, is being closely watched by many stakeholders. The drugs that fall into this category are generally high-risk and high-reward. Members of the supply chain take on risk to develop, manufacture, distribute, and dispense specialty drugs with the possibility of great return that comes in the form of reputation, sales, and job satisfaction. Patients accept risk for side effects and take on responsibility of administering and doing their part to manage complex therapy with the possibility of slowing disease progression, inducing disease remission, and, in some cases, being cured. As this segment evolves, it is important for pharmacists who dispense or wish to dispense these drugs to stay up-to-date on regulatory changes, accreditation standards, payer contract terms, and patient demand. ■

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Editor's Note: For the list of references used in this article, please contact *America's Pharmacist* Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.

Continuing Education Quiz

Select the correct answer.

1. Which of the following is not currently included in one or more published definitions of a specialty drug?
a. Monthly drug cost is at least $600.
b. No retail pharmacies are permitted to stock the drug.
c. The drug treats a chronic medical condition.
d. The drug requires special handling.
e. The drug is administered by injection.

2. Which of the following has not published a definition of specialty drug?
a. Texas Health and Human Services
b. The Center for Supply Chain Research
c. IMS Health
d. The Centers for Medicare & Medicaid Services
e. All of the above have published a definition of a specialty drug.

3. Which of the following statements is FALSE?
a. CMS requires that all drugs that cost $600 or more per month go into a Part D plan's specialty tier.
b. CMS requires that all drugs that cost $600 or more per month go into a state Medicaid managed care plan's specialty tier.
c. The specialty drug definition from Texas HHSC does NOT use price as a criteria.
d. A and B are both FALSE.
e. A and C are both FALSE.

4. Which of the following is not an option for obtaining specialty pharmacy accreditation?
a. Accreditation Commission for Health Care (ACHC)
b. Center for Pharmacy Practice Accreditation (CPPA)
c. National Association of Specialty Pharmacy (NASP)
d. URAC

5. Which of the following are important considerations for successful operation of a specialty pharmacy?
a. Access to working capital
b. On-call availability of a pharmacist
c. Home delivery logistics
d. Access to REMS registries and limited distribution programs
e. All of the above.

Use the following case to answer questions 6-8.
R.W. is a 33-year-old male and a patient at City Pharmacy. He was recently diagnosed with rheumatoid arthritis. Today, R.W. asks the pharmacist about a treatment the rheumatologist has prescribed (an injectable disease modifying agent) and what it

means that this drug is listed as a specialty drug on his prescription plan.

6. Which of the following would NOT help the pharmacist explain why this drug is in the plan's specialty tier to R.W.?
a. Specialty drugs may be high in cost, typically $600 or more counting copay and what insurance pays.
b. Specialty drugs may be administered by injection or another non-oral route.
c. Specialty drugs may require special patient monitoring; for example, patients who take this type of drug must have a negative tuberculosis test before starting.
d. Specialty drugs may be available only from certain pharmacies as determined sometimes by the insurance company and sometimes by the manufacturer.
e. All of the above might help explain why this drug is in the plan's specialty tier.

7. Which of the following must be true before the pharmacist dispenses the drug to R.W.?
a. The prescription plan does not restrict which pharmacies can dispense drugs in the specialty tier.
b. The patient has scheduled home visits for the pharmacist to administer the subcutaneous injections.
c. City Pharmacy is an accredited specialty pharmacy.
d. A and B only
e. A, B, and C

8. The prescribed drug may causes immunosuppression and serious side effects including hepatotoxicity, peripheral neuropathy, and interstitial lung disease. What monitoring might the pharmacist perform to detect an adverse event?
a. None. The patient sees a rheumatologist and there is no REMS registry for the pharmacy.
b. Ask the patient about coughing or changes in breathing and about any pain, tingling, or numbness in feet and legs.
c. Ask R.W. when he next goes in for labs and request a copy to double check that liver function tests are done and no changes are detected.
d. B and C only

9. Which of the following is NOT addressed by an accreditation program standard?
a. Credential of pharmacist and pharmacy technician staff
b. Compliance with manufacturer REMS programs
c. The pharmacy is open for business 24 hours a day.
d. The pharmacy collects patient satisfaction data.
e. The pharmacy has a plan for coordination of care between the specialist prescriber, primary care physician, lab, patient, etc.

10. Which of the following are NOT affected by a definition of specialty drug?
a. Prescriber and pharmacy
b. Patient and prescription insurance
c. Drug manufacturer and drug wholesaler
d. All the above are affected by the definition of specialty drug.