

Specialty Services in Community Pharmacies—What to Consider

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March 1, 2016 (expires March 1, 2019)

Activity Type: Application-based

To earn continuing education credit:

**ACPE Program 207-0000-16-003-H04-P;
207-0000-16-003-H04-T**

Upon successful completion of this article, the pharmacist should be able to:

1. Set or assist in setting reasonable goals for the pharmacy to strive for when entering the specialty pharmacy space.
2. Determine or assist in determining staffing, technology, marketing, and physical needs for the pharmacy to achieve its established goals.
3. Identify or assist in identifying third party companies including consultants, partners, and accrediting bodies and how they may be of assistance to the pharmacy in pursuing its specialty pharmacy goals.

Upon successful completion of this article, the pharmacy technician should be able to:

1. Assist in setting reasonable goals for the pharmacy to strive for when entering the specialty pharmacy space.
2. Assist in determine staffing, technology, marketing, and physical needs for the pharmacy to achieve its established goals.
3. Assist in identifying third party companies including consultants, partners, and accrediting bodies and how they may be of assistance to the pharmacy in pursuing its specialty pharmacy goals.



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Specialty medications have caused everyone from presidential candidates, the *Wall Street Journal* and most major news agencies to turn their heads, not to mention the spinning heads of employers and their health plan partners over what looks like an amazing opportunity to manage costs. Although the marketplace is relatively undefined because there is no consensus definition of a specialty medication, we can think of the 'specialty' class as including medications that are usually high-cost and have at least one characteristic that makes them significantly more complex than a 'traditional' medication. This factor might be strict temperature control, difficult manufacturing processes (such as biologics), complex regimens, a severe adverse effect profile, an in-depth REMS program, or simply the complexity of the disease itself. These medications tend to be used in areas including oncology, immunology, multiple sclerosis, fertility, HIV, hepatitis C, and a wide variety of rare diseases.

CVS Health estimates that by 2020, specialty will be a \$400 billion marketplace and is expected to account for over half of total expenditures on medications. These total expenditures will represent 3-5 percent of total prescriptions written. When headlines and blurbs are written claiming that everyone is working to get part of the specialty pie, they are hardly exaggerating. Over the last few years, everyone from community and mail-order pharmacies to health plans and PBMs, health systems, wholesalers, and even employers have found ways to be a part of this growing market. Despite all of the moving parts, payers (mostly pharmacy benefit managers), and manufacturers, including small up-and-coming biotechnology firms, control everything that is specialty. Manufacturers sometimes restrict access to their medications by adopting a limited distribution model such that only pharmacies and/or wholesalers within the network are able to purchase the medication for dispensing to the patient. Limited distribution provides good insight on supply and demand but may also be an element to assure safe use in a risk evaluation and mitigation strategy (REMS) the manufacturer submitted to gain FDA approval of the drug. Payers also restrict access by limiting who they will reimburse for these medications. Since the average specialty medication can cost more than \$2,500 a month, very few patients are willing or able to pay out of pocket at their pharmacy of choice. AARP recently released a report claiming that the average specialty medication costs more than the median American family income of \$53,000 a year. Regardless of the definition and the analysis of the numbers, the costs of these medications are challenging for payers, patients, and pharmacies.

COMMUNITY PHARMACY'S ROLE IN SPECIALTY

Community pharmacies have long served as an accessible health care provider and the neighborhood medication

expert for patients. In communities both large and small, independent pharmacies are mainstays as trusted, friendly professionals. As specialty costs have exploded, payers have worked to streamline as many processes as possible in an effort to control costs. This has often led to outsourcing specialty pharmacy services to pharmacies other than the local neighborhood pharmacy. While this might help to control prescription drug costs, not all patients will respond well to automated calls and medication delivery via their mailbox. The process also tends to split a patient's medications, as many will continue to receive their traditional medications from their local pharmacy while their specialty drugs will come from somewhere else. If they are really unlucky and need several specialty medications, they may come from multiple specialty pharmacies as no single pharmacy has access to every medication or every payer contract. A community pharmacy with the capabilities to deliver specialty services can provide all of the pharmacy services for their patients under one roof.

WHAT TO CONSIDER

For an independent pharmacy, the idea of entering the huge specialty marketplace can seem overwhelming. Although there are certainly some barriers to competing directly against Accredo, Diplomat, CVS Health, and Walgreens, there are lots of areas within specialty that are achievable for most, if not all, pharmacies. Every pharmacy is already dispensing at least one medication that requires cold-storage and injection training—insulin—and many more have demonstrated the ability to comply with detailed REMS programs to dispense products like isotretinoin, clozapine, and Tikosyn. Following are a number of different topics to consider when thinking about or planning your approach to specialty. By far, the most important consideration is the first one: what are your goals as a pharmacy and a business looking at specialty? Without clear knowledge of what you are trying to accomplish, there is no way you will hit your target. The next most important topic is who, at the store level, is going to be the point-person for the specialty pharmacy initiative. For many community pharmacies, not having a capable person designated for the growth of the specialty pharmacy program leads to stagnation and an end to the program.

1. SET YOUR PHARMACY'S GOALS

There are many ways you can bring value to your community through the specialty pharmacy services you offer. These five are representative of the variety of end-games you might be dreaming of for your pharmacy. Each will have different paths to achievement that should become clearer as you continue learning. Keep reading to help clarify what goes into achieving each of these and set your goals accordingly.

1. I want to be able to service my existing patients' needs for specialty services.
2. I want to be the 'go-to' pharmacy for a particular disease state (e.g. HIV, fertility) in my area.
3. I want to be the 'go-to' specialty pharmacy for all—or many—disease states in my area.
4. I want to become a major regional specialty player.
5. I want to compete with the large specialty pharmacies on a national level.

Most independent pharmacies likely only need to aim for the first goal, although many will find the second achievable and profitable. The goals beyond the first two, although absolutely achievable, are not likely the path many independent pharmacies are looking to pursue and will cost significant amounts of time, treasure, and talent resources. Before you start your process toward specialty, be sure you can fill in this sentence confidently:

"In ____ years, _____ (your pharmacy name) will be _____ (goal: such as, a viable option, a regional player) for specialty services."

2. CONSIDER YOUR STRENGTHS

There are several factors beyond you and your pharmacy staff that can have a big impact on your potential success in the specialty space. It is important to consider three external factors and whether or not they play to your strengths. First, who are the specialist physicians in your area? Do you have relationships with any specialists already? If your area has a concentration of a particular type of specialist, such as a nearby hepatology clinic, it might make sense to pursue building a specialty pharmacy practice that caters to them. It is also important to understand what diseases your patients are dealing with to understand what offerings they would expect from you. As you complete medication therapy management cases and engage in everyday conversations with your patients, make mental or physical notes of the diseases they discuss that you are not currently treating. Finally, try to find out which pharmacies your patients are currently using, whether it be a large specialty pharmacy, another local player, or even one owned by a physician group or a health system. Who else in the community is filling these prescriptions? There may be a large hole for a local provider of specialty services to fill, which also gives the pharmacy entrepreneur a growth opportunity.

3. CONSIDER A PARTNER

As you consider your future in specialty, you may be wondering what service providers or consulting companies offer to make your operations more efficient, maximize

your strengths, and compensate for weaknesses. There are several companies to consider engaging with to help you achieve your specialty pharmacy goals. These companies offer some or all of the services listed in Table 1. Which one, if any, you choose is a question to answer based on your existing relationships and the goals for your organization.

Table 1. Services Offered

(Note: This list may not be all inclusive)

- Patient onboarding including benefit investigation and verification.
- Prior authorization assistance including follow-up and appeals.
- Assistance with co-pay and patient assistance programs.
- Fulfillment of orders for limited distribution products.
- Patient education and clinical assistance.
- Adherence to medication regimens support and data collection.
- Network-wide data collection and reporting.
- Contract negotiations on behalf of network pharmacies with payers and manufacturers.
- Marketing assistance and materials.
- Wrap-around technology programs to improve workflow and clinical services.
- Assistance in obtaining specialty pharmacy accreditation.

Table 2. Companies Offering Services to Specialty Pharmacies (Note: This list may not be all inclusive)

- Armada Healthcare
- Aureus Health Services
- Diplomat
- KloudScript, Inc.
- Therigy

4. CONSIDER OUTSIDE HELP

In addition to the partners in Table 2 who can help you on your path to specialty, there are several other companies who may be of assistance. Many of the full service wholesalers, buying groups, and PSAs across the country have at least some resources to help their members in the specialty space. Some offer full services, some have already developed partnerships with one of the companies listed in Table 2, and others may be able to help with access to medications or assist in negotiating for payer contracts. In addition to these companies there are numerous consultants who offer assistance in and around specialty. Consultants walk you through accreditation, advise on technology and workflow solutions, and stand ready if you have a technical

question that only someone in this field can answer. If you are considering a consultant specifically on the accreditation angle, be sure to consider one who is certified by the accrediting body from which you are seeking accreditation. This process helps reduce the risk of you investing in help from someone who does not actually know enough about the accreditation body's particular standards to help you achieve them. Information about consultants can be found online and at many industry meetings, but it may be wise to ask for recommendations from peers who have used consultants to move their practice forward.

5. CONSIDER ACCREDITATION

The question of specialty pharmacy accreditation is an aspect of pharmacy start-up and operations that arises for all pharmacies evaluating specialty. Accreditation certifies that the services and systems you are using for your specialty program are both adequate and in line with industry standards. In other words, it allows payers to know that Pharmacy A, Pharmacy B, and Pharmacy C all meet known standards. Though accreditation is not a legislated mandate, to dispense any specialty product, it is, in a growing number of cases, a condition to gain access to payer networks. Additionally, some payers specify qualifying accreditation programs. As you consider your goals and the networks you would like to be involved in, consider the advantages accreditation would bring. It is commonly said by those who have gone through an accreditation process that 'my business is better than it was before.' This certainly may be true, but be sure to consider how much better it is and how much value that brings before investing. Accreditation brings different value to different pharmacies based on goals, the accrediting body chosen, and the network requirements of the area in which the pharmacy is located.

Accreditation is not free and should be researched and evaluated as a start-up cost. When evaluating the cost of accreditation, consider the full cost, not just the sticker cost to be paid to the accrediting body. The full cost of accreditation may include a computer system upgrade, additional staff members, a physical remodel, and/or outside consultant help as discussed above. Recall that accreditation has to be renewed on a regular basis as well when thinking about cost. There are five specialty pharmacy accrediting bodies to choose from if you decide pursuing accreditation is right for you: the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA), The Compliance Team, the Joint Commission, and URAC.

6. CONSIDER PHYSICAL NEEDS

Depending on the goals of your pharmacy, you may need to consider investing in a new space to house your specialty

Table 3. Five Specialty Pharmacy Accrediting Bodies

Accreditation Commission for Health Care (ACHC)
Center for Pharmacy Practice Accreditation (CPPA)
The Compliance Team
Joint Commission
URAC

services and pharmacy staff. In some cases, because of contracts with wholesalers or payers or state legal issues, you may be required or financially incentivized to build a closed-space for your specialty pharmacy. You may also just need a new office and desk space for patient management personnel, billing personnel, in-house auditing, marketing, and/or additional pharmacy staff. There are independent specialty pharmacies that operate out of no more than 200 square feet, others that operate out of state-of-the-art 10,000-square foot facilities, and still others that complete all of the specialty services from their current retail pharmacy space. What you need depends on your situation and your goals in specialty.

7. CONSIDER STAFFING ISSUES

Again, depending on your goals and your current pharmacy structure, there are potentially half a dozen or more positions that could be created in the process of starting a specialty pharmacy. It is highly unlikely that you would start with all of them, but you should consider if and at what point in your growth you will need a larger staff. Will you need to add an additional pharmacist? Depending on your growth plans, you may need an additional pharmacist to work full-time on the specialty services to serve your patients. If you are pursuing accreditation you will undoubtedly need 24-hour on-call access to a pharmacist, and another pharmacist on staff may be needed to meet this requirement. Will you need an additional part- or full-time technician? From processing referrals to working patients through benefits investigation and verification processes, processing prior authorizations and appeals, searching for and completing patient assistance program enrollment and other co-pay programs, and handling the actual procurement and dispensing of the products, talented technicians are extremely important for specialty programs looking to grow. You may have this person on your team already, but even if you do, consider what void he or she will leave in your current team if he or she starts spending a significant amount of hours on specialty.

Beyond traditional pharmacy staff, you may have to consider the addition of any number of support staff including

a biller, an internal auditor, an accreditation manager, an analyst for payer contract reporting, and/or a marketing manager. Specialty pharmacy is highly competitive, so most pharmacies should plan on, at minimum, a part-time marketer to both detail physicians and raise awareness in the community of your capabilities to dispense specialty medications. As you deal with specialty medications that may run in the tens of thousands per claim, an internal auditor to assure all i's are dotted and t's are crossed may be a very wise investment. If they catch one error that could have resulted in having reimbursement recollected, they may have paid for themselves.

As you plan, be sure to think about at what point you add these and other support staff to your team along with additional pharmacists and pharmacy technicians to continue your program's growth.

8. CONSIDER CLINICAL TRAINING

There are a wide variety of medications that fall under the specialty umbrella: recently approved or not approved; and injectable; some with REMS and some without. Be sure to have a plan to train your pharmacists on disease pathophysiology, treatment guidelines, and medications so your team can ensure appropriate use and desired outcomes. NCPA has several written continuing pharmacist education programs (also accredited for pharmacy technicians) on the most common specialty diseases and their treatments (HIV, hepatitis C, multiple sclerosis, and rheumatoid arthritis). In this same line of thought, consider how you are going to keep your pharmacists up-to-speed with new treatments as the pipeline for specialty is ever-growing.

9. CONSIDER YOUR MARKETING STRATEGY

Regardless of your goals, you need to market new specialty pharmacy capabilities. How you market and to whom will depend on the goals you have set, but no marketing is not a viable strategy. Chances are your current patients who are using specialty medications are already using a specialty pharmacy—if you want them to switch to you, you must market your program. In many cases, however, the patient is not the ideal target for your marketing efforts. It is not unheard of for a physician to write a prescription and suggest sending it to a specialty pharmacy if the formulary information in their EHR flags the drug as specialty tier. The physician may send it directly to a specialty pharmacy that they are confident will provide all the patient management services needed to get the patient started as soon as possible and keep the patient adherent to the medication as long as possible. If you want these referrals to get sent to you, the local providers have to know you can provide that level of service, and only through marketing are they going to find out. Which

and how many physicians you target will depend on your pharmacy's goals for specialty.

10. CONSIDER TECHNOLOGY

There are many technology programs and equipment that may help you achieve your goals in specialty. From systems that wraparound your current dispensing system to stand alone turnkey programs and technology to assist in logistics and cold-chain storage verification, there are dozens of technology ideas to consider. Even if you plan on launching without any technology changes, be sure to plan for when technology will become a part of your program, if it fits your goals.

11. CONSIDER FINANCIAL ISSUES

Because of the substantially higher average cost of specialty medications compared to traditional medications, there are major financial issues that must be considered when making a plan to begin providing specialty services. The obvious one is, how are you going to pay your wholesaler in two weeks for a \$30,000 bottle if you don't get reimbursed for six weeks? Medium-sized specialty pharmacies regularly have million dollar weekly wholesaler invoices. You likely will need a larger line of credit or equity to help alleviate cash flow issues and you may need cash up-front to stay afloat. Many pharmacies have wholesaler contracts that are incentivized based on percent generic drug spend. A single bottle of a breakthrough hepatitis C drug can drive your generic spend toward zero in a hurry. Be sure to understand what effect this will have on your contracts and rebates and talk to your wholesaler about recommendations for your particular situation. You may also need to think about financial issues surrounding your infrastructure. If you are building out a new specialty pharmacy location, do you need a loan? There are potential financial rewards in specialty pharmacy, but the processes themselves also bring challenges.

12. CONSIDER ACCESS ISSUES

Although specialty conferences and large specialty pharmacies will talk continually about limited distribution drugs, it is important that you consider what drugs you already have access to and what you need to get access to in order to achieve your goals. Currently, several of the top 10 specialty drugs (by gross sales) are available through traditional retail channels.⁹ If there are specific drugs that you do not have access to that you need in order to achieve your goals, talk to your wholesaler about ideas to obtain reliable access. Remember, to be a valuable, respected specialty pharmacy, you cannot dispense a medication once and then not have access to dispense it again and try to transfer the prescription. There are too many moving parts for that to be an 'acceptable' function

of a specialty pharmacy. Consider partners as discussed above and what help they may be able to offer in obtaining access to medications.

13. CONSIDER PAYER CONTRACTING ISSUES

In setting your goals and looking at what is feasible for your pharmacy on a projected timeline, it is critical to understand how you will be reimbursed for medications and by whom. Review your current contracts to see where you currently stand in regard to specialty medications. You may find that for many of your current patients, you can fill and bill for their specialty medications without any additional work. For others, you may be able to fill three times before the patient has to go to a network pharmacy. Some you may be able to alter your contract by claiming to be a specialty pharmacy without changing any of your practice; some contracts, however, will require accreditation and additional documentation to be able to bill for any specialty product. Understanding what your current contracts look like helps shape where you have to go next. If you are looking to grow and your current contracts are not favorable, reach out to the payers you want to contract with to find out what you would have to do to be able to contract with them. Some of the requirements may be strenuous and push you to alter the goals you were considering for your specialty program.

14. CONSIDER PATIENT ASSISTANCE PROGRAMS

Regardless of how well you are able to secure payer contracts, patients are likely still going to face a steep copayment, coinsurance payment, or deductible payment for specialty medications. Specialty pharmacies are generally able to navigate the networks of manufacturer-provided patient assistance programs along with foundations that provide patient copay assistance through grant funding on behalf of their patients. Understanding sources of assistance, the forms required for the assistance, and having someone trained to track down assistance for patients is a service that can be marketed to providers and patients alike.

15. CONSIDER ISSUES WITH AUDITS

As noted above in the staffing section, audits in a specialty pharmacy are potentially catastrophic. Losses on audit takebacks of a traditional medication at \$200 a month for a year are tough to swallow; losses on an audit takeback of three fills of a \$30,000 a month medication would put many businesses on the verge of bankruptcy. Hiring someone to serve as an internal auditor or compliance officer, or outsourcing the audit process, may be a very wise measure to prevent an incredibly difficult situation down the road.

16. CONSIDER LEGAL ISSUES

There may be state legal issues to consider when planning support of specialty pharmacy services. If you are think-

ing about building out a closed-door specialty pharmacy with its own pharmacy license number, recall that in many states a single pharmacist may not be the pharmacist-in-charge at more than one location.

Be sure also to consider timing for credentialing if you are going to incorporate a specialty pharmacy separate from your retail pharmacy business. Be sure to review your state and local laws for anything that might pose a future roadblock to your goals.

17. CONSIDER PATIENT NEEDS

All of the above business considerations are only important to improve the care offered to these patients. When considering specialty pharmacy, it is important to remember that these patients tend to be more seriously ill than the average community pharmacy patient. They are also highly educated about their disease state and their options for their care. With this in mind, it is crucial to build specialty pharmacy services around compassionate, patient-centered care that promotes patience with patients and their caregivers, a willingness to listen and learn from them and their experiences, and an ability to empathize with them on the deepest level.

18. CONSIDER THE FUTURE OF SPECIALTY

The oncoming wave of 'personalized medicine' is intricately connected with the future of specialty pharmacy. As the science continues to progress, a growing number of medications will likely require genomic testing to verify a patient is a candidate for treatment. These medications will likely be incorporated into the specialty pharmacy space. Currently, most of the screenings for medications like these that are already on the market are being completed by the physician, but as pharmacogenomics and specialty pharmacy expand, these screenings may move to the pharmacy.

Along with this growth and overall growth of the specialty pharmacy pipeline, we must consider the future impact of biosimilars on the marketplace. Biosimilars are medications designed to be as close as possible to a biologic 'reference product.' Unlike traditional medications and their generics, biosimilars are not exact chemical matches of the reference product and therefore may have slightly different effects in patients. At this point, the legislation surrounding biosimilars is being decided by the states and therefore varies across the country. Moving forward, it will be important to monitor new medications for their required genomic tests and the new biosimilar marketplace and how your state is handling their regulation.

19. PLAN TO CONTINUALLY IMPROVE

In any plans for your pharmacy, you should always be planning on measuring yourself and getting better. In your initial plans, be sure to lay out what you are going to use to measure success and also what you are going to use to measure a failure to achieve goals. If you are rocketing past the goals you initially have set, what is the next thing you are going to shoot for? If you are falling short, can you identify where the weakness is and how you can improve that part of the process? Who is going to hold the team accountable for the goals you have set and constantly look to improve processes? If you start a venture like this without knowing how you are going to evaluate yourself, you are unlikely to achieve your goals and, even if you do, how will you know?

CONCLUSION

There are many potential goals for an independent pharmacy to strive for when considering entering the specialty marketplace. There are also many potential issues or barriers that may stand in the way of achieving those goals. Evaluation and understanding of these potential issues before starting the process of specialty implementation can make them significantly less problematic later on. Building a comprehensive plan to enter the specialty market before starting and taking into account all of these potential issues will tremendously help pharmacies achieve their goals and be able to provide high-quality care for all of their patients' medication needs, whether 'specialty,' 'traditional,' or some combination of both. ■

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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.

- Which of the following most accurately describes a specialty medication, as defined by the industry?
 - A biologic
 - A medication with a very high cost
 - An infused oncology medication
 - A medication with one or more 'complexing factors' that is also often expensive
- Which of the following is not a specialty pharmacy accrediting body?
 - CPPA
 - ACHC
 - CHIP
 - URAC
- Why are issues with audits more pressing in specialty pharmacy?
 - Claims are so much larger
 - High script volume
 - The process of completing an order is much more complicated
 - A & C
 - All of the above
- A pharmacy with a goal of being a regional player in HIV and hepatitis C should market to which of the following groups?
 - Primary care physicians
 - Hepatologists
 - Patients at risk of HIV and hepatitis C
 - All patients via radio and television advertisements
- Which of the following national specialty pharmacies offers a partnership opportunity for community pharmacies?
 - Accredo
 - CVS Health
 - Diplomat
 - Walgreens
- Thus far, who is handling the regulation of biosimilars?
 - The U.S. Congress
 - The DEA
 - States
 - Individual pharmacists

- 7.** Who requires pharmacies to be accredited for specialty pharmacy services?
- State Boards of Pharmacy
 - Manufacturers
 - FDA
 - Third party payers
- 8.** True or False: In most states one pharmacist can be listed as the pharmacist-in-charge for more than one pharmacy.
- True
 - False
- 9.** Which of the following is false?
- Specialty medications are treated differently by different payers.
 - There is no way to bill for specialty medications if you are not an accredited specialty pharmacy.
 - You may be able to bill for a specialty medication three times before having to transfer it to a network pharmacy.
 - Some payers require specialty pharmacy accreditation to be able to bill for specialty medications.
- 10.** True or False: Most medications recognized as specialty medications are limited distribution drugs.
- True
 - False
- 11.** Specialty pharmacy accreditation consultants are:
- Paid by the specialty pharmacy accreditation body to help pharmacies achieve accreditation.
 - Sometimes certified by the specialty pharmacy accreditation body to help pharmacies achieve accreditation.
 - Employees of the specialty pharmacy accreditation body.
 - Not needed because specialty pharmacy accreditation is a simple, straightforward process.
- 12.** Which of the following is not a technology add-on that needs to be considered for growing specialty pharmacies?
- Cold-chain verification programs
 - Patient management software which wraps around a dispensing platform
 - Biometric screening devices
 - Logistics software to help with delivery tracking
- 13.** Which of the following staff positions is not likely to be needed in a growing specialty pharmacy practice?
- An additional clinically trained pharmacist
 - A compliance officer
 - A full time biller
 - A security officer
- 14.** Which of the following accurately describes a biosimilar?
- The FDA-approved generic form of a specialty medication
 - A therapeutic substitute for a specialty medication
 - A biologic product that is nearly identical to its reference product
 - A patient that responds to a medication the same way as a peer
- 15.** Who is currently completing pharmacogenomic screenings for patients being prescribed medications which require genetic verification of applicability of treatment before treatment begins?
- The medication's manufacturer
 - The patient's insurance company
 - The specialty pharmacy
 - The physician completing the order