

Ambulatory Pharmacy Development Committee

# Toolkit for establishing a new outpatient or retail pharmacy

Pharmacy Network  
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# Contributors

Joe Cesarz

University of Wisconsin Health

Amrita Chabria

Brigham & Women's Hospital

Sandra Durley

University of Illinois Hospital & Health Sciences System

Karen Malcolm

UF Health (Jacksonville)

Laurel Marsden

VCU Medical Center

Lisa Mascardo

University of Iowa Hospitals and Clinics

Katharine McCarthy

University of Rochester Medical Center

Alicia Pence

University of Cincinnati Medical Center

Jordan Rush

The Johns Hopkins Hospital

Jordan Spillane

Froedtert Health

Specialty pharmacy

Stephanie Barrus

University of Utah Health

Udobi Campbell

Duke University Hospital

Erica Diamantides

University of Washington Medicine

Huda-Marie Kandah

University of Chicago Medicine

David Mitchell

UC Davis Medical Center

William Rickley

Atlantic Health System

Matthew Rim

University of Utah Health

Amy Rorer

Maine Medical Center

Bryan Schuessler

Saint Luke's Medical Center

JoAnn Stubbings

University of Illinois at Chicago

Karen Thomas

University of Utah Health

Nathan Thompson

Johns Hopkins Home Care Group

Molly Wascher

Johns Hopkins Home Care Group

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## Introduction

In 2016, the Pharmacy Network Executive Committee of the Vizient™ University Health System Consortium released a position statement on insourcing and outsourcing of retail pharmacy services that included the following recommendations:

- Vizient members should strongly consider investing in their own ambulatory (outpatient, retail) and specialty pharmacy infrastructure to meet the need for high-quality comprehensive pharmacy services in the outpatient setting.
- Member hospitals that opt to contract with an outside pharmacy to manage their 340B programs should be able to demonstrate that the partnership benefits patients by improving access to health care, and should ensure that it be used to reach more eligible patients and provide more comprehensive services.
- Retail and specialty pharmacy services, including associated services such as bedside prescription delivery at discharge, discharge medication reconciliation, care-transition drug therapy management, postdischarge medication teaching and follow-up, and chronic disease medication and compliance management, should be insourced.
- If members have existing agreements with retail pharmacy chains in the areas of immediate and primary care services, the risks of such arrangements should be identified and delineated. Transparent data sharing among pharmacies and other health care providers is in the patients' best interest, so exchange of information should be bidirectional; patient care policies should be established by the member hospital and provided to the retail pharmacy; and firewalls should be established to prevent the retail pharmacy partner from mining member prescription data to target patients to solicit their business.

The executive committee determined that there was a need for a comprehensive resource for building the necessary infrastructure to insource pharmacy services as recommended in the position statement. This toolkit was developed by the Ambulatory Pharmacy Development Committee of the Vizient University Health System Consortium Pharmacy Network in response to that need.

The toolkit is intended to provide you with a comprehensive but easy-to-use resource guide with practical information for establishing or expanding pharmacy dispensing services.

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## Step 1. Building the business case

### Identifying the opportunity

Developing internal pharmacy programs to meet patients' needs has been shown to improve patients' experience and outcomes, as well as the hospital's financial performance. While member organizations' reasons for establishing or expanding dispensing pharmacy services vary, it is important for each hospital to understand its unique opportunities early in the planning process. Most organizations find that dispensing pharmacies:

- Decrease fragmentation of care between the hospital (or clinic) and community settings, resulting in fewer medication errors
- Expand the patient care team to include the outpatient pharmacist
- Provide better transparency and management for patients with barriers to medication compliance
- Generate new revenue and margin for the organization
- Improve patient satisfaction by ensuring that the pharmacy's scope of services meets the needs of the member's specific patient population
- Establish systems to better care for patients who require financial assistance to obtain prescriptions

### Determining the scope of pharmacy services

Determine the scope of services for your dispensing pharmacy early on in building the business case for implementing or expanding such services. Consider several factors:

- **Organizational goals.** Pharmacy services should align with patient care services, taking into account variations across specialty and primary care clinics and your organization's population health goals.
- **Resources.** Establishing new pharmacy services requires extensive planning, preparation and leadership. Other support departments within the organization may be affected by the addition of a departmental unit that requires input from fiscal, regulatory, marketing, facilities and operational stakeholders.

Expense is also a consideration in building or expanding dispensing pharmacy services. The return on investment (ROI) for dispensing pharmacies varies based on organizational characteristics (such as 340B eligibility) and on product and payer mix. Assess prescriptions currently being written to help determine specialty and non-specialty pharmacy volumes, as well as the potential to recruit prescription business from within the organization into the pharmacy.

- **Payer mix.** Understanding the primary payers in the marketplace is critical for evaluating the profitability of a dispensing pharmacy network. Each payer has different techniques for controlling access, affordability, and pharmacy reimbursement, and this variation may pose unique challenges. Understanding common payers and the dispensing pharmacy's participation in payer networks will clarify the potential impact on your internal prescription capture rates.

The services that can be offered in a dispensing pharmacy location vary, but fall into four primary categories:

- Dispensing
- Clinical
- Transitional care
- Mail and delivery

There are many subservices within each of these categories; more details are provided in steps 2 and 3. Keep these categories in mind when you explain the benefits of pharmacy services to stakeholders and develop the initial service offering for the dispensing pharmacy.

### Demonstrating return on investment

Return on investment is a measure of the economic return of a project or investment. It is important to complete an ROI or pro forma financial statement to gauge the financial feasibility of opening and maintaining a dispensing pharmacy.

Additional resources for developing a business case and determining potential ROI can be found in Appendix A.

## Step 2. Preparing for pharmacy implementation

Establishing a new dispensing pharmacy or a new pharmacy location can be a daunting task with many details to consider. The majority of tasks fall into one of these categories:

- Pharmacy licensure and registration
- Reimbursement contracts
- Supply chain contracts
- Facilities considerations
- Technology and automation

This section reviews each of these categories in depth and provides resources to guide you through the process.

A high-level implementation checklist and timeline is provided in Table 1. Note that many steps in the timeline depend on obtaining a state pharmacy license and federal Drug Enforcement Administration (DEA) license. Be sure you understand your state's requirements; many states require construction and inspection before they will issue a license.

**Table 1. Timeline for dispensing pharmacy implementation**

Category	Task	Lead time <sup>a</sup>	Complete?
Facilities and space planning	Review state laws for space requirements	12 mo	<input type="checkbox"/>
	Design pharmacy space based on scope of services	12 mo	<input type="checkbox"/>
	Perform initial crime rate assessment to determine security risk	12 mo	<input type="checkbox"/>
	Review security considerations, explore vendors and develop procedures <ul style="list-style-type: none"> <li>• Centralized alarm system</li> <li>• Panic alarms</li> <li>• Surveillance</li> <li>• Pharmacy access</li> <li>• Controlled substance storage</li> </ul>	6 mo	<input type="checkbox"/>
	Develop procedures for refrigerator temperature monitoring	3 mo	<input type="checkbox"/>
	Determine waste management plans	3 mo	<input type="checkbox"/>
Licensing	Review state board of pharmacy regulations	12 mo	<input type="checkbox"/>
	Apply for state board of pharmacy license	12 mo	<input type="checkbox"/>
	Schedule state pharmacy inspection (if applicable)		<input type="checkbox"/>
	Apply for NPI number	3 mo	<input type="checkbox"/>
	Apply for NABP/NCPDP number	3 mo	<input type="checkbox"/>
	Complete state controlled-substance application (if applicable)		<input type="checkbox"/>
	Apply for DEA license	6 mo	<input type="checkbox"/>
Reimbursement contracts	Determine plan for negotiating reimbursement contracts (insource or PSAO)	6 mo	<input type="checkbox"/>
	Complete appropriate paperwork for reimbursement contracts	3 mo	<input type="checkbox"/>
340B planning (if applicable)	Review 340B program resources and develop understanding for program compliance	12 mo	<input type="checkbox"/>
	Register with HRSA OPA	> 3 mo	

Category	Task	Lead time <sup>a</sup>	Complete?
Technology and automation	Discuss pharmacy plans with information technology department	18 mo	<input type="checkbox"/>
	Review core software and automation options for pharmacy services	18 mo	<input type="checkbox"/>
	Send technology requests for proposal when needed	12 mo	<input type="checkbox"/>
	Select appropriate vendors and develop plans for implementation	9 mo	<input type="checkbox"/>
Marketing	Develop marketing and promotional materials targeted at stakeholders (physicians, clinic staff, hospital staff) and customers	3 mo	<input type="checkbox"/>

<sup>a</sup> Recommended time to allow before the desired opening date for the pharmacy.

Abbreviations: HRSA OPA = Health Resources and Service Administration Office of Pharmacy Affairs; NPI = National Provider Identifier; NABP = National Association of Boards of Pharmacy; NCPDP = National Council for Prescription Drug Programs; PSAO = pharmacy services administration organization.

## Pharmacy licensure and registration

Figure 1 shows the order of steps to take to obtain appropriate licensure for a new dispensing pharmacy. Although many of the steps in states' pharmacy licensure and accreditation processes are similar, this toolkit is not intended to serve as a comprehensive resource for state requirements. Review your state's pharmacy laws to be sure you're not overlooking state-specific requirements.

The following information is often requested by entities that offer licensure and registration, so be sure to have it available when completing applications:

- Federal tax ID number (electronic filing identification number [EFIN])
- State tax ID number
- Sales tax authority
- City and/or county taxing authority

**Figure 1. Steps in obtaining a license for a new dispensing pharmacy**



Abbreviations: DEA = Drug Enforcement Agency; NCPDP = National Council for Prescription Drug Programs; NPI = National Provider Identifier.

## Obtain a state pharmacy license

### Square footage considerations

Dispensing pharmacies have unique space requirements governed by state-specific legislation and by your planned scope of pharmacy services. Square footage and a final pharmacy blueprint are often required. To find space requirements for pharmacies, consult the board of pharmacy (see [nabp.pharmacy/boards-of-pharmacy](https://www.nabp.org/pharmacy/boards-of-pharmacy)) for the state where the pharmacy is located.

Appendix B shows square footage recommendations for different components of a dispensing pharmacy. Note that anticipated prescription volume and staffing should also be taken into consideration when determining space requirements.

When developing the pharmacy blueprint, consider the following questions:

- What type of over-the-counter business model will the pharmacy have?
- What is the primary patient population that will be served by the pharmacy?
- Are concierge or triage services needed for patients entering the pharmacy?
- How will the pharmacy ensure patient privacy? Will there be a dedicated pharmacy consultation room?
- Will the pharmacy have any automated dispensing systems that need to be taken into account?

- Will the pharmacy process a high volume of mailed or delivered prescriptions?
- Does the proposed pharmacy location have shared breakroom or employee support areas nearby, or will it require dedicated support space?

Once these questions are answered, consult Appendix B for recommendations and considerations for pharmacy size and layout.

### Security considerations

Dispensing pharmacies have unique security considerations, often governed by state laws. Review applicable laws in your state as well as the recommendations in Table 2 before applying for pharmacy licensure.

Involve your hospital's security department to ensure that pharmacy security procedures align with those of the organization.

If the pharmacy is not located on the health system campus, establish a plan for off-site security and review it with local law enforcement. Assess the crime rate in the geographical region where the pharmacy is located to determine how strong your security measures need to be.

Medication diversion is a significant risk in retail pharmacies. Your security systems should take this into account and include mitigation strategies.

**Table 2. Recommendations for dispensing pharmacy security**

Security consideration	Recommendations
Physical space	<ul style="list-style-type: none"> <li>• The physical space should be locked and secured outside of business hours.</li> <li>• Access from common areas (e.g., waiting room) to restricted areas should require badge access.</li> <li>• Consider steel window curtains and secured doors.</li> </ul>
Centralized alarm system	<ul style="list-style-type: none"> <li>• A centralized alarm system that includes door and window alarms must be used.</li> <li>• Glass break, motion sensor, fire and vibration alarms should be considered.</li> </ul>
Panic alarms	<ul style="list-style-type: none"> <li>• A hidden silent alarm system should be enabled and available to employees in case of threats.</li> </ul>
Surveillance	<ul style="list-style-type: none"> <li>• Security cameras should be installed throughout the pharmacy. Consider its functionality: <ul style="list-style-type: none"> <li>- Color or black and white</li> <li>- Field of view</li> <li>- How long security camera footage is archived</li> <li>- Who can access and audit security camera footage</li> </ul> </li> <li>• Consider programming or hardwiring lights to stay on at all hours to ensure surveillance footage can be captured.</li> </ul>
Pharmacy access	<ul style="list-style-type: none"> <li>• Organizational policy should establish restricted access to the pharmacy for authorized personnel. The policy should cover: <ul style="list-style-type: none"> <li>- Processes to track specific individuals with access to the pharmacy</li> <li>- Frequency of review for individuals with access</li> <li>- Procedures for adding or eliminating access to the pharmacy</li> </ul> </li> <li>• Hours of access for pharmacists, technicians and other personnel must be established.</li> <li>• Access for contracted services, such as housekeeping, should be limited to business hours when pharmacy staff is present.</li> </ul>



Security consideration	Recommendations
Software access	<ul style="list-style-type: none"> <li>• Software access should be limited to authorized personnel.</li> <li>• Organizational policies should cover: <ul style="list-style-type: none"> <li>- Who has access to the pharmacy software systems</li> <li>- Frequency of reviewing software access</li> <li>- Procedures for adding or eliminating access to pharmacy software</li> </ul> </li> </ul>
Controlled substance storage	<ul style="list-style-type: none"> <li>• Policies and procedures should be developed to prevent the diversion of controlled substances.</li> <li>• Access to controlled substances, especially CII (Schedule II) substances, should be auditable and limited to authorized personnel.</li> </ul>

### Submit a state pharmacy license application

Each state has its own procedures for applying for a state pharmacy license. Many state boards of pharmacy provide forms and checklists you can use to ensure that all legislative and regulatory criteria are met. This toolkit provides broader guidance and should not be considered a substitute for state-specific information. To apply for a state pharmacy license:

- Determine how many license categories are needed by considering the following questions:
  - Are pharmacies required to register under multiple designations?
  - Must nonresident pharmacies be licensed (i.e., is it necessary to obtain out-of-state licensing)?
  - Are training sites required to register separately with the state board?
  - Will the pharmacy be a centralized filling facility?
    - If yes, note that some states require these locations to be licensed separately.
    - Consider specific requirements for verification and labeling, sharing electronic files, continuous tracking of prescription drug orders and patient counseling.
- Submit the initial licensing fee before the date specified by your state board of pharmacy.

Many states also have registration or licensure requirements for dispensing and reporting controlled substances. If necessary:

- Complete the application for a state controlled-substance license and submit the initial license fee.
- Register for the state's prescription monitoring program.

Many states require a pharmacy inspection before licensure or opening of a new pharmacy; keep that in mind when developing your timeline.

### NPI registration

Your pharmacy must have a National Provider Identifier (NPI) number to send and receive HIPAA-covered transactions. Registration information can be found at <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProviderIdentifierStandards/apply.html>. The application takes about 20 minutes to complete; turnaround time for processing the application is usually two or three days.

Required application information includes:

- Organization name
- Employer identification number (EIN)
- Name of authorized official for the organization
- Phone number of authorized official
- Organization mailing address
- Practice location address and phone number
- Taxonomy
- Contact person name
- Contact person phone number and email address

Note that any pharmacists providing care at the pharmacy will need to obtain NPI numbers as well.

### DEA application

Many of the remaining steps in the licensure and registration process require a DEA number. Review the DEA's Pharmacist's Manual before applying for a pharmacy license (<https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2>).

A DEA form 224 (new application) is required for pharmacies that dispense any controlled substances. The application is available at <https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>. Registration support is available at <https://www.deadiversion.usdoj.gov>. Processing time is four to six weeks.

Two other applications that should be considered are:

- Optional: Disposal of controlled substances ([www.deadiversion.usdoj.gov/webforms2/spring/disposalLogin?execution=e2s1](http://www.deadiversion.usdoj.gov/webforms2/spring/disposalLogin?execution=e2s1))
  - Allows pharmacies to take back controlled substances from the ultimate users (patients) to be disposed of in accordance with DEA legislation.
- Highly recommended: Controlled substance ordering system (CSOS) registration ([www.deaecom.gov](http://www.deaecom.gov))
  - Allows electronic orders of controlled substances without a supporting paper form.
  - You will need to work with wholesalers to integrate the CSOS into your pharmaceutical ordering processes.

## NCPDP registration

The National Council for Prescription Drug Programs (NCPDP) establishes national standards for electronic transactions used in prescribing, dispensing, monitoring, managing and paying for medications and pharmacy services. Pharmacies must register with the NCPDP ([sso.ncdp.org](http://sso.ncdp.org)) as producers/providers to electronically submit claims to prescription benefit managers (PBMs).

You'll need the following information for the registration application:

- Pharmacy class designation
  - Most health-system pharmacies will be either "alternative dispensing sites" or "chain pharmacies."
- Primary pharmacy information
  - Legal name and "doing business as" (DBA) name
  - Open/effective date
  - Email address
- Addresses
  - Physical address
  - Mailing address (Address to which checks from third-party payers are sent — e.g., the hospital's finance department, a Post Office box for a bank account or a pharmacy billing department)
- NPI number and confirmation document

- License information
  - State license number
  - Copy of state license (as a PDF file)
  - Federal tax ID number
  - Federal tax ID document
- Medicare license type and number (if applicable)
- Medicaid license type and number
- Class and taxonomies
  - Pharmacy type
  - Taxonomy code(s) (i.e., classification of services provided by the pharmacy)
- Hours of operation
- Authorized official
- Primary contact
- Third-party contracting group (PSAO chain ID code), if applicable

## PCI compliance

If your pharmacy processes credit card payments, you must ensure that card information is secure. This section reviews background information on payment card industry (PCI) security standards and compliance (i.e., adherence to the security standards put in place to protect credit card information during and after a financial transaction). Since credit card processing likely occurs elsewhere in your organization, identify other leads in this area and work with them to ensure that pharmacy transactions meet the organization's current level of compliance.

The PCI Security Standards Council provides baseline technical and operational requirements to protect account data. The PCI Data Security Standard (DSS) was developed to enhance cardholder security and facilitate consistent data security measures globally. The DSS applies to *all* entities involved in payment card processing as well as those that store, process, or transmit cardholder data or sensitive authentication data. Table 3 shows the 12 requirements for compliance with the PCI DSS. Table 4 provides a checklist of best practices for DSS compliance.

**Table 3. Requirements for PCI DSS compliance**

Domain	Requirement
Build and maintain a secure network and systems	1. Install and maintain a firewall configuration to protect cardholder data. 2. Do not use vendor-supplied defaults for system passwords and other security parameters.
Protect cardholder data	3. Protect cardholder data. 4. Encrypt transmission of cardholder data across open, public networks.

Domain	Requirement
Maintain a vulnerability management program	5. Protect all systems against malware and regularly update antivirus software or programs. 6. Develop and maintain secure systems and applications.
Implement strong access control measures	7. Restrict access to cardholder data by business need to know. 8. Identify and authenticate access to system components. 9. Restrict physical access to cardholder data.
Regularly monitor and test networks	10. Track and monitor all access to network resources and cardholder data. 11. Regularly test security systems and processes.
Maintain an information security policy	12. Maintain a policy that addresses information security for all personnel.

**Table 4. PCI compliance best practices checklist**

<input type="checkbox"/>	Implement PCI DSS into business-as-usual activities to monitor security controls effectively and on an ongoing basis.
<input type="checkbox"/>	Monitor security controls to ensure efficacy. <ul style="list-style-type: none"> <li>Types of security controls include firewalls, intrusion-detection/intrusion-prevention systems, file-integrity monitoring, antivirus and access controls.</li> </ul>
<input type="checkbox"/>	Confirm that all failures in security controls are detected and responded to promptly.
<input type="checkbox"/>	Review any changes made to the environment before the change is implemented. <ul style="list-style-type: none"> <li>Changes include addition of new systems or changes in the current system or network configurations.</li> </ul>
<input type="checkbox"/>	Review the impact of PCI DSS scope and requirements if there are changes in the organizational structure. <ul style="list-style-type: none"> <li>Types of changes include company merger or acquisition.</li> </ul>
<input type="checkbox"/>	Perform periodic reviews and communicate with stakeholders to confirm that PCI DSS requirements are in place and staff are following secure processes.
<input type="checkbox"/>	Review hardware and software annually to confirm that vendor support and security needs are met.

Abbreviation: PCI DSS = Payment Card Industry Data Security Standard.

## Reimbursement contracts

Reimbursement contracts for prescription benefits can be managed internally or by contracted vendor. This section covers factors you should consider when choosing between these options.

### Internal contracting strategy

You might prefer to contract directly with a PBM for full transparency of negotiated terms and conditions within PBM contracts. (Note that a pharmacy that is part of a state entity may not be allowed to outsource its contracting services.) If contracting is managed internally, a specific person or group should be responsible for requesting, reviewing and signing contracts. Your pharmacy

department should collaborate with your organization's legal department with regard to contracting; such collaboration is required if the official authorized to sign the contract is the hospital CEO.

The contracting process includes requesting and reviewing contracts, facilitating the legal review and redline process, and responding to compliance attestation requests. If you opt to manage it within the pharmacy, plan to dedicate 0.5 to one full-time equivalent staff person to the process.

### PSAO contracting strategy

A pharmacy services administration organization (PSAO) facilitates reimbursement contracts between its members and third-party payers (PBMs). Typically, PSAOs offer

contract negotiations, contract management, claims payment, reconciliation and business support services.

There are more than 20 PSAOs currently operating in the United States, but most health care organizations use one of the three major wholesalers that offer PSAOs: AmerisourceBergen (GNP Provider Network), McKesson (AccessHealth) or Cardinal Health (LeaderNET).

The primary benefit of using a PSAO is that it enables the pharmacy to deal with multiple payers more easily, thereby improving patient service. A PSAO can manage a wide array of payers and plans, eliminating the need to contract individually with each payer. However, a health system that works with a PSAO has little say in negotiating rates or controlling terms and conditions. Transparency between the PSAO and health system with regard to payer service fees and other fees that may be included in each contracted payer plan is minimal. In addition, PSAOs may have eligibility criteria the pharmacy must meet to be included.

Consider payer mix and patient population before joining a PSAO. If your pharmacy will serve only a small number of plans (e.g., employee-focused prescription services through a self-insured plan), a PSAO may not offer much benefit.

Pharmacy ratings on quality metrics are another consideration that is becoming increasingly important. If your pharmacy contracts with payers or PBMs are managed by a PSAO, your flexibility in negotiating tiers or preferred networks is based on the performance of the PSAO, not of your pharmacy. For pharmacies that do not use a PSAO, individual pharmacy quality has a more direct impact on contract negotiations with Medicare preferred plans.

## Facilities considerations

### Temperature monitoring

Many pharmacy and health system accrediting bodies require that refrigerators and freezers in dispensing pharmacies be continuously monitored to ensure that drug integrity and stability are maintained. Room temperature should also be monitored if any investigational medications are dispensed from the location.

Procedures for refrigerator and freezer monitoring should cover who should be alerted when temperature is out of range to:

- Assess the alert to determine if there is risk to drug integrity or stability
- Transfer drugs to an alternative storage location
- Facilitate repair or replacement of refrigerator or freezer

Several vendors offer wireless or remote temperature monitoring systems:

- Checkpoint  
([monitoring.mesalabs.com/checkpoint](http://monitoring.mesalabs.com/checkpoint))
- Primex  
([www.primexwireless.com](http://www.primexwireless.com))
- TempTrak by Cooper-Atkins  
([www.cooper-atkins.com/Products/TempTrak](http://www.cooper-atkins.com/Products/TempTrak))
- REES monitoring  
([www.reesscientific.com](http://www.reesscientific.com))

Questions to consider when selecting a wireless temperature vendor:

- How often should temperature be recorded?
- What is the alert pathway when temperature is out of range?
- How sensitive are the monitoring probes?
- Is there wireless coverage in the area where monitoring devices are installed?

### Waste management

Your new dispensing pharmacy will need services including removal of garbage, medication waste, hazardous medication waste, biological waste and sharps, as well as destruction of protected health information (PHI). If the pharmacy is located in a hospital or health system building, extending existing contracts to cover the new pharmacy is usually the best option. You may also want to establish a contract with a reverse distributor to get credit for expired medications.

### Protected health information

Many organizations have contracts in place with vendors to manage PHI. Procedures for managing PHI should cover:

- Policy on management of PHI
- How PHI is collected in the pharmacy
- Process for destruction of PHI
- Staff training on destroying PHI

### Sharps

To prevent accidental needlestick injuries, ensure that a sharps disposal container is available. Containers can be collected and replaced either by approved third-party vendors or by a designated group within the organization.

## Pharmaceutical waste

On Aug. 31, 2015, the Environmental Protection Agency signed a rule proposing a set of regulations for the management of hazardous waste pharmaceuticals. Be sure that processes to manage how both hazardous and nonhazardous waste are managed, segregated and collected by a third party meet the applicable regulations.

## Patient take-back programs

Offer patients handouts or other materials explaining the available options for medication disposal, such as:

- Disposal in a designated public, central location
- Community drug take-back days
- Transfer of unused medications to collectors authorized by the DEA to take back or mail back drugs (<https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>)
  - If your state regulations allow it, consider implementing an in-house take-back program. Note that to take back controlled substances, the pharmacy must be registered with the DEA as an authorized collector.
  - Sharps Compliance, Inc. ([www.sharpsinc.com](http://www.sharpsinc.com)) offers MedSafe medication collection kiosks and disposal services.

The FDA offers additional information on drug disposal at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm>.

Patients who use needles at home can dispose of them in home sharps containers, which can then be brought to collection sites (<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/ucm263240.htm>).

## Technology and automation

### Information technology infrastructure requirements

When planning a new or expanded dispensing pharmacy, work closely with your institution's information technology (IT) department. Connect with stakeholders from the following IT areas:

- Telecommunications
- Network

- Information security
- Hardware and desktop
- Server management
- Interface management

It is important to understand your health system's IT infrastructure and integrate the pharmacy with it where possible.

Dispensing pharmacies often have unique software and hardware needs; plan to dedicate specific resources within the pharmacy department to clinical and operational oversight of these areas. Also engage appropriate pharmacy staff in IT meetings and governance to ensure that they understand the support systems and development teams.

This section reviews crucial dispensing pharmacy IT needs and considerations for implementing or changing software systems.

### Software and automation

Core software programs that dispensing pharmacies use include:

- Dispensing
- Point of sale (POS)
- Shipping and logistics
- Remote dispensing and telepharmacy
- Interactive voice or web response (IVR/IWR) and patient connectivity
- Dispensing automation
- Prescription claim clearinghouse ("switch") vendors

When considering a new software or automation vendor:

1. Identify technology vendors and solutions.
2. Develop a detailed list of all potential business needs.
3. Develop a request for proposal (RFP) requiring potential vendors to describe how and to what extent they can meet those needs.
4. Use the RFP responses to identify the vendors that are the best fit and arrange for product demonstrations.
5. Select the vendor that best meets your organization's needs.

## Dispensing

Dispensing software is used to perform the core functions in the pharmacy: dispensing, inventory management, claims submission and electronic record retention.

Common dispensing software vendors include:

- EnterpriseRx (McKesson)
- Epic Willow Ambulatory
- PanaceaRx
- PDX
- QS/1

Advantages	Considerations
<ul style="list-style-type: none"><li>• Promotes efficient pharmacy workflows</li><li>• Identifies opportunities for medication therapy management</li><li>• Facilitates adjudication with insurance companies</li><li>• Provides interaction checking (medication, disease state, allergy)</li><li>• Scans bar codes (including the National Drug Code) during dispensing and verification to promote medication safety</li><li>• Offers monographs containing drug and safety information</li></ul>	<ul style="list-style-type: none"><li>• Software cost can be a significant driver of nondrug expense</li><li>• Clinical knowledge is beneficial during system setup</li><li>• Significant up-front staff training is needed</li><li>• Larger vendors have less flexibility to customize the system to organization's specific needs</li></ul>

## Point of sale (POS)

A POS system acts as an electronic cash register and can track prescription sales and customer accounts, process credit cards, connect with other systems in a network and manage over-the-counter (OTC) inventory.

Common POS vendors include:

- Emporos
- Epicor
- McKesson Point-of-Sale
- Micro Merchant Systems
- RMS

Advantages	Considerations
<ul style="list-style-type: none"><li>• Integrates with dispensing system to provide checks and balances between prescription fulfillment and financial workflows</li><li>• Helps manage front-end (OTC) business needs and provides inventory management</li><li>• Creates and tracks customer accounts to manage patient billing needs</li><li>• Enables rewards and discount programs for customers</li><li>• Allows for multiple methods of payment (cash, credit, debit, flex-spending accounts, checks)</li></ul>	<ul style="list-style-type: none"><li>• Software cost can be a significant driver of nondrug expense</li><li>• Systems must be in place to maintain PCI compliance for credit card transactions</li><li>• Interfaces between POS and dispensing software vary in functionality</li><li>• Many vendors offer systems for employee payroll deduction transactions</li></ul>

## Shipping and logistics

Shipping and logistics software helps manage the transport of medications and other pharmacy-related products and coordinate pharmacy operations, including supplies, people and facilities.

Common shipping and logistics vendors include:

- Pitney Bowes
- UPS or FedEx

Advantages	Considerations
<ul style="list-style-type: none"><li>• Helps identify the most cost-effective method of shipping a product based on its weight and destination</li><li>• Allows for integration between dispensing software and shipping couriers</li><li>• Provides product tracking and auditing information that may be needed for payer audits</li></ul>	<ul style="list-style-type: none"><li>• Shipping volume and courier variability may drive need</li><li>• Work with the vendor to determine how long archived information should be maintained in the system</li></ul>

## Remote dispensing and telepharmacy

Both technologies allow pharmacists to counsel patients, perform drug utilization review and verify prescriptions from remote locations.

Common remote dispensing and telepharmacy vendors include:

- Comprehensive Pharmacy Services (CPS)
- ScriptPro
- TelePharm

## Interactive voice or web response (IVR/IWR) and patient connectivity

Interactive voice response is an automated technology that allows for patient connectivity via voice and key tones. Inbound IVR solutions allow patients to call the pharmacy and request refills by entering a prescription number. This functionality can be integrated with dispensing software to automatically insert requested refills into the dispensing queues. Outbound IVR solutions automatically communicate with patients to let them know that their prescriptions are ready or remind them to refill their prescriptions.

Interactive web response is similar to IVR but works via the web: Patients can request refills through a pharmacy website, and the prescription can be automatically inserted into the dispensing queues.

Many IVR and IWR companies offer smartphone apps — Ateb, AIS, TeleManager, Market Touch Media and MScripts are some commonly used apps — that can streamline the refill process and may help improve patient compliance with prescribed medication therapy.

Common IVR and IWR vendors include:

- AIS
- Ateb
- Cenduit
- Market Touch Media
- TeleManager
- VoiceTech

### Advantages

- Expands pharmacy services to rural areas
- Improves efficiency by centralizing prescription verification and patient counseling
- May allow expansion of services to clinics whose volume does not warrant a full-fledged on-site pharmacy

### Considerations

- Laws regarding remote dispensing vary by state and may affect ability to use this technology
- A remote dispensing site must have a highly capable technician who is accountable for day-to-day services

### Advantages

- Offers many options for customization
- Allows patients to connect with the pharmacy 24/7
- Inbound IVR allows “phone tree” options to direct patients or providers to the appropriate location
- Allows for consistent and automated patient communication

### Considerations

- It is important to involve your telecom department in setup and support
- Consider characteristics of the patient population (language, age, access to phone or internet)
- Explore systems that integrate with the dispensing system to maximize functionality



## Dispensing automation

Automated dispensing is a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, packaging, counting, labeling and dispensing of medications.

Common dispensing automation vendors include:

- McKesson Automation
- Parata
- ScriptPro

### Advantages

- Improves workflow efficiency
- Reduces medication errors
- Reduces patient wait time
- Increases prescription fill rate
- Improves inventory management

### Considerations

- Cost can be a significant driver of nondrug expense
- Must interface with the dispensing system
- High-volume, central fill or mail service operations will get the most value
- Locking cells are often available for controlled-substance dispensing
- Should not be used with hazardous medications or those with high allergy risk
- Time needed to replenish and maintain the system daily is significant

## Prescription claim clearinghouse ("switch") vendors

Claims clearinghouses receive prescription information from the pharmacy, ensure that it meets NCPDP standards, and route it to the PBM and then from the PBM back to the pharmacy.

Common prescription claim clearinghouse vendors include:

- RelayHealth
- Change Healthcare Pharmacy Services
- RxMedic
- OmniSYS, LLC

### Advantages

- Allows for real-time submission and approval of prescription claims
- Provides information on reimbursement, patient copay and additional processing information to the dispensing pharmacy in real time
- An editing functionality available from some vendors can "clean" claims before they are submitted to the PBM

### Considerations

- Vendor must meet NCPDP standards for pharmacy claim format and content
- Many of the add-on services promoted by vendors may not be necessary for basic pharmacy needs



## Marketing

Marketing pharmacy services to capture prescription business is vital to a pharmacy's profitability. This section covers pharmacy marketing strategies and considerations that you should review with your liaisons in your marketing or public affairs departments.

- Target audience
  - Identify different strategies for patients, providers and payers.
- Service definition
  - How is your pharmacy's service different?
  - Why should the target audience use your pharmacy?
  - Keep in mind that different audiences have different expectations. Patients consider value, convenience and quality, while providers and payers put more weight on outcomes and cost-effectiveness.
- Target audience's perceptions of need
  - Use questionnaires and meetings with prescribers to determine how potential users of your pharmacy services perceive their need for those services.
- Internal marketing
  - Train current staff to field questions.
  - Develop relationships with clinic managers and staff members.
  - Display promotional items in waiting rooms.
  - Mail out program information.
- External marketing
  - Marketing to a target audience outside the hospital can be done through:
    - Radio or TV
    - Newspaper
    - Web page information
    - Email
    - Social media

- Maintaining customer base
  - Conduct satisfaction surveys to evaluate audience response and identify areas for improvement.
  - Consider offering inducements:
    - Coupons
    - Promotional items
    - Auxiliary services (immunizations, medication therapy management [MTM], delivery)

## Revenue cycle management and fiscal requirements

Since the pharmacy is a revenue-generating business unit within the health system, having an effective strategy for managing the pharmacy revenue cycle is crucial. Establishing a strategy requires a great deal of preparation and strong collaboration between the pharmacy and finance departments. Discussions should include:

- Setting up a pharmacy-specific bank deposit box for pharmacy-related checks from payers
- Establishing procedures for electronic remittance and payment collection from payers
- Establishing procedures for cash handling for pharmacy employees
- Creating processes for cash bag circulation, reconciliation and auditing
- Setting up accounts for patients who are unable to pay at the point of sale
- Managing patient accounts (i.e., sending bills and collecting and recording payments)
- Building systems for reporting expenses and revenue to the organization's general ledger

It is also a good idea to include a member of your internal audit department when creating or modifying revenue cycle-related policies and procedures.

## Step 3. Establishing core services and workflows

### Dispensing workflows

Each pharmacy offers unique services to its patients, but the basic workflow (Tables 5 and 6) is similar for all dispensing pharmacies.

**Table 5. Primary workflows**

Workflow step	Description
Reception	<ul style="list-style-type: none"><li>• Patient registration</li><li>• Collection of appropriate billing information (PBM)</li><li>• Prescription intake (via e-prescribing, facsimile, hard copy, phone, etc) and scanning into dispensing software</li></ul>
Data entry	<ul style="list-style-type: none"><li>• Transcription of prescription information into dispensing software</li><li>• Selection of the appropriate dispensed product based on the written prescription</li></ul>
Adjudication	<ul style="list-style-type: none"><li>• Sending claim to the PBM to determine patient and product eligibility<ul style="list-style-type: none"><li>- If prior authorization or other approval is required, the prescription may be held until required steps are completed</li></ul></li></ul>
Preverification	<ul style="list-style-type: none"><li>• Clinical review of prescription, completion of drug utilization review, and review of prescription information entered in the prescription dispensing system to ensure accuracy (conducted by the pharmacist)<ul style="list-style-type: none"><li>- Dispensing software may include a separate preverification step or preverification may be included with final product verification</li></ul></li></ul>
Prescription renewal	<ul style="list-style-type: none"><li>• Submission of an automated refill renewal request, when required, to the prescriber via the dispensing software</li></ul>
Product dispensing	<ul style="list-style-type: none"><li>• Transfer of the appropriate medication and quantity from the manufacturer-supplied stock to the quantity and formulation required by the prescription</li></ul>
Product verification	<ul style="list-style-type: none"><li>• Review by the pharmacist of what was prepared during product dispensing to ensure that the filled medication matches the prescribed medication</li></ul>
Patient copayment collection	<ul style="list-style-type: none"><li>• Processing of prescription through the POS system or cash register to collect any copayment the patient is responsible for</li></ul>
Patient counseling	<ul style="list-style-type: none"><li>• Providing pharmacist-to-patient education on the prescribed product and reviewing information to ensure safe and appropriate medication use</li></ul>
Return to stock	<ul style="list-style-type: none"><li>• Returning medication from the dispensed vial back to general inventory in the event a prescription is filled but never picked up</li></ul>

**Table 6. Secondary workflows**

Workflow	Consideration
Compounding	<ul style="list-style-type: none"> <li>• Evaluate the need for compounding services.</li> <li>• Determine if sterile (eye drops) or nonsterile (creams, ointments, suspensions) compounding will be needed. <ul style="list-style-type: none"> <li>- For sterile compounding, ensure compliance with US Pharmacopeia (USP) General Chapter 797.</li> <li>- For nonsterile compounding, ensure compliance with USP General Chapter 795.</li> </ul> </li> <li>• If the organization has multiple dispensing locations, determine if compounding services will be provided at a particular location(s) or at all sites.</li> <li>• Consult the inpatient formulary when formalizing recipes to avoid concentration mismatches and potential issues when a patient is transitioning from one care setting to another.</li> </ul>
Hazardous medications	<ul style="list-style-type: none"> <li>• Assess the receiving, handling, dispensing and compounding of hazardous medications to be compliant with USP General Chapter 800.</li> </ul>
Prescription delivery	<ul style="list-style-type: none"> <li>• Consider whether to offer prescription delivery to patients or employees via either internal or external couriers.</li> <li>• Considerations include turnaround times, delivery fees (if any), special packaging (e.g., for refrigerated products) and method for obtaining confirmation of delivery.</li> </ul>
Pediatric prescriptions	<ul style="list-style-type: none"> <li>• Perform pediatric dose checks based on weight for any patient 12 years of age or under.</li> <li>• For liquids with small doses, it may be preferable for the pharmacy to pull up the doses in syringes for patients.</li> <li>• Provide flavoring services if the pharmacy has a large pediatric population.</li> </ul>
Benefits investigation and prior authorizations	<ul style="list-style-type: none"> <li>• Consider offering centralized resources to help patients understand prescription benefits, assist with obtaining prior authorization if needed, and identify sources of financial assistance for prescriptions.</li> </ul>
Employee prescriptions	<ul style="list-style-type: none"> <li>• If employee prescriptions will be filled, consider whether to use specific workflows (e.g., drop-off and pickup kiosks) and set specific expectations for prescription turnaround times.</li> </ul>
Discharge prescriptions	<ul style="list-style-type: none"> <li>• Discharge prescriptions, if provided, should be treated as a high priority.</li> <li>• Consider a discharge delivery service to inpatient units or rooms to improve the patient experience and improve discharge prescription capture rates.</li> </ul>
Adherence packaging	<ul style="list-style-type: none"> <li>• If the your patient population has a high medication burden, consider providing medication adherence packaging. <ul style="list-style-type: none"> <li>- Options include filling medication boxes manually or exploring technology that enables blister packaging.</li> </ul> </li> </ul>
Inventory management	<ul style="list-style-type: none"> <li>• Looks for ways to effectively manage drug expense, the highest operating cost for a dispensing pharmacy.</li> <li>• Ensure that systems are in place to handle expired medications, orders, returns and 340B inventory replenishment, and to identify dead inventory or slow movers.</li> </ul>

## Inventory management

### General considerations

For a community pharmacy, drug inventory is typically its largest investment. The continuing growth in specialty pharmacy and medication costs means that pharmacy drug expenses are increasing. Inventory costs tie up available cash that could be used towards other investments. Drug inventory also incurs carrying costs such as insurance and handling. Therefore, poor inventory management affects the pharmacy's financial performance as well as creating unnecessary waste.

The inventory turnover ratio (the total cost of goods sold divided by the average inventory costs over a given time period) is a common method of assessing the effectiveness of inventory management. The ratio is a measure of how efficiently an organization supplies goods to meet the demands of its customers. An optimal inventory turnover ratio for a pharmacy is considered to be 12; most pharmacies have ratios between 8 and 10. For a pharmacy that purchases \$100,000 in monthly inventory, a single-digit increase in the inventory turnover ratio may yield \$20,000 in savings.

Several inventory control methods and tools have proven to be effective in retail inventory management. The ABC classification system is used to identify which medications in the inventory should be specifically targeted for management. Using this classification system, medications are divided into three different categories by percentage of annual purchasing costs. Class A medications account for the greatest proportion — 70 to 80 percent — of inventory costs and therefore are high-priority targets for management.

Most pharmacies use prescription dispensing software to manage inventory; many vendors offer supplemental inventory management modules. Review these products to see if they can be of use in managing your high-cost pharmacy inventory.

### Wholesaler returns

Most pharmacies use a third party (reverse distributor or returns companies) to manage wholesaler returns. Pharmacies should track and trend:

- Drugs that are most commonly wasted
- The dollar value of wasted drugs *or* whether credits were received

Reverse distributor returns reports should be routinely reviewed to identify opportunities to reduce wasted drugs and ensure that all credits from the manufacturers are received.

### Methods of inventory management

There are three common methods for determining when drugs need to be ordered:

- **Visual method.** The pharmacy counts existing inventory and compares that against the quantity that should be carried. An order is placed when the quantity in inventory falls below the desired amount.
- **Periodic method.** The pharmacy counts existing inventory at predetermined intervals and compares it with minimum desired levels. An order is placed when the quantity in inventory falls below the minimum.
- **Perpetual method.** Inventory is entered into the computer and updated automatically as prescriptions are filled. Orders are triggered based on preset minimum levels.

The perpetual method is recommended, as it is the most efficient and allows real-time tracking of inventory.

### Inventory management recommendations

- Incorporate ways to encourage the selection of generic products.
- Use ordering groups or formularies (based on GCN or GPI) to promote preferred generic products. This has the benefit of minimizing line items in the pharmacy inventory.
- If your pharmacy operates more than one location, develop systems for transferring “dead inventory” and “slow movers” between locations.
- Monitor common out-of-stock situations to modify par levels and avoid partial fills.
  - Monitor “shrinkage” resulting from shoplifting, employee theft, and robbery and consider inventory-control bars, cameras, remote monitoring and electronic article surveillance to discourage theft. The largest source of shrinkage for most retailers is employee theft.

### Useful reports for pharmacies

- **Purchase-trend report.** Describes quantity of OTC products or prescription drug products purchased by month or quarter.
- **Sales-analysis report.** Includes order quantity, shipped quantity, unavailable quantity, returns, credits and dollars spent in a rolling 12-month statement.
- **Item-movement report.** Lists which items are selling the best.

## Controlled substance management

Retail pharmacies within health systems pose a significant risk to the controlled substance supply chain because of the potential for theft and the risk of fraudulent prescriptions. Retail pharmacies are at risk for both internal and external theft. Schedule III, IV and V controlled substances are often stocked in bulk containers on shelves, providing little control of physical access. To prevent external theft, these bulk containers should be mixed with non-controlled substance inventory or stored in a locked cabinet.

Because of the high risk of diversion, be sure to include owned retail pharmacies in the scope of your controlled substance diversion prevention program and proactively improve controls.

### Recommendations

- Security measures such as camera surveillance throughout the pharmacy are imperative to monitor theft and to allow the pharmacy to identify and resolve discrepancies quickly.
- Badges or biometric scans should be required to access all schedule II controlled substance storage areas. This requirement limits physical access to appropriate staff and creates a perpetual log of which employees have accessed the storage cabinet.
- Schedule II controlled substances that require refrigeration should be dispersed among other refrigerated medications or stored in a refrigerator lockbox.
- Inventory adjustments of controlled substances pose a significant internal diversion risk.
  - If frontline pharmacy staff members have security clearance to perform inventory adjustments, consider establishing auditing systems to track and validate the adjustments.
  - Additionally, run reports regularly to compare controlled substance purchases against utilization to identify dispensing trends and discrepancies in inventory.
- In addition to inventory adjustments, controlled substances in will-call and cancelled prescriptions pose risks for internal diversion.
  - Consider using prescription management software to develop reports that can identify controlled substances that have not been picked up from will-call within 10 days or that need to be returned to stock after cancellation of the prescription.
- Interfacing the POS system with the prescription management software will allow you to develop a report that reconciles processed prescriptions with those that have been picked up and those in will-call.
- Fraudulent prescriptions are also a significant risk to the controlled substance supply chain.
  - A variety of diversion and monitoring tools can be used to review controlled substance prescriptions — internal pharmacy documentation and dispensing records, third-party utilization reviews and prescription drug monitoring programs.
  - Controlled substances should be prescribed electronically, and retail pharmacies should work to promote the practice. If hard-copy prescriptions are accepted, develop a system to document which employee received the prescription and which processed it, as well as to validate that the prescription is not fraudulent. Controlled substance prescriptions should be filed sequentially. It may be worthwhile to audit hard-copy prescriptions for documentation of employee chain of custody.
- Staff should keep a complete and accurate written or electronic perpetual inventory record for the receipt (CSOS and DEA form 222) and disposition of all schedule II medications, filed in sequential order.
  - The perpetual inventory should be updated and verified by two employees, one of whom is a licensed provider, every time a schedule II medication is received.
  - The same update and sign-off process should be used each time a prescription for a schedule II medication is filled.
- Use labels from the prescription management software to record quantity filled in the perpetual inventory log.
- Consider implementing a system for partial fills of schedule II controlled substances, as they pose a significant risk for diversion.
- The schedule II medication inventory should be audited every month to ensure that counts are correct and that the perpetual log has been verified by two employees.
- When discrepancies are identified, they should be evaluated by a third party such as your controlled substance diversion prevention program or internal auditing staff.
- All records, including prescriptions, DEA 222 forms, CSOS receiving documents, perpetual inventory logs and discrepancy reports, should be kept for the specified time set by your state board of pharmacy.

## Staffing and training

### Staffing resources and workload standards

Determining the appropriate staffing level for a health system dispensing pharmacy can be challenging. There are not many publicly available time standards available for retail or community pharmacies, and many factors may influence workload:

- Percentage of new versus refill prescriptions
- Volume of pediatric prescriptions
- Number of controlled substance prescriptions dispensed
- Number of compounded medications dispensed
- The amount of support the pharmacy provides to ensure medication access and affordability

Workload and staffing needs vary depending on the scope of services, patient population and payer mix. However, workload standards should be developed, included in the budget and routinely measured to evaluate productivity and adjust staffing levels as needed.

Many prescription dispensing software systems can generate reports that show time spent on filling prescriptions. These reports, however, should be validated by direct observation to ensure that they are accurate.

Pharmacies may choose to use nonweighted prescription volumes to develop a staffing grid. Some pharmacies have developed a system to weight prescriptions based on category; an example of such a system is shown in Table 7.

Weighted categories allow for factors that increase processing times. New prescriptions, for example, require patient registration and setup in the dispensing system. Prescriptions for schedule II drugs may require employees to double-count physical inventories at multiple steps

**Table 7. Sample weighted prescription categories**

Category		Weight
Adult	Refill	1
	New (non-CII)	1.2
	New (CII)	1.4
	Refill (compound)	1.4
	New (compound)	1.5
Pediatric	Refill	1.1
	New (non-CII)	1.3
	New (CII)	1.5
	Refill (compound)	1.5
	New (compound)	1.6

Abbreviation: CII = schedule II controlled substance.

throughout the filling process. Pediatric prescriptions may require weight-based dosing and compounds take significantly more time to prepare. Using this type of weighting, a pharmacy can set goals for how long it should take to process a refill prescription for an adult (e.g., 10 minutes) versus a new schedule II prescription (14 minutes).

Consider also how to staff pharmacists and technicians based on workload or prescription volumes. As above, many variables that need to be taken into account when developing staffing models. As a point of reference, one health system's staffing model is provided in Table 8; this example takes into account the weighting described above for various prescription volumes.

**Table 8. Sample staffing model based on weighted prescription categories**

Weighted Rx volume	RPh FTE	Rx/h/RPh (max)	Tech FTE	Rx/h/Tech (max)	Rx/h/FTE (max)
50-100	1	12.5	1	12.5	6.3
100-150	1	18.8	1.5	12.5	7.5
150-200	1.5	16.7	2	12.5	7.1
200-250	2	15.6	2.5	12.5	6.9
250-300	2	18.8	3.5	10.7	6.8
300-350	2.5	17.5	4	10.9	6.7
350-400	3	16.7	4.5	11.1	6.7
400-450	3	18.8	5.5	10.2	6.6
450-500	3.5	17.9	6	10.4	6.6
500-550	4	17.2	6.5	10.6	6.5

Abbreviations: FTE = full-time equivalent employee; RPh = registered pharmacist; tech = pharmacy technician.

## Step 4. Incorporating adjunct pharmacy services

### 340B considerations

#### Resources

The 340B program requires drug manufacturers to provide covered outpatient drugs to eligible health care organizations (covered entities) at significantly reduced prices. The program enables covered entities to stretch limited federal resources as far as possible to reach more underserved patients and provide more comprehensive services.

There are many resources available for the 340B drug pricing program. Table 9 provides a list of a few of the most valuable resources with brief descriptions.

Table 9. 340B program resources

Resource	Description
<i>Federal Register</i>	Outlines laws and regulations; source of truth
HRSA	Responsible for interpreting and implementing the program
Apexus	Contracted by HRSA to provide program support
340B Health	Serves as a program advocate, examines audit outcomes, provides connections with similar contracted entities

One of the first places to look is the 340B section of the Health Resources & Services Administration's (HRSA's) website ([www.hrsa.gov/opa](http://www.hrsa.gov/opa)), which offers a wealth of information and resources on eligibility and registration, implementation, program requirements, Medicaid and orphan drug exclusions, audits and recertification, manufacturers, and more. You will also find published audit results detailing the findings of the Office of Pharmacy Affairs (OPA), which may help you build an audit program to ensure that you remain in compliance with program requirements. The website also provides news updates and information on other programs such as the 340B Prime Vendor Program, whose goal is to improve access to affordable medications for covered entities and their patients. The program is voluntary and free to facilities that are eligible to participate in the 340B program.

Another source of news on the 340B program, updates on HRSA policy, tools and educational offerings such as 340B university and other events is [www.apexus.com](http://www.apexus.com). The Apexus 340B University offers an in-depth educational program that covers basics, program integrity and audits, implementation and policy, pricing and Medicaid. Apexus also offers educational tools online and information about certification programs.

The 340B Peer-to-Peer Program, found on the HRSA website ([www.hrsa.gov/opa/peertopeer/webinars.html](http://www.hrsa.gov/opa/peertopeer/webinars.html)), is another educational resource designed to provide practical examples from high-performing covered entities (leading practice sites) that demonstrate continuous quality improvement and compliance with 340B program requirements. Representatives from the leading practice sites showcase best practices and policy knowledge to elevate all 340B stakeholders and promote integrity within the 340B program through free monthly webinars.

Another great resource is [www.340BHealth.org](http://www.340BHealth.org), the website of a membership organization comprising more than 1,200 public and private nonprofit hospitals and health systems throughout the U.S. that participate in the Public Health Service 340B drug pricing program. Membership in 340B Health provides access to many resources relating to the 340B Drug Pricing Program, including the 340B Coalition Conferences. These valuable meetings, held twice a year, draw hundreds of 340B stakeholders from the provider, drug industry, pharmacy, pharmacy service, government, advocacy and related sectors — all of whom share the goal of providing quality pharmaceutical care to low-income and vulnerable populations while complying with drug pricing laws.

The 340B Drug Pricing Program is always changing, so finding the sources of information that are best for you will require that you spend some time reviewing and navigating the various websites, educational offerings and news updates.

Table 10 provides an outline of the resources available to you at each step of setting up a 340B program.



**Table 10. Steps and resources for setting up a 340B program**

Step	Goals	Resources
Understanding 340B Program rules and regulations	<ul style="list-style-type: none"> <li>• Understand the program and mission</li> <li>• Understand which regulations will affect your organization</li> <li>• Analyze whether you have the resources to support the program and if the savings will be significant</li> <li>• Analyze cost/benefit of contract pharmacies</li> </ul>	HRSA <i>Federal Register</i> 340B Health
Registration	<ul style="list-style-type: none"> <li>• Determine whether your entity meets the program criteria</li> <li>• Define the stakeholders that need to be part of the conversation (finance, C-suite, billing, pharmacy, compliance, etc.)</li> <li>• Decide who will be the authorizing official</li> <li>• Determine whether to carve in or out</li> <li>• Establish eligible clinics (for disproportionate share hospitals, use the Medicare cost report)</li> </ul>	HRSA website Apexus 340B Health
Pharmacy designation	Consider: <ul style="list-style-type: none"> <li>• In-house versus contract pharmacy</li> <li>• For contract pharmacy: registration with HRSA; establishing contract agreement between contract pharmacy and contracting entity</li> <li>• Reimbursement fees</li> <li>• Identifying eligible 340B prescriptions and a 340B management system</li> <li>• Carve in</li> </ul>	340B Health <i>Federal Register</i> Apexus HRSA
Operations	Consider: <ul style="list-style-type: none"> <li>• Inventory management</li> <li>• 340B policies and procedures</li> <li>• Identifying 340B-eligible dispenses</li> </ul>	Apexus 340B Health
Compliance and program integrity	<ul style="list-style-type: none"> <li>• Maintain checks and balances within the program</li> <li>• Perform audits to ensure that regulations are met</li> <li>• Ensure transparency</li> <li>• Establish a 340B committee</li> <li>• Determine an approach to third-party audits</li> </ul>	340B Health Apexus HRSA
Savings	<ul style="list-style-type: none"> <li>• Document how savings achieved through 340B are used</li> </ul>	340B Health
Recertification		HRSA 340B
Education	<ul style="list-style-type: none"> <li>• Find relevant conferences and webinars</li> </ul>	340B Health Apexus HRSA



## HRSA audits

### Rationale

To ensure compliance with 340B program requirements, the OPA conducts routine audits of covered entities. Basic elements of compliance include:

- Ensuring that the information about the covered entity in the OPA database is accurate and supports the entity's eligibility
- Ensuring that 340B drugs are only dispensed to eligible patients to help prevent diversion
- Confirming that the covered entity has safeguards in place to ensure that a manufacturer is not required to provide a 340B discount and a Medicaid rebate on the same drug
- Confirming that disproportionate share hospitals do not purchase covered outpatient drugs through a group purchasing organization

Hospitals that fail to comply with program requirements may be removed from the program and/or required to repay discounts to manufacturers.

### Selection for audit

Although the OPA has had the authority to conduct audits of 340B-covered entities since 1992, routine audits did not begin until 2012. Audits are conducted on:

- Hospitals at greater risk of noncompliance, based on the number of outpatient facilities and contract pharmacies within the hospital, the complexity of the program and/or purchase volume
- Targeted hospitals that have had reported violations or allegations or follow-up corrective action plans from previous audits

### Timeline

#### Pre-audit:

- An engagement letter is sent to the hospital's authorizing official. An initial conference call is held to schedule a date for an onsite visit and to request submission of necessary data (usually two weeks before the onsite visit).
- Requested data includes:
  - Documents to confirm eligibility (e.g., Medicare Cost Report)
  - 340B policies and procedures
  - Lists of 340B-eligible sites and prescribers
  - Organizational charts
  - Information on:
    - Contract pharmacies (including agreements)

- 340B drug purchasing accounts
- Computer systems used to manage pharmacy claims and 340B purchases (e.g., split-billing software)
- Medicaid enrollment
- Self-audits and other monitoring
- Records of 340B purchases and dispenses for a six-month time period
- Audit experiences vary from one auditor to another. 340B Health maintains a database of disproportionate share hospital audit results and auditors. When you receive an audit notification, consult 340B Health to identify hospitals that have been audited by your specific auditor; most institutions will share their stories and can provide valuable insights.

#### Onsite visit:

- The auditor will conduct a data sample review to ensure eligibility of 340B dispenses (the number of claims reviewed will vary for each site). The auditor will also interview the staff directly responsible for management of the 340B program and visit pharmacy sites where 340B drugs are purchased to observe ordering processes. The auditor may also ask for a demonstration of split-billing software.
- An onsite audit will take two to four days depending upon the complexity and size of the hospital's 340B program.
- The auditor may follow up with clarifying questions after the onsite visit to ensure that the information submitted in the OPA report is accurate.

#### Post audit:

- The OPA will issue preliminary findings and recommendations for improvement if appropriate.
- If the covered entity agrees with the findings, a corrective action plan, if needed, must be submitted within 60 days of receipt of the audit report.
- To dispute the audit findings, the covered entity must submit notice of disagreement in writing within 30 days of receipt of the preliminary audit report. HRSA will then send a follow-up letter with the final decision.
- Final audit findings are posted on the OPA website.

## Value-added services

### Overview

Clinical pharmacy services are integral to optimizing patient outcomes, particularly with regard to minimizing adverse events while promoting medication safety, adherence, education and overall patient engagement. Figure 2 shows some of the services that may involve pharmacists.

**Figure 2. Services involving pharmacists**

PCMH	Disease-state management	Specialty pharmacy	Other
<p>Patient-centered medical homes: comprehensive primary care centers focused on the patient's overall health</p>	<ul style="list-style-type: none"> <li>• Diabetes</li> <li>• Anticoagulation</li> <li>• Asthma /COPD</li> <li>• Cardiology, heart failure</li> <li>• Mental health</li> </ul>	<ul style="list-style-type: none"> <li>• Solid organ transplant</li> <li>• Oncology</li> <li>• Hepatitis C, HIV</li> <li>• Multiple sclerosis</li> <li>• Rheumatology</li> </ul>	<ul style="list-style-type: none"> <li>• Palliative care</li> <li>• Long-term care</li> <li>• Drug information</li> <li>• Population health management</li> </ul>

Clinical initiatives may either target a specific outcome or serve a number of functions; however, all services need standardized workflows to ensure high-quality care for every patient served. Incorporating proactive methods for addressing patient education needs, drug-drug interactions, dose adjustments, adverse drug reactions and medication cost concerns can improve efficiency during the downstream dispensing process.

Common reasons for implementing clinical work-up workflows include:

- Improving patient adherence to medication therapy
- Optimizing clinical outcomes and meeting therapeutic goals
- Increasing collaboration with providers and other health care professionals
- Promoting positive patient experiences through better education and engagement
- Improving the prescription capture rate
- Minimizing adverse events and their associated costs
- Obtaining direct reimbursement for clinical services

### Development and implementation

To develop and implement high-quality clinical pharmacy services and consistently improve patient care, you need standardized workflows. Consider the following factors

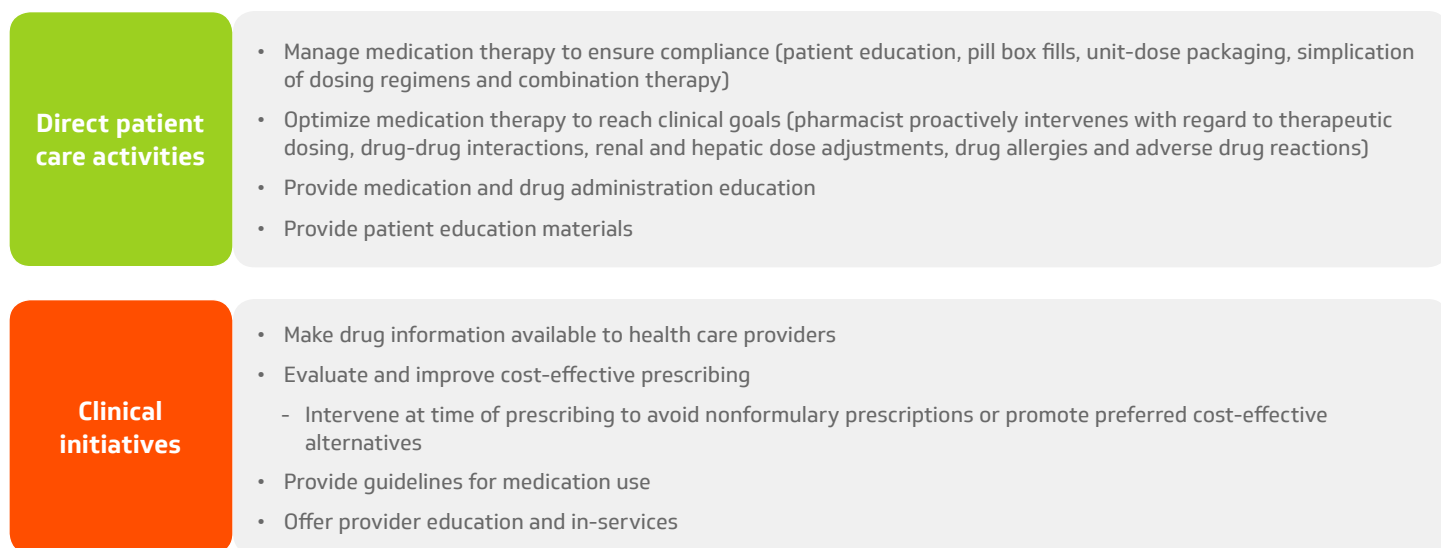
when researching, planning and outlining your new pharmacy to be sure you have accommodated the pharmacy's and health system's specific patient population and available resources.

- Service development
  - Prepare a needs assessment
  - Research desired clinical services
  - Evaluate service gaps and feasibility
- Identification of stakeholders
- Plan development
  - Establish workflow processes
  - Create relevant policies and procedures
  - Develop a business plan for any needed resources
- Implementation
- Measurement of outcomes
  - Evaluate outcomes and improve services if needed
  - Expand to additional disease states as appropriate

### Service functions

Examples of general clinical pharmacy services often provided are shown in Figure 3. Figure 4 shows specialty pharmacy services. (Appendix C provides guidelines for developing specialty pharmacy services within a health system.)

**Figure 3. General clinical pharmacy services**



**Figure 4. Specialty pharmacy services**



## Factors to consider

- Staff qualifications for providing clinical or specialty pharmacy services
  - Pharmacist: residency, board certifications, competencies
  - Pharmacy student and resident opportunities
  - Pharmacy technician: certifications, competencies
- Reallocation of pharmacists from operations to clinical services
  - Separate operations and clinical staff, compared with a mixed model
  - Cross-coverage and on-call or after-hours considerations
- Integration of clinical programs with dispensing services
  - Clinical delivery and pick-up (particularly for pill box fills, injection and administration training)
  - Retail pick-up
  - Mail order and home delivery
- Communication and documentation
  - Patient interactions
    - Telephone: desk vs mobile, call center (e.g., automatic call distribution, tracking telephone statistics including speed of answer and call waiting time)
    - Clinic: location, space and resources
    - Remote pharmacy and telemedicine
  - Provider interactions
    - Referral process
    - Method for providing recommendations and obtaining provider approval
    - Collaborative drug therapy management protocols
  - Service documentation
    - Electronic medical record
    - Scheduled appointment tracking, follow-up calls and reminders (case management software vs electronic medical record or mixed model)
  - Patient education materials
    - Medication list, medication action plan, after-visit summary, etc.
    - Medication demonstration supplies
  - Promotional handouts
- Reimbursement model and sustainability
  - Billing for clinical services: codes for incident-to physician, MTM, chronic care management and transitions of care

- Cost-saving initiatives (university wellness programs, minimizing adverse events, etc.)
- Other: grants, utilization of residents and students

## Metrics to evaluate

It is important to define and measure outcomes to evaluate the effectiveness of clinical workflows. Metrics for demonstrating pharmacy value differ from one pharmacy to another based on the services provided, but some metrics to consider include:

- Adherence
- Clinical outcomes:
  - Percentage of patients who attain blood pressure or A1c goals
  - Percentage of patients with anticoagulation time within therapeutic range
  - Vaccination rates
- Compliance with medication therapy guidelines
- Cost-effective prescribing
- Prescription capture rates
- Patient satisfaction
- Provider satisfaction
- Percentage of patients receiving clinical services
- Number of pharmacist interventions
- Reduction in adverse drug events and resulting cost savings
- Financial improvements

## Meds-to-beds workflows at hospital discharge

Providing discharge medication delivery services is an effective method of ensuring that patients have access to and can afford their medications after they are discharged from the hospital. Benefits of implementing this service include:

- Improved patient experience
- Proactive focus on the discharge process
- Improved prescription capture rate
- Ability to assess product access and patient affordability before discharge
- Elimination of last-minute discharge issues that pharmacists may otherwise have to deal with
- Possible improved first-fill adherence
- Possible reduction of workload in the dispensing pharmacy and improved efficiency

The recommended steps for developing and implementing a discharge medication delivery service are outlined below.

- Obtain resources for the program
  - Reallocate technicians
  - Create a business case or proposal for new resources
- Develop service
  - Identify eligible patients or target populations or units
    - Start with units with lower turnover
    - Patient populations at risk for first-fill medication adherence issues (e.g., transplant patients) may realize the most benefit
    - Collaborate with areas that are amenable to exploring new discharge workflows
  - Determine whether technicians will be centralized (in the outpatient pharmacy) or decentralized (on the patient units)
    - Consider the pros and cons of both arrangements with regard to efficiency and obtaining buy-in for the program
    - Compare the two models and select the best based on existing discharge workflows
  - Develop patient and nurse educational materials
    - Consider ways to capture refills (e.g., enrollment in mail-order programs)
  - Develop systems to flag and prioritize discharge delivery patients in the dispensing pharmacy computer system, such as:
    - Physical prompt (e.g., colored bin)
    - Unique delivery method or status in dispensing software
    - Default ready time (similar to a waiter)
  - Develop procedures for delivering prescriptions to the unit or patient
    - Maintain chain of custody, especially with controlled substances
    - Determine where prescriptions will be delivered — directly to the patient or to a unit-based pharmacist (this decision may be driven by state laws on transferring prescriptions to patients)
  - Determine how cash will be handled and payments processed
    - Mobile credit card readers may be used to facilitate payment and ensure that it is secure
  - Identify method(s) for patient counseling (e.g., inpatient pharmacist, remote counseling)

The following metrics should be used to measure program success:

Discharge prescription capture rate

- Patient satisfaction (direct patient sampling is recommended; the HCAHPS survey has too much lag time and too many variables)
- Percentage of patients being discharged that receive the service
- Pharmacist and pharmacy satisfaction
- Financial improvements

## Quality

Outpatient or retail pharmacies, including those owned by health systems, are increasingly being evaluated on quality by payers. Both the Centers for Medicare & Medicaid Services and commercial payers are choosing pharmacies to participate in their drug plans based on their ability to help patients achieve desired clinical outcomes and control the overall costs of care.

## Quality metrics

### Medicare

The performance of both Medicare Advantage plans and stand-alone Medicare Part D plans is evaluated and publicly reported as Medicare Star Ratings, a system designed to help consumers choose the best plan for their situation. Overall scores are based on metrics covering:

- Helping patients stay healthy
- Helping patients manage chronic conditions
- Member experience with the health plan
- Member complaints and changes in the plan's performance
- Health plan customer service

Plans covering medications (Part D plans) are evaluated on the following metrics:

- Drug plan customer service
- Member complaints and changes in the drug plan's performance
- Member experience
- Drug safety and accuracy of pricing

### Commercial payers

Many commercial payers and pharmacy benefit managers have adopted performance goals similar to those used by Medicare and are limiting pharmacy network participation to pharmacies that can help meet those goals. Some plans even have reimbursement incentives for pharmacies that help patients meet adherence goals.

## Accountable care organizations

Accountable care organizations are groups of health care providers, including hospitals and pharmacies, that work together to provide high-quality, coordinated care to patients in the most cost-effective manner. If they are successful, the members of the accountable care organization share the savings achieved for the payer (either government or commercial).

## Pharmacy impact

Pharmacies can affect quality by ensuring that patients are taking appropriate medications for their conditions and complying with their medication regimens. They can also help patients minimize overall health care costs (specifically, by reducing emergency department utilization and hospital admissions and readmissions) with preventive strategies such as vaccinations.

To ensure that your pharmacy is positioned to contribute to high-quality care for your patients:

- Understand pharmacy quality measures and how they are used by different payers by reviewing information from the Pharmacy Quality Alliance.
- Develop methods to measure and improve adherence.
  - Calculate the proportion of days covered or the medication possession ratio in your outpatient pharmacy system.
  - Create a medication synchronization system.
- Leverage access to your health system's electronic medical record to ensure that outpatient pharmacists can review pertinent lab test results and documentation.
- Create transitions of care programs to ensure that patients are discharged with appropriate medications and remain compliant. Such programs should cover:
  - Bedside medication delivery
  - Follow-up phone calls or clinic appointments with pharmacists
- Consider enrolling in a formal MTM program such as Cardinal Health's OutcomesMTM or Mirixa
- Measure performance using:
  - Data mining from outpatient pharmacy system
  - Commercial tools such as EQulPP

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## Appendix A. References and resources

### Step 1. Building the business case

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## Step 2. Preparing for pharmacy implementation

### Pharmacy licensure

1. Individual state board of pharmacy rules and regulations (<https://nabp.pharmacy/boards-of-pharmacy>)
2. NABP Survey of Pharmacy Law (<https://nabp.pharmacy/publications-reports/publications/survey-of-pharmacy-law>): annual publication; differentiates licensure details between states
  - a. Cost: \$195; multiuser licenses available
3. NABPLAW Online (<https://nabp.pharmacy/publications-reports/publications/nabplaw>): online access to law in all 50 states
  - a. Annual license fee: \$845–\$5,000, depending on number of users
  - b. Short-term: 1 day, \$45; 1 week, \$155
4. PCI compliance
  - a. PCI Security Standards Council. Payment Card Industry (PCI) Data Security Standard: Requirements and Security Assessment Procedures ([https://www.pcisecuritystandards.org/document\\_library?category=pcidss&document=pci\\_dss](https://www.pcisecuritystandards.org/document_library?category=pcidss&document=pci_dss))

### Square footage considerations

State boards of pharmacy  
(<https://nabp.pharmacy/boards-of-pharmacy>)

### Security considerations

Purdue Pharma pharmacy security checklist  
(<http://www.rxpatrol.com/pdf/A7957-draft.pdf>)

### Refrigerator temperature monitoring

Centers for Disease Control and Prevention guidelines for storage and temperature monitoring of refrigerated vaccines (<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/toolkit-resources.pdf>)

## Step 3. Establishing core services and workflows

### Inventory management

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### Controlled substances

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5. Title 21 United States Code (USC) Controlled Substances Act, § 802. 21 USC 802. (<http://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>)



## Step 4. Incorporating adjunct pharmacy services

### 340B considerations

1. Health Resources and Services Administration 340B Drug Pricing Program (<http://www.hrsa.gov/opa>)
2. 340B Health overview of the 340B Drug Pricing Program (<http://www.340bhealth.org/340b-resources/340B-program/overview>)

### Value-added services

1. American College of Clinical Pharmacy. *ACCP's Ambulatory Care Survival Guide*, 3rd ed ([www.accp.com/docs/prns/ambu/AMBULATORY\\_CARE\\_SURVIVAL\\_GUIDE\\_3RD\\_EDITION.pdf](http://www.accp.com/docs/prns/ambu/AMBULATORY_CARE_SURVIVAL_GUIDE_3RD_EDITION.pdf))
2. ACCP standards of practice for clinical pharmacists ([www.accp.com/docs/positions/guidelines/standardsofpractice.pdf](http://www.accp.com/docs/positions/guidelines/standardsofpractice.pdf))
3. Berdine HJ, Skomo ML. Development and integration of pharmacist clinical services into the patient-centered medical home. *J Am Pharm Assoc*. 2012;52(5):661-667.
4. American Pharmacists Association. *Creating a Patient Care Process: Medication Therapy Management Services* ([www.pharmacist.com/sites/default/files/files/mtm\\_creating\\_patient\\_care\\_process.pdf](http://www.pharmacist.com/sites/default/files/files/mtm_creating_patient_care_process.pdf))
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10. Stubbings J. Top ten checklist for launching a specialty pharmacy. *Pharmacy Purchasing & Products*. 2015;12(3):1-5

## Appendix B. Dispensing pharmacy square footage recommendations

			Core space (ft <sup>2</sup> )		Optional space (ft <sup>2</sup> )
Pharmacy area		Comments	≤ 250 prescriptions	> 250 prescriptions	
Reception and waiting area	Waiting room	If there are more than 2 patient service windows, add 60 ft <sup>2</sup> for each additional	200	200	≥ 60
	Play area	Option for locations with large pediatric populations	-	-	120
	Concierge, triage	Option to improve customer service and help patients navigate the pick-up or drop-off process	-	-	60-100
	Kiosk, check-in	Option to help with patient queueing or to separate employee prescription pick-up from patient prescription pick-up	-	-	30
	OTC space	Variable based on front-end strategy	200	200	-
	Consultation	Private room where the pharmacist can speak discreetly with patients, family or caregivers about medications or provide immunizations	120	120	-
	<b>Subtotal</b>		<b>320</b>	<b>≥ 520</b>	<b>Variable</b>



Pharmacy area			Comments		Core space (ft²)		Optional space (ft2)
					≤ 250 prescriptions	> 250 prescriptions	
Work area	Drop-off and pick-up windows	Add 1 patient service window for every 200 prescriptions dispensed per day	60	120	-		
	Prescription filling and assembly	For prescription counting, labeling and physical review of prescriptions Add 135 ft² for every 400 prescriptions per day Consider dispensing workflows (e.g., manual versus automated dispensing) and adjust accordingly	135	≥ 135	-		
	Nonsterile compounding	Add 30 ft² for every 400 prescriptions per day	60	≥ 60	-		
	Automated dispensing	Variable, based on the footprint of the automated technology. A minimum of 120 ft² is likely. An additional 120 ft² may be needed for functions associated with the automation (sorting, collating, replenishment).	-	-	240		
	Pneumatic tube station	May be valuable if the pharmacy serves hospital discharge patients	-	-	30		
	Mail and delivery preparation	Required for locations where mail and delivery services are consistently provided. Add 100 ft² for every 400 prescriptions per day.	-	-	100		
	Inventory management	For receiving, breakdown, and verification of new inventory	120	-	-		
	Subtotal		375	≥ 315	Variable		
Storage	Bulk inventory		180	-	-		
	Controlled substances		150	-	-		
	Flammable liquids		-	-	60		
	Refrigerated products		120	-	-		
	Durable medical equipment		-	-	150		
	Investigational drug products		120	-	-		
	Subtotal		570	-	Variable		

Pharmacy area			Comments	Core space (ft²)		Optional space (ft2)
				≤ 250 prescriptions	> 250 prescriptions	
Support	Break room	Having these areas in the pharmacy is beneficial, but they may not be needed if there are breakrooms nearby for pharmacy staff to use.	100	-	-	
	Conference room		-	-	100	
	Toilets		-	-	60	
	Environmental services (housekeeping)		-	-	60	
	Training room		-	-	75	
	Subtotal		100	-	Variable	
	Total recommended core space needs			1,365	≥ 835	Variable

## Appendix C. Establishing a new specialty pharmacy within a health system

### Introduction

Spending on specialty drugs has increased in the last decade; in 2018, specialty drugs accounted for 46% of total U.S. prescription drug expenditures.<sup>1</sup> More health systems are developing their own specialty pharmacy services to support integrated patient care. In 2017, 26% of health care providers (hospitals, health systems, physician practices and providers' group purchasing organizations) had their own specialty pharmacies, as did 50% of large hospitals (more than 600 beds).<sup>1</sup>

Planning a specialty pharmacy entails unique considerations such as payer relationships, cold chain shipping management, specialty pharmacy accreditation and access to limited-distribution drugs (LDDs). Given the high cost and complex nature of specialty diseases and drug therapies, specialty drug management requires significant investment in infrastructure to be successful. Health systems that are developing specialty pharmacies should consider additional clinical and operational infrastructure, which may include a clinical management system, call center, and data collection and reporting capabilities. These foundational components are necessary to track data on outcomes, operational efficiencies, patient satisfaction and care quality, which in turn is required to attain accreditation and access specialty payer networks.

The guidelines in this appendix are intended to help you plan and develop specialty pharmacy services, augment clinical programs, apply for specialty pharmacy accreditation and provide enhanced pharmacy services.

### Determining the scope of specialty pharmacy services

**Planning specialty pharmacy services:** There are many considerations when building a specialty pharmacy including its physical and operational structure, the patient population and geographic area it will serve, therapy management software needed and requirements for specialty pharmacy accreditation. Initial services to introduce in conjunction with an existing retail pharmacy include prior authorization, patient financial assistance, case management, shipping and delivery, refill reminders and patient outreach. As services evolve and volumes grow, additional considerations should focus on the physical structure, operational components (such as cold chain shipping), financial considerations (e.g., payer contracting) and clinical management of the specialty pharmacy.

**Scope of services:** The patient population and geographic service area should be defined. Initial patients may vary based upon the needs of the individual health system; however, it is important to evaluate future opportunities to expand services, better support patient populations, improve efficiency and maximize pharmacy revenue opportunities.

A major challenge for new specialty pharmacies will be gaining access to local and regional specialty pharmacy payer networks and accessing LDDs. But health systems can begin with products they have access to and specific clinics with providers that are supportive of specialty pharmacy. A new specialty pharmacy may initially target

specialty prescriptions for patients covered by the health system's own self-insured benefit plans (e.g., employee plans). Or you may decide not to focus on any specific population, but instead identify practices that are prescribing specialty medications and the most commonly prescribed of those medications. This will provide a framework for discussing with payers what services your health system can provide. It is also important to verify the system's access to specialty drugs and develop a strategy to gain access to LDDs. Requirements for gaining access to LDDs (e.g., URAC accreditation) vary among manufacturers.

Preparing for specialty pharmacy implementation

**Physical structure:** It is important to consider whether specialty prescriptions will be filled by the health system's existing retail pharmacies or by a standalone specialty pharmacy. While the costs of establishing a new specialty pharmacy facility are much higher than integrating services, there are several advantages in keeping the two services separate. Retail pharmacies focus on high prescription volume, customer service and maintaining inventory to sustain business. In contrast, specialty pharmacies have lower prescription volume and require

greatly enhanced customer service and care coordination activities such as prior authorization, patient financial assistance and refill coordination. Specialty pharmacies must also consider special needs including communicating directly with providers and office staff to complete fulfillment services, building strong patient relationships to increase treatment compliance and manage adverse effects, meeting storage requirements for drugs and ancillary supplies (cold chain shipping packages), and offering services to improve compliance such as refill reminders and mail-order services.

While a standalone specialty pharmacy is preferable, it does not have to be established before implementing specialty pharmacy services. You can start with existing retail space and transition to standalone facilities as volumes grow.

**Workflow and fulfillment:** Table 1 includes a list of questions to answer when creating a specialty pharmacy workflow. The most visible area of the specialty pharmacy is fulfillment. If the specialty and retail pharmacies operate together, it is important to separate specialty from nonspecialty prescriptions at intake so that pharmacy staff can apply specialty pharmacy processes appropriately. It is crucial to have clear policies and procedures in place for handling specialty prescriptions.

Table 1. Specialty pharmacy workflows

Workflow step	Questions to consider
Patient financial assistance	<ul style="list-style-type: none"><li>• Do you provide financial assistance to cover prescription costs for noninsured patients or patient responsibilities (copayments) for insured patients?</li><li>• Does the patient's insurance plan allow for manufacturer copay assistance (i.e., not government funded)?<ul style="list-style-type: none"><li>- If so, does the manufacturer provide copay assistance? How do patients get access?</li><li>- If not, is any foundation support funding available (e.g., PAN Foundation)?</li></ul></li><li>• Is the patient uninsured?<ul style="list-style-type: none"><li>- Will your pharmacy provide medications at no charge or a discounted rate?</li><li>- Does the manufacturer support a patient assistance program and if so, how can patients access it?</li><li>- Can your pharmacy team refer patients for institutional financial counseling?</li></ul></li><li>• Will your pharmacy allow payment plans (e.g., paper billing)?</li></ul>

Clinical assessment	<ul style="list-style-type: none"> <li>• What is the process for determining the appropriateness and effectiveness of therapy? (The list of questions to consider when assessing appropriateness below is not comprehensive. Clinical assessment before initiating a prior authorization can be valuable to ensure that authorization is obtained for an appropriate therapy.) <ul style="list-style-type: none"> <li>- Is the medication indicated to treat the patient's disease state?</li> <li>- Does the patient have any contraindications to this medication?</li> <li>- Does the patient have any medication or disease-state interactions with this medication?</li> <li>- Does the patient require tuberculosis testing prior to starting therapy?</li> </ul> </li> <li>• How and where is the clinical assessment documented?</li> <li>• How often are patients reassessed to ensure safety and effectiveness of drug therapy?</li> </ul>
Fulfillment	<ul style="list-style-type: none"> <li>• See Table 5, "Primary Workflows," in Step 3 of the toolkit.</li> </ul>
Shipping and home delivery	<ul style="list-style-type: none"> <li>• What kind of delivery service(s) will be used (FedEx, UPS, USPS, courier, etc.)?</li> <li>• How will the method of delivery be selected by the staff (cold vs room temperature based on weather and distance)?</li> <li>• What will the coverage area be? <ul style="list-style-type: none"> <li>- If delivering to patients out of state, what will your process be for ensuring that your pharmacy is licensed in that state?</li> </ul> </li> <li>• Will packages be insured?</li> <li>• Will signatures be required?</li> <li>• Cold chain: <ul style="list-style-type: none"> <li>- How will packaging be determined (e.g., stability data and certification)?</li> <li>- How will testing be performed and documented (e.g., biannual or quarterly temperature monitoring)?</li> <li>- Is there sufficient storage space for shipping materials?</li> </ul> </li> </ul>

Abbreviation: EHR = electronic health record.

**Customer support, case management, and clinical responsibilities:** Case management (also known as care management or patient management) is essential for effectively communicating with patients and providers. Because specialty medications are complex, clinical pharmacists and pharmacy technicians must work closely

with providers and staff to ensure that the patient's entire medication regimen is optimized to achieve the desired outcomes. This coordination is critical when medications have requirements for risk evaluation and mitigation strategies (REMS).

Case management can begin when the patient is enrolled in the specialty pharmacy program, establishing a relationship with the patient and providing or reinforcing medication and disease-state education. Follow-up calls to assess medication adherence and tolerability and to schedule refills, are often used to ensure that the patient is using the medication as directed.

The specialty pharmacist monitors lab test values and documents monitoring parameters and patient interactions in the electronic health record (EHR). Specialty pharmacies should consider using a therapy or case management system or software specifically designed for specialty pharmacy case management. The system should be part of or interface with the EHR, to ensure continuity of care and transparent communication. Retail pharmacy dispensing systems are not designed for the complexity of specialty pharmacy management and reporting.

Some therapy and case management software vendors commonly used by Vizient members include:

- Asembia<sup>1</sup>
- Epic Specialty Navigator (EHR)
- Medidata CareTend/CPR+
- TherigymSTM

**Specialty personnel:** Plan for adequate staffing to support high-quality service for your patients once workload requirements have been assessed. Staff dedicated to prescription intake and dispensing include pharmacists and pharmacy technicians knowledgeable in all aspects of retail pharmacy, including shipping and handling in temperature-controlled environments. Additional pharmacy technicians or case management personnel are required to manage prior authorizations and financial assistance. Clinical pharmacists to manage patients may also be necessary.

A survey conducted in November 2017 of Vizient members that offer specialty pharmacy services examined staffing ratios. While the ratio varied among the 17 members that responded, the average patient-to-pharmacist ratio was 51.8:1, while the patient-to-pharmacy technician ratio averaged 90.5:1. Note that these numbers reflect well-established specialty pharmacy services; a new facility will likely start with fewer personnel. Your five-year plan should include projections for service expansion and appropriate increases in staffing.

## Marketing and advertising for prescription capture

Marketing is critical to differentiate your program from the competition. Even if your goal is to manage only patients within your health system, there may be no mandate to send specialty prescriptions to your pharmacy (unless directed by health plans). Specialty pharmacies can use consistent communication, relationship building and reminders to encourage providers and staff to refer patients to your service. Brochures, magnets, pens, pads, and so on, may be distributed to clinic staff to promote your services.

Consistently providing high-quality, integrated care, and promoting provider awareness of that consistency, is the formula for success—which is measured by increased prescription volume, revenue, patient and provider satisfaction, and improved patient outcomes.

## Accreditation

Many payers and manufacturers require that specialty pharmacies be accredited by one or more of the major accreditation organizations to remain in the payers' preferred networks. Examples of specialty pharmacy accrediting organizations are:

- Accreditation Commission for Health Care
- Center for Pharmacy Practice Accreditation
- The Joint Commission
- URAC (previously known as Utilization Review Accreditation Commission)

Accrediting organizations differ with regard to costs, timeline and standards. All of these characteristics should be evaluated in choosing which type(s) of accreditation to pursue.

## Challenges in specialty pharmacy

Some of the more common challenges and considerations for developing and managing a specialty pharmacy are outlined in Table 2. The path to success when establishing a specialty pharmacy is paved with unique challenges that, whether internal or external to the organization, can present themselves at any point in the development process. Health system specialty pharmacies are better positioned to overcome these challenges if they are fully considered during development and implementation. It is also important to recognize that these challenges may evolve as the specialty pharmacy grows.

**Table 2. Challenges in specialty pharmacy**

Step	Challenge	Description	Considerations
<b>Internal</b>			
Planning	Understanding the opportunity	Identifying patient and provider groups to engage and monitoring prescription capture rate	<ul style="list-style-type: none"> <li>• Seek to understand data reporting capabilities of the EHR.</li> <li>• Use objective data to describe the opportunity.</li> </ul>
Workflow	Process development	Developing clear and effective policies and procedures to ensure efficiency and sustainability.	<ul style="list-style-type: none"> <li>• Develop and maintain vital relationships. <ul style="list-style-type: none"> <li>- Identify key stakeholders and partners early.</li> <li>- Identify team leaders and decision-makers for your group.</li> </ul> </li> <li>- Learn from your peers; collaborate with specialty pharmacy teams in similar organizations.</li> <li>- Communicate frequently and openly about problems.</li> </ul>
	Cold chain management	Implementing cold chain processes, which can be complicated and difficult.	<ul style="list-style-type: none"> <li>• Review processes early and often to determine what is working, what is not, and what could be better.</li> <li>• 340B-eligible institutions should develop proper processes to ensure program compliance with regard to inventory management.</li> </ul>
	Inventory management	Managing specialty pharmacy inventory, which is expensive and may be difficult if items are only required for a few patients or must be drop shipped, or if there are multiple physical locations and multiple suppliers for LDDs (e.g., direct purchase from manufacturers).	
	Training	Ensuring that the necessary specialized training and skills to support your specialty pharmacy are provided. Ongoing training is necessary to keep up with the continual changes in specialty pharmacy.	
Demonstrating value	Outcomes and metrics	Measuring outcomes and tracking metrics is necessary to demonstrate the value of the specialty pharmacy service to the organization and its patients and payers.	<ul style="list-style-type: none"> <li>• Carefully consider which outcomes and metrics you will measure, in the context of what is important to decision-makers at your organization.</li> <li>• Review outcomes and metrics you are already measuring.</li> <li>• Consider partnering with clinical staff to evaluate patient-specific metrics.</li> <li>• Maintain a process to periodically share metrics with key stakeholders beyond the pharmacy.</li> <li>• Develop strong relationships with informatics support.</li> </ul>

Step	Challenge	Description	Considerations
<b>External</b>			
Regulatory	Accreditation	Obtaining accreditation is increasingly required to be able to access certain payer networks or drugs; some payers also require pharmacists to carry specialty certifications. Several different types of specialty pharmacy accreditation are available.	<ul style="list-style-type: none"> <li>• Review the requirements of your payers to identify which accreditation(s) to pursue.</li> <li>• Plan as far ahead as possible.</li> <li>• Ask for advice from peers that have already received accreditation.</li> <li>• Consider using a consulting service.</li> </ul>
Access	Payer networks	Many payers now restrict pharmacy access to a few select specialty pharmacies.	<ul style="list-style-type: none"> <li>• If possible, work with your contracting department to identify your biggest payer networks and establish relationships with those payers.</li> <li>• Carefully weigh the benefits and costs of gaining access to LDDs.</li> </ul>
	Limited-distribution drugs	Many new specialty medications are only available through limited-distribution networks. Gaining access to certain LDDs is time consuming and resource intensive.	

Abbreviation: EHR = electronic health record.

## Specialty pharmacy operational and outcome measures

Table 3 describes metrics that are commonly measured by specialty pharmacies. These metrics are important in demonstrating the value of specialty pharmacy services and the effectiveness of specialty medications. Specialty pharmacy stakeholders—manufacturers, pharmacy benefits managers, accrediting organizations and the health system itself—require data for many different

purposes. Accrediting organizations such as URAC, for instance, may require external data validation. Finally, consider which metrics are relevant to your specialty pharmacy program. Choose metrics that can emphasize the success and growth of the program. Investigate and utilize the information technology resources available to you, and frequently evaluate your processes to ensure that they will suffice for the future as well as current state of the pharmacy.

**Table 3. Specialty pharmacy measures**

Metric type	Description	Limitation	Consideration
Clinical	<ul style="list-style-type: none"> <li>Clinical outcomes for medications or disease states               <ul style="list-style-type: none"> <li>Hepatitis C: SVR (cure rate), F score, viral load, etc.</li> <li>Adherence: PDC/MPR, primary nonadherence</li> <li>General: hospitalizations, ED visits, patient-reported quality-of-life score</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Inability to access your data</li> <li>Difficulty incorporating data from nonintegrated clinical systems</li> </ul>	<ul style="list-style-type: none"> <li>Focus on the data important to management, your teams and key stakeholders.</li> </ul>
Operational	<ul style="list-style-type: none"> <li>Patient access               <ul style="list-style-type: none"> <li>Telephone metrics from ACD system                   <ul style="list-style-type: none"> <li>Average speed of answer or percentage of calls answered within 30 seconds</li> <li>Abandonment rate</li> <li>Blockage rate</li> </ul> </li> </ul> </li> <li>Prescription turnaround time</li> <li>Dispensing errors</li> <li>Distribution errors</li> <li>Complaints</li> <li>Satisfaction surveys               <ul style="list-style-type: none"> <li>Patients, providers, clients (i.e., payers), staff</li> </ul> </li> <li>Number of unique patients by disease states</li> <li>Number of prescriptions dispensed by disease states and capture rate</li> <li>PA turnaround time and approval rate</li> <li>Complaints</li> </ul>	<ul style="list-style-type: none"> <li>Constraints set by your IT department on building reports</li> <li>Complexity of the calculations and/or difficulty implementing</li> </ul>	<ul style="list-style-type: none"> <li>Map out foreseeable data needs for operations, stakeholders, payers and accrediting bodies.</li> <li>Work with internal stakeholders, IT, departments of finance, pharmacy staff and others to develop data analysis.</li> </ul>
Financial	<ul style="list-style-type: none"> <li>Total reimbursements, drug expenses or COGS, labor expenses</li> <li>Financial data for each therapeutic area or drug</li> <li>Payer mix, gross margin, financial assistance</li> </ul>		<ul style="list-style-type: none"> <li>Consider creation of a specialty pharmacy financial dashboard.</li> </ul>

Abbreviations: ACD = automated call distribution; COGS = cost of goods sold; ED = emergency department; IT = information technology; MPR = medication possession ratio; PA = prior authorization; PDC = proportion of days covered; SVR = sustained virologic response.



## Conclusion

All signs in the marketplace point toward continued growth of specialty pharmacy. Specialty pharmacies within health systems are uniquely positioned to show an overall benefit with integrated patient care models and to provide value to organizations, payers, and patients. These guidelines can help you develop in-house specialty pharmacy services, revamp clinical programs, attain specialty pharmacy accreditations, and consistently provide high-quality pharmacy services to your patients.

There are numerous challenges in entering and surviving in the specialty pharmacy market; however, health systems with a clear vision, structured operations and reliable data sources, will be well-positioned to provide exceptional specialty pharmacy services.

- 1 Schumock GT, Stubbings JA, Hoffman JM, et al. National trends in prescription drug expenditures and projections for 2019 [published online ahead of print June 14, 2019]. *Am J Health-Syst Pharm*. doi:10.1093/ajhp.zxz109.



290 E. John Carpenter Freeway  
Irving, Texas 75062  
[www.vizientinc.com](http://www.vizientinc.com)