ACCP White Paper

Developing a Business-Practice Model for Pharmacy Services in Ambulatory Settings

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A business-practice model is a guide, or toolkit, to assist managers and clinical pharmacy practitioners in the exploration, proposal, development and implementation of new clinical pharmacy services and/or the enhancement of existing services. This document was developed by the American College of Clinical Pharmacy Task Force on Ambulatory Practice to assist clinical pharmacy practitioners and administrators in the development of business-practice models for new and existing clinical pharmacy services in ambulatory settings. This document provides detailed instructions, examples, and resources on conducting a market assessment and a needs assessment, types of clinical services, operations, legal and regulatory issues, marketing and promotion, service development and exit plan, evaluation of service outcomes, and financial considerations in the development of a clinical pharmacy service in the ambulatory environment. Available literature is summarized, and an appendix provides valuable citations and resources. As ambulatory care practices continue to evolve, there will be increased knowledge of how to initiate and expand the services. This document is intended to serve as an essential resource to assist in the growth and development of clinical pharmacy services in the ambulatory environment.
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Section 1: Introduction

This document was developed by the American College of Clinical Pharmacy (ACCP) Task Force on Ambulatory Practice to assist clinical pharmacy practitioners and administrators to develop business-practice models for new and existing clinical pharmacy services in the outpatient and ambulatory setting. Translating the evidence supporting clinical pharmacy services into practice in the ambulatory setting has been hampered by the lack of a clear business-practice model. A business-practice model is a guide, or toolkit, to assist managers and clinical pharmacy practitioners in the exploration, proposal, development, and implementation of new clinical pharmacy services and the enhancement of existing services. The goal of this publication is to provide pharmacists with a framework to build a clinical practice in an ambulatory setting within

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the premise of a business model.

Definition of Ambulatory Practice

Clinical pharmacy has been defined by the ACCP as "that area of pharmacy concerned with the science and practice of rational medication use."[1] Clinical pharmacy services in the ambulatory environment can be broadly defined as pharmaceutical care services for patients who walk in to seek care.[2] Ambulatory environments may include, but are not limited to, pharmacists practicing in physician's offices, physician residency programs, community pharmacies, and institutional ambulatory environments. Institutional ambulatory environments can include clinics in hospitals, specialty clinics (e.g., transplant, cardiology), emergency departments, urgent care centers, outpatient treatment centers (e.g., cancer chemotherapy, dialysis), correctional institutions, managed care clinics, and government programs (e.g., Indian Health Services, federally qualified health centers, Veterans Affairs hospitals).[2, 3] In addition, pharmacists may have independent practices providing medication therapy management.

The scope of this business-practice model is for pharmacists practicing in ambulatory care environments providing clinical services. Clinical services include those where a pharmacist works directly with individual patients to evaluate their drug regimen and to identify, prevent, and resolve drug-related problems. In a community pharmacy setting, these services may be an adjunct to dispensing or consultative services, but are provided as a distinct service. Services such as immunization and screening programs are generally not considered to be comprehensive clinical services. Clinical services may include disease-oriented services or phone-based services (e.g., anticoagulation services) only when individual patient evaluations are performed.[2]

In most ambulatory practices, the pharmacist works collaboratively with other health care providers. This may occur within the same physical location, as with an institutional ambulatory clinic or physician's office practice, or at a distance, as with community pharmacy practice. Distant collaboration is often accomplished through collaborative practice agreements. Pharmacists in ambulatory clinical practice can be independent providers or work as part of an interprofessional team.[2]

Section 2: Market Assessment

The key to building a successful ambulatory pharmacy practice is matching personal interest, professional knowledge, and the specific needs of potential customers. A market assessment allows the pharmacist to determine the customers' needs in the context of the business environment. Such an evaluation is the foundation on which the business will be built. Everything from starting the business to future growth is based on an accurate market assessment.[4] Many resources are available to help conduct a market assessment. Helpful literature and web sites for starting a new business and identifying customers are included in Appendix 1, and a list of all pharmacy organizations, with a description of the association and its Web site address, is provided in Appendix 2.

Steps to Successful Market Assessment

The first step in a successful market assessment is to look at the industry and assess trends. The following three questions should be answered: What is the current state of the proposed service? What is the current standard of care? What current and future developments may affect the service?

What is the Current State of the Proposed Service?

Is the provided service new and growing, or is it on the downswing? Is it affected by managed care? Is there proposed legislation pending? Will it be affected by government regulation? Pharmacy associations that may specialize in the specific area of pharmacy practice can help in answering these questions. Attendance at national pharmacy meetings and networking with other pharmacists who may be involved in similar clinical services are also helpful. The medical and pharmacy literature is another excellent source to determine the current state of a specific practice.[5]

What Is the Current Standard of Care?

There should be a standard of care at which a practitioner is expected to provide a certain level of quality to a patient. It has also been defined as "the set of behaviors of a practitioner that is subject to evaluation by peers, regulators, and the public."[6] The first definition focuses on actual patient care whereas the second leans toward legal liability. Legal requirements for the business need to be determined. Legal

requirements for equipment, Clinical Laboratory Improvement Amendments requirements for blood monitoring, and professional licenses, if any, will need to be obtained.

What Current and Future Developments May Affect the Service?

The answer to this query is very important to the longevity of the business. In order for the business to grow and prosper, it must provide drug therapy management for years to come. Consideration may also be given to drugs that are in the pipeline. A state law requiring a pharmacist to have a certain credential for the service would create an instant demand for pharmacists with that credential.

The location of the new service should be convenient and accessible to most patients. Consideration should be given to patients who do not have their own transportation and who may rely on public transportation. The parking lot should be big enough to accommodate increased patient load for the new service. Patients may appreciate the quality of service provided but if they cannot get in and out of the building or parking lot, the quality of service may be overshadowed by problems with accessibility.[7]

It should also be determined whether the service will be local or regional. This will provide an estimate of the total number of people within the target market area. Once all this information has been collected, the pharmacist will be able to better estimate the number of customers and growth potential for the business.

Factors to Be Considered

Before implementing the service, several things must be considered: factors in customer decision-making, customer needs to be addressed, and the timing of the service.

Identify Factors in Customer Decision-Making

To survive, the service must meet the needs of the customers. Table 1 provides examples of customers to target in planning for a new service. Understanding the audience that will approve the business plan will help the pharmacist make a stronger case regarding the need and financial viability of the proposed service(s). The customers will base their decision to use the service on their perception of the quality, value, and convenience of the service.[4] In a time when there is a shortage of qualified clinical pharmacy practitioners, will there be enough pharmacists to provide such service? Other factors that need to be considered are the value and quality of the service, and the convenience of referral.

The price of the service is important and may be the determining factor for some customers.[8] The pharmacist's wage, benefits, and overhead costs must all be factored in the cost considerations. Only after the cost of the service has been determined can the price to the customer be derived. The customer's previous experience with similar services should also be considered.

Customer Needs to Be Addressed

Customer needs must be addressed when beginning the service. Customers will often look outside of their own organization for solutions to their problems. Contracting the service to a pharmacist may be less costly than initiating their own services internally.

Improving quality of care and clinical outcomes are two customer needs that the service will address. Pharmacists should be prepared to show customers that the service will help increase quality of care and improve clinical outcomes. Financial outcomes will also be of importance, and the effect may be more on cost savings. Examples can be obtained from the literature (Appendix 1).

Timing of the Service

Is the timing right for beginning a new business offering clinical pharmacy services? Any current changes taking place in the proposed business area should be evaluated, including new laws or regulations; shortage of pharmacists and other health care providers; and patient safety initiatives. A need for an outside service can be brought about by a change in a regulation or by legislative action. Pharmacists that have kept abreast of new laws and regulations will be poised to take advantage of changing situations and fill the void created by regulations.

Operational Advantages Over Competitors

As an ambulatory care clinical pharmacy service is planned, pharmacists should project the advantages and distinctive attributes of their service over the services currently provided by other practitioners. It will also be necessary to identify what clinical pharmacy services are already being provided in close proximity. The

Table 1. Targeted Customers and Interest Areas

Practice Environment	Customer	Key Areas of Interest and Driving Forces
Physician or provider, office-based practice	Physician or provider staff	Improved patient care outcomes, consultation on complicated drug-related problems, assistance with financially viable options to obtain drugs, direct patient care for drug-related needs.
	Administrators	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, increased physician or provider productivity, and potential new revenue stream.
Managed care	Physician or provider staff	Improved patient care outcomes, consultation on complicated drug-related problems, assistance with financially viable options to obtain drugs, direct patient care for drug-related needs.
	Administrators	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, and cost-benefit of a pharmacist providing the care versus another health care provider.
Physician residency program	Physician educators and program director	Enhanced education of physician residents leading to improved patient outcomes, consultation on complicated drug-related problems, assistance with financially viable options to obtain drugs.
	Administrators	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, increased physician or provider productivity, and potential new revenue stream.
Institutional ambulatory clinic	Physician or provider staff	Improved patient care outcomes, consultation on complicated drug-related problems, assistance with financially viable options to obtain drugs, direct patient care for drug-related needs.
	Administrators	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, increased physician or provider productivity, and potential new revenue stream.
Community pharmacy	Pharmacy staff	Improved job satisfaction, increased career opportunities, and impact on current services provided.
	Pharmacy administrators	Potential new revenue stream, increased prescription, over-the-counter, and store sales, improved employee satisfaction and retention, enhanced public perception of pharmacy and company.
	Community physicians	Improved patient care outcomes, consultation on complicated. drug-related problems, assistance with financially viable options to obtain drugs, direct patient care for drug-related needs.
	Community organizations	Access to reliable health information, enhancement of services provided to the community.
	Health plans and insurer groups	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, and cost-benefit of a pharmacist providing the care versus another health care provider.
	Employers	Financial impact of improved patient care outcomes, improved formulary adherence, reduction in hospitalizations and emergency room visits, cost-benefit of a pharmacist providing the care versus another health care provider, a decrease in lost days from work, and improved employee satisfaction with their health care and employer.
	Patients	Improved patient care, comprehensive educational services, drug therapy management.
Academia	College of pharmacy experiential director	High-quality advanced practice experiences.

advantages and strengths of the proposed new services should be determined.[5]

Within the Organization

Pharmacists should evaluate the services of other practitioners within the organization. Specifically, pharmacists should consider the drug-related services already offered by other departments, particularly those of physicians, physician assistants, and nurse practitioners. Whenever possible, pharmacists should develop services that draw on their distinctive

qualifications and are complementary rather than duplicative. Practitioners from other disciplines will often embrace the clinical activities of pharmacists when they are viewed as contributing to the overall care of patients. Perhaps one of the best ways to achieve acceptance from other disciplines is for pharmacists to focus on drugs and drug-related issues, particularly in areas in which pharmacists have specialized education, training, and experience. In the event that a pharmacist would like to offer a service similar to one already offered by another practitioner, the pharmacist should carefully coordinate his/her mission, objectives, and specific activities with those of the established practitioner in order to identify the unique attributes of the new service. To the extent that complementary roles can be identified, the pharmacist may have more or less success with offering a new service. However, if the new service is viewed by patients and/or practitioners as duplicative, the new service may fail, often simply because of the allegiance to the established service. In this situation, the pharmacist should identify other potentially successful roles and move toward establishing a service that will be more favorably received. In some circumstances, the pharmacist may collaborate with other health care providers.

Outside the Organization

Pharmacists should also evaluate the services provided by pharmacy, medical, or other groups outside the organization in planning their new service. As above, practitioners may easily accept new services that are not currently available to patients, even outside the organization by referral. In such situations, pharmacists may choose to associate with an outside group rather than independently develop a new service. Pharmacists should plan services with the expectation of having as few disadvantages as possible. These disadvantages should be identified and minimized early in the planning process.

Section 3: Needs Assessment

Establishing an ambulatory clinical pharmacy practice begins first with an understanding of the needs of the patients that will be served by the practice and the potential revenue streams that can financially support the service. The medical literature describes numerous examples regarding the drug-related needs of patients and the benefits of including a pharmacist both in the clinical decision-making process and in providing care directly to patients. The concept of pharmaceutical care has been explored for more than two decades, but there are still few published examples of financially sustainable ambulatory clinical pharmacy practices in existence.[9]

The "business" behind the practice being developed should begin when the service is planned. The goal of caring for unmet needs of patients should be combined with the goal of being a financially viable service. Understanding the financial drivers within the organizational structure of the pharmacist practice will allow the provision of care to a wider patient base and will help sustain the service over time. The long-term and short-term goals for proposed clinical services should be described.

The type of patient care service a pharmacist designs is based on two primary factors: the practice environment and the needs of the patient population to be served. Table 2 describes several practice environments and the business models that exist. Understanding the business model will assist in proposing a particular type of practice. For example, if the practice will be in a physician's office where the physicians are provided incentives for "best practices," and they are not meeting the goals of their patients with diabetes, a proposal might be written to begin a service directed toward the patient population with diabetes. Understanding the business model where the clinical service will be established aids in directing the proposed plan to the appropriate audience, including those who have the authority to approve the plan. Collaboration with other health care providers should be described, and the overall goals should be clarified.

The mission for all ambulatory clinical pharmacy services is to improve patient care. Numerous studies clearly demonstrate that many patients are not achieving optimal results from their drugs. In 2003, only 56% of patients in the United States with chronic medical illnesses received the recommended treatment.[10] Furthermore, patients continue to experience drug-related adverse effects at increasing rates. In the ambulatory environment, the most common problems in the drug use process that result in preventable adverse effects occur during the prescribing and monitoring stages.[11] Drug safety is highlighted in many recent studies in community-dwelling populations[12–15] and in

Table 2. Existing Business Models in Ambulatory Clinical Pharmacy Practice Environments

Practice Environment	Business Model	Pharmacy Business Opportunities
Physician or provider, office-based practice	Fee-for-service	Direct billing for services under physician with a level 1 (99211) office code; direct billing using medication therapy management Current Procedural Terminology reimbursement codes, when available.
	Per-member-per-month (health maintenance organization)	Risk-sharing model where a physician or provider agrees to pay the pharmacist a certain amount per-member-per-month to avoid unnecessary emergency room or hospital utilization; anticoagulation services is a common example.
	Incentives for "best practices," meeting predetermined treatment goals	Similar to above, physicians or providers agree to pay a certain amount to have pharmacist assist practice to achieve best practices; physicians or providers choosing this method are likely to have incentives from insurance carriers to achieve disease-state goals; this savings may be passed on to the pharmacist.
Managed care	Office-based practice	See options 2 and 3 in office-based practice examples above.
Physician residency program	Education and training model (Federal funding for training)	Unique to this practice, funding may be available directly for residency training of physicians; in this role, pharmacists may consider seeing patients collaboratively with physicians to provide education and training in advanced patient care.
	Office-based practice	See all three office-based practice examples.
Institutional ambulatory clinic	Clinic code	When an ambulatory clinic is a part of a health care system, a basic "facility fee" may be charged per patient visit with the pharmacist.
	Office-based practice	See all three office-based practice examples.
Community pharmacy	Prescription and over-the-counter product sales	More prescription and over-the-counter product sales can serve to pay for clinical services; amount of services provided limited by product sales.
	Partnership with office-based practices	Can participate in per-member-per-month or incentives for best practice (options 2 and 3 in office-based practice examples).
	Partnership with self-insured employer group	Self-insured employers often seek means to decrease drug costs, improve patient quality of life, and increase healthy days working. Since the Asheville Project, self-employers are more willing to establish paid partnerships with pharmacists to improve employee health; payment methods may be modeled after any of the office-based practice examples.
	Consulting services	As an adjunct to the business model, pharmacists are often paid for speaking engagements, community events, screenings, and consultation to nursing homes and physician practices; these funds can support clinical services including expansion and serve as a mechanism to advertise pharmacist services.
	Fee-for-service	A pharmacist in a community pharmacy may provide a service for a fee to patients; the patient may be directly billed.
Academia	Practice in a college of pharmacy	Clinics may be set up within a college of pharmacy; often this is done as a fee-for-service, or as a free service due to the educational nature of the clinic for students.
All practice environments	Medication therapy management services (per pharmacy benefit manager)	With the initiation of Medicare Part D in January 2006, many health plans are developing payment mechanisms for pharmacists to provide advanced care to patients; this care can be provided in all areas of ambulatory practice listed above; some states may have payment for medication therapy management for Medicaid patients.

home health care patients.[16] Adverse drug events often can result in hospital and emergency room visits.[17–19] The Institute of Medicine report in the Quality Chasm series, titled "Preventing Medication Errors" outlines changes needed in the health care system to reduce medication errors.[20]

Because there is a clear societal need to improve the drug use process, it is important to demonstrate how pharmacists can meet this

need. Numerous studies demonstrate how a pharmacist can positively affect a patient's care. The American Pharmacists Association[21] provides an extensive overview of studies demonstrating a pharmacist's impact on patient care, including patient safety, asthma, diabetes, drug therapy compliance, dyslipidemia, immunization, pain management, and vaccinations. Furthermore, studies demonstrating the economic benefit of clinical pharmacy services have been summarized.[9] In addition, the Lewin Report is a useful resource.[22] The reference list included in this paper provides studies in practice environments specific to community practice, institutional ambulatory care, managed care, and family medicine (Appendix 1).

The pharmacist must also recognize the financial driving forces in a particular practice environment. A practice can be financially viable through a number of mechanisms such as cost avoidance (e.g., reduction in hospitalizations) and direct payment of services.

Section 4: Description of Services

Essential Components of a Service

In the medical model, the patient care process is the same whether the physician is a generalist or specialist. The same is true for other health care providers.[6] The identical concept needs to be applied to ambulatory clinical pharmacy services. The work of the American Pharmacists Association and National Association of Chain Drug Stores Foundation points to a clear framework of the design of a pharmacist medication therapy management (MTM) service in the community pharmacy setting,[23] which can serve as a model for all areas of pharmacy practice. One model of ambulatory clinical pharmacy practice is important to set the standard for patients and health care providers to understand the value they will receive when a pharmacist meets with a patient.

Patient Enrollment or Referral

There are multiple sources for patient enrollment or referrals to a clinical pharmacy service. A physician or other health care professional may refer the patient for MTM, disease state management, monitoring or adjustment (e.g., anticoagulation service), and/or education (e.g., diabetes or asthma). A pharmacist at the point of dispensing in a community pharmacy may enroll a patient after detecting nonadherence or a drug-related problem that could not be easily addressed at the time of dispensing. Alternatively, a patient or caregiver may self-refer after learning of the pharmacist's service. If the pharmacist is a part of an interprofessional practice, the service or referral may be an integrated component of the patient care process. In some cases, a referral may not be necessary. In an interprofessional practice, it may be a standing policy that any patient taking more than a certain number of drugs or with certain conditions sees the pharmacist before seeing other practitioners. Once a referral to the pharmacist is made, an individual appointment or consultation with the patient should be set up.

The Patient Encounter

Patient encounters ideally should occur in a private area where the pharmacist, patient and/or caregiver can comfortably discuss the patient's drug-related needs. The encounter should begin with a simple introduction of the pharmacist to the type of service and follow-up the patient can expect. The second step is gathering from the patient the reason for the visit and drug experience.[6] The medical record or other patient documentation, if available, can provide important details of the patient's medical history and laboratory and test results, and may aid in further identifying the patient's needs. In most cases, the pharmacist would also complete a thorough medication therapy review.[23] The components of this review are described in Table 3.

Documentation

Documentation of the patient encounter is absolutely necessary not only to record the nature of the encounter, the patient problems identified, and the follow-up plans, but also to serve as evidence of the service(s) provided. The format of the documentation can take different forms depending on the practice environment and the resources available. Patient records can be stored in either paper or electronic medium. Documentation should minimally include patient demographics, reason for visit, subjective and objective information obtained, the pharmacist's assessment and plan, any interventions or recommendations made, and planned follow-up.

National organizations offer standards for community practice[23] and for documentation in medical records.[24, 25] Standardization of the pharmacist's documentation for each patient

Table 3. Components of a Medication Therapy Review[6, 23]

Component	Description
Perform medication regimen review	Inquiry and comprehensive review of all prescription and nonprescription medications the patient is taking as well as any herbal or vitamin products
Gather patient's medical history	Medication-related medical history, including physical examination findings, history of diagnoses, hospitalizations, and surgeries
Gather social history, cultural, and lifestyle preferences	Relevant social history; cultural and patient preferences toward drug therapy as it may relate to adherence and drug choice; lifestyle management
Review laboratory and physical examination data (as available)	Review of laboratory data and test results, and the performance of any physical examination or laboratory procedures as appropriate based on the patient's medication therapy needs and as allowable by state law
Assess overall medication therapy and identify medication therapy needs and problems; evaluate and monitor response to medication therapy	Review of the patient's medication regimen for appropriate indication, efficacy, and safety for the individual patient, as well as the patient's adherence patterns; evaluate the patient's response to medication therapy, and identify potential adverse events and drug-drug interactions; financial and cultural considerations must be considered in addition to appropriate monitoring suggestions and dosage regimens
Create a medication therapy plan	A plan to address and resolve medication therapy problems identified during the visit; the plan should be developed collaboratively with the patient and other health care providers as appropriate; the plan may include a lifestyle change by the patient, a call or collaboration with the physician or other health care provider, or the pharmacist resolving a financial or therapy concern
Provide education, patient recommendations, and follow-up	At the conclusion of the visit, patients should be given appropriate medication- and disease-related education as well as therapy and lifestyle recommendations as considered appropriate with their other health care providers; patients should be provided with a personal medication record (comprehensive medication list) and a medication action plan detailing how they should take their drugs as well as lifestyle recommendations
Communicate results to other health care providers	Results of the visit and medication therapy recommendations should always be documented and provided to the patient's other health care provider(s) if necessary; in an interdisciplinary setting, documenting in the medical record in written, verbal, or combination form is usually sufficient; in addition, patients should be referred to other health care providers as needed to support their medication therapy regimen (e.g., dietician referral)

encounter is essential. Within existing medical records, pharmacists may elect to use a standard "SOAP" note (i.e., subjective data, objective data, assessment, and plan) to be consistent with other providers or may use a separate pharmacy note using a standardized documentation template. If the pharmacist practices independently, the documentation (written or electronic) should be stored in an easily retrievable location. A consultation letter should be sent to the patient's health care provider(s), and a copy should be maintained in the medical record. The consultation letter may be sent to the prescriber by standard mail, fax, or secured electronic method.

Communication with the Patient's Other Health Care Providers

Collaborating with a number of individuals within the health care team is essential to build and sustain a patient care practice. The collaborations, both formal and informal, depend on the practice environment and may include physicians and physician assistants; nurses and nurse practitioners; dieticians; other pharmacists; pharmacy technicians; and other support personnel. Communication with the patient's health care provider(s) is essential to ensure optimal use of drugs. The type of communication is determined by the urgency of the patient's need. An acute need should be communicated verbally followed by written communication. A chronic care need should always be communicated in written format. In addition, patient-focused communication with other health care providers helps to build working relationships and encourage continued referrals from providers for future consultations regarding patient drug therapy needs.[26] In order to document the pharmacist's findings and recommendations in the patient's medical records, some institutions require pharmacists to obtain privileges and provider numbers.[27]

Table 4. Operational Processes and Facility and Equipment Needs for a New Clinical Service[28, 30]

Requirements	Recommendations
Operational processes	
Information services	Adequate information systems are required and should be online and computerized, if possible; examples include Micromedex, Lexi-Comp, DynaMed, Up To Date, and Cochrane Library; access to MEDLINE is required; when possible, PDAs should be available for access to drug information; access to full-text pharmacy and medical journals is desirable
Record systems	Should be user friendly and designed with pharmacist's input to allow full pharmacist documentation; electronic medical record (EMR) should integrate with pharmacy systems, if possible; if EMR is available, pharmacist should seek full access; if no medical record (e.g., at a community pharmacy), patient care notes should interface with available record keeping methods, and a method of providing documentation to other health care providers should be determined; also, if no medical record, patients can sign release statements so that records from physicians' offices can be obtained
Materials and supplies	Patient education materials, personal drug records, preprinted materials often available from government organizations, drug manufacturers and national associations (e.g., American Diabetes Assocation, National Kidney Foundation); demonstration devices and kits for product and device education (e.g., placebo inhalers, insulin pens, topical patches); general office and computer supplies
Data analysis and reporting	Director or coordinator is responsible for compilation, analysis, and reporting of all pertinent data (general or specific); data may be collected in an ongoing fashion or retrospectively; data that should be collected include patient demographics, medical conditions, drug therapy, drug-related problems, action taken during visit, and quality indicators and goals achieved
Facility and Equipment	
Space for clinical services	At least one examination or consultation room, fully equipped with necessary items (e.g., blood pressure cuff, examination table or chair, work area for basic laboratory supplies, scales, sharps container)
Space for pharmacists	Office space or work area; office furniture, file cabinet, computer, printer, photocopy-fax machine, bookshelves
Computer services	Types and level of service may vary; ideally located in both examination room and office area, especially for EMR
Special equipment	May become apparent as services are developed; depends on type of service (e.g., glucometer, point-of-care testing)

Section 5: Operations

Organization

An organizational structure that represents the array of ambulatory care services provided by pharmacists is extremely important. Job titles and descriptions for pharmacists and pharmacy technicians providing ambulatory care pharmacy services should be positioned within the organizational structure in a manner denoting a high level of commitment. All services must be included in the overall mission statement as well as in the goals and objectives of the organization and must be represented accordingly in the structure of the pharmacy department and the institution or the overall organization. Anything less than full representation at these levels may result in a diminished outcome.

Reporting Structure

In a hospital setting in which the ambulatory care pharmacy services are provided through a department of pharmacy, the coordinator of these services should report directly to the director of pharmacy to ensure a commitment to these services equal to that acknowledged for other key services of the department. In the case of freestanding ambulatory clinics or community pharmacies, pharmacists should either provide direct leadership for ambulatory services or report to an appropriate administrator. Additional reporting lines to physicians and other health care providers may be appropriate, based on day-to-day clinical activities.[28]

Operational Processes and Facility and Equipment Needs

In starting a new clinical pharmacy practice in an ambulatory setting, several operational processes, and facility and equipment needs, are necessary. These are discussed in detail in Table 4.[28–30]

Personnel Requirements

Adequate attention for determining the overall personnel requirements for each ambulatory care pharmacy service is critical. There should be an adequate mix and number of personnel to provide appropriate backup and coverage. Failure to provide adequate personnel for each service will lead to frustration of physicians and others who refer patients, of patients themselves, as well as of the pharmacy personnel involved in providing the specific service.[28]

Areas of Practice

Determining the specific areas of practice for ambulatory care pharmacy services will depend on a number of factors, including availability of pharmacists and support personnel to provide each specific service as well as the time, space, equipment, and funding available to devote to each service. Each of these variables should be considered in advance of actually beginning a service, allowing more opportunity for success and continuation. The service may be general MTM or specific disease-state management. Factors outside the control of the pharmacy department or the pharmacist that may affect any pharmacy service may include the participation of physicians and other health care practitioners who also have an interest in such services. Physicians may be involved in determining the overall direction and success of clinical services, particularly if their referral of patients is critical for receiving patients.

Number of Full-Time Equivalents Needed

The number of full-time pharmacists and pharmacy technicians needed for any specific service will vary depending on the number of patients to be served and the depth and breadth of the service. The director or coordinator for the service should cautiously predict the need for personnel, employing additional personnel for anticipated growth and unexpected details. Administrators should attempt to calculate the maximum number of patients who can appropriately receive the service in a given day based on review of medical records for the occurrence of specific diseases or medical problems; pharmacy profiles for the occurrence of specific drugs or drug categories; discussions with physicians who may be associated with the service, and any other means of understanding the demand for each service. In addition, administrative time for pharmacists must be included in their total time. As a general rule, the length of time allotted for a patient visit may be as much as 1 hour for an initial session and may range from 10–30 minutes in the case of an established patient session or encounter, depending on the required levels of assessment and intervention. When needed, administrators should seek new positions for the department so that the service can be successful.

Qualifications of Pharmacists Participating in the Service

Each pharmacist who participates in the service must be appropriately educated and trained. Strong consideration should be given to require residency training and board certification (e.g., Board Certified Pharmacotherapy Specialist). If appropriately trained and experienced pharmacists are not available to provide a new service at the time it is desired, the director or coordinator should seek training programs or other methods to assist the pharmacist(s) to acquire the necessary skills and experience. Continuing education and certification programs are often available to assist pharmacists in developing new skills and practice expertise while remaining in their positions. Pharmacy residents and fellows may be involved in provision of services when appropriate, but never in the absence of qualified personnel to supervise their activities. A resident or fellow should not be the sole provider of the service, unless he/she has already demonstrated expertise in this service through previous training or experience.

Areas of Support

Pharmacy technicians and clerical and financial personnel can play important roles in establishing and maintaining ambulatory care pharmacy services. Pharmacy technicians can assist in the preparation of drugs, record-keeping activities, and supervised patient interactions. Clerical personnel can place phone calls and send e-mail or letters to patients regarding appointment scheduling and follow-up information. Financial personnel may be responsible for billing and keeping ledgers necessary to track the flow of money through the system.

Desired Areas of Expansion

Desired areas of expansion may become apparent after a service has been offered for a

period of time based on requests from patients, physicians, administrators, or others. These expansion areas should be considered carefully using all the variables used initially to determine need and capability. Qualifications for personnel needed for expansion of services may be different from those initially in developing the service. Specifically, pharmacists with more specialized training may be required as the depth and breadth of the overall services become more defined and detailed. For example, an ambulatory care pharmacy service may begin with activities for general medicine patients and develop over time to include more complex patients who may need specific services in cardiology, pulmonology, infectious disease, nephrology, and/or other specialties in a similar manner to the services offered by physicians. As more specialized services are desired, the demand for specialized practitioners will follow.

Subcontracting and Outsourcing

Subcontracting and outsourcing for specific services associated with an ambulatory care pharmacy service may be desirable when the needed personnel or services are not available on site, particularly in the early stages of a new program when full-time staff or services cannot be financially justified. However, a commitment of full-time personnel to each area will provide the continuity of care that is often needed. Examples where this may be helpful are in the areas of information technology and dispensing.

Evaluating the Need for Training

The director or coordinator should assess the need for additional training when new personnel are recruited or new programs are established. In each case, training should be based on the need to provide updated policies and methods required for excellence in specific clinical practice areas. The director or coordinator should provide adequate material and time to become established in the performance of expected activities before these personnel take full responsibility for the service.

Operational Impact of Services

The impact of ambulatory care pharmacy services should be anticipated prior to initiating the service. Pharmacists should identify gaps in the types and levels of service already being provided in an area and begin services that are projected to have the greatest positive impact, while not duplicating the services of other practitioners. Pharmacists should identify areas of practice in which their education, training, and experience will allow their optimal level of practice, and they should evaluate their practices as often as possible to determine their impact on overall patient care.

Within the Department Organization

The primary impact of ambulatory care pharmacy services within the department or organization may be on personnel and staffing. Administrators should make every effort to ensure that changes in professional rank or appointment levels, staffing patterns, salaries, professional advancement, and other important personnel issues are understood by all personnel. Any new arrangements brought about by the implementation of a new service or the hiring of new personnel should not negatively affect the overall department. The primary clinical impact of ambulatory services may be most realized within the department or organization by the benefits observed from patient care, such as improved surrogate markers, actual outcomes, or positive financial impact.

Other Departments and Practitioners

When pharmacists initiate clinical services, there may be either a positive or a negative impact on other departments or practitioners. Depending on the methods in which patients are identified for ambulatory care clinical pharmacy services and the outcomes associated with the service, the impact on other departments and practitioners, particularly physicians and nurses, may vary. However, the impact of each ambulatory care pharmacy service should be anticipated before initiation of the service. By anticipating such impact, other practitioners and administrators can be consulted in the early planning stages so that the primary impact will be positive and the service will be viewed for its strengths rather than as a source of competition.

Section 6: Legal and Regulatory Issues

Compliance with Practice Standards

Several factors must be evaluated and considered when implementing ambulatory pharmacy services, including organizational structure, opportunities for collaboration, access to patients and patient information, employment

requirements, affiliation needs and agreements, and policies and procedures for the service.[2, 31]

When establishing a collaborative practice agreement, the following steps should be considered and outlined during the planning and early implementation process: define scope of practice, apply for privileges at the practice site, identify evidence-based practice standards, establish policies and procedures, determine qualifications for participants, create a continuous quality improvement process, measure outcomes (economic, clinical and humanistic), document activities, and investigate compensation processes.[31]

Collaborative Drug Therapy Management

Pharmacy and medical organizations have published position statements supporting the pharmacists' role in collaborative drug therapy management (CDTM).[31, 32] As of November 2005, 43 states have enacted legislation that grants pharmacists the authority to engage in some form of CDTM.[33] Several resources provide an overview of CDTM and summarize state-specific regulations.[31, 34, 35] A survey of ambulatory care pharmacy practices identified collaborative practice agreements as a significant enabling factor for the integration of pharmacists in the ambulatory care setting.[36] To facilitate further expansion of the pharmacist's role in the ambulatory setting, states should review and make necessary changes in the pharmacy practice laws and regulations to allow pharmacists to participate in CDTM. Examples and descriptions of collaborative practice agreements may be found in the literature (Appendix 1).

Medication Therapy Management Services

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 was intended to increase access to prescription drugs by providing drug coverage for beneficiaries.[37] Furthermore, specified patients enrolled in the prescription drug benefit are entitled to receive MTM services. Although pharmacists were not granted "provider status" and are ineligible to receive compensation for services under Medicare Part B, the legislation requires prescription drug plans to pay for MTM services as a Part D benefit. Other providers are not excluded from providing MTM services; pharmacists are the only health care practitioners specified in the regulation. The prescription drug plans create and implement MTM programs for their members. Because the legislation does not stipulate details related to these plans, there is significant variability in the design of MTM services. The Lewin Group was enlisted to create a resource to assist with designing and implementing MTM services.[22] To specifically assist the community pharmacist, the American Pharmacists Association and National Association of Chain Drug Stores jointly identified the core elements and a framework to deliver MTM services within this setting.[23] Some states are now reimbursing pharmacists for providing MTM to Medicaid patients.[38, 39]

Health Insurance Portability and Accountability Act Compliance

All health care practitioners and medical practices must understand and comply with the Health Insurance Portability and Accountability Act (HIPAA). Compliance with the HIPAA legislation requires careful evaluation of policies and procedures related to patient information and implementation of measures to ensure the privacy and security of patient information. At the first office visit, patients should receive a Notice of Privacy Practices, and a written acknowledgement of receipt must be obtained. Although patient authorization is not required for routine disclosures related to treatment, payment, or health care operations, it is required when protected health information is disclosed to a third party; for marketing of products or services (except if marketed in a face-to-face encounter); for raising of funds for other organizations; and for conducting research, unless a waiver was approved by the institutional review board.[40] To facilitate the implementation of HIPAA policies and procedures, adequate training of all staff should be conducted and documented. Appendix 1 includes resources for HIPAA compliance.

Miscellaneous Regulations

The Occupational Safety and Health Administration (OSHA) has established standards that apply to all employees who may be exposed to blood or other potentially infectious materials.[41] These regulations describe requirements that employers must fulfill to protect individuals who have a risk of occupational exposure. Pharmacists in ambulatory care settings, including community pharmacies, who perform point-of-care testing may be exposed to bloodborne pathogens and

other potentially infectious materials. These sites would need to comply with OSHA standards (Appendix 1).

The Clinical Laboratory Improvement Amendments were initially passed in 1988. The Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services published final regulations that have been effective since 2003.[42] The purpose of the laboratory amendments is to create standards that will ensure quality laboratory testing and procedures. A laboratory is defined as any facility that performs laboratory testing, including ambulatory and community pharmacies performing point-of-care testing. Many resources summarize the procedures and regulations associated with laboratory testing. Appendix 1 includes a list of Web-based resources.

Certification and Credentialing

Credentialing and privileging for pharmacists are important and complex issues intended to protect patients from incompetent providers, to safeguard organizations from malpractice allegations, and to meet regulatory agency and third-party payer requirements. When establishing ambulatory care services, developing CDTM protocols or providing MTM services, the public and other members of the health care team need to have an agreement on and common understanding of the education and training of pharmacists and their contribution to patient care. Thirteen national pharmacy organizations founded the Council on Credentialing in Pharmacy to provide leadership, standards, information, and coordination for professional credentialing programs in pharmacy. Pharmacist credentials may be divided into three fundamental categories: college or university degree; licensure; and certificates, awards or postgraduate work.[43] Privileging is the process used by a health care organization, after evaluating a practitioner's credentials and performance, to grant an individual permission to provide certain patient care services.[43] A pharmacist may be recognized by the organization to be credentialed and obtain a provider number.[27] Some states, such as Minnesota, may require the pharmacist to be credentialed through the state government, especially if providing services for Medicaid.[38] Credentialing may also be necessary for billing purposes.

Pharmacists are pursuing postgraduate training, becoming more specialized, and attaining certification in a specific domain of practice (e.g., certification through the Board of Pharmaceutical Specialties, Commission on Certification in Geriatric Pharmacy), specific disease states (e.g., certified diabetes educator, certified asthma educator), or specific therapy (e.g., certified anticoagulation care provider). Other than the requirements for pharmacy licensure, no credential is required by law to provide specific clinical pharmacy services in an ambulatory care setting. However, each institution, health care system, or organization can establish its own criteria for pharmacist practice descriptions and credentialing and/or privileging processes.[27] The Lewin Group concluded that MTM services can be provided at multiple levels of complexity, with licensed pharmacists providing first-line drug management and more highly trained or credentialed pharmacists delivering more complex services.[22] Appendix 1 includes a list of resources on this topic.

Liability Insurance

Professional liability insurance is needed and should provide coverage for any activity that pharmacists can do legally in the state in which they practice, including CDTM if permissible by state law.[44] Generally, the institution is liable for an employee's acts of professional negligence that occur within the practitioner's typical scope of practice. Therefore, most employers and institutions carry a professional liability policy on their employees. An employed pharmacist who is covered by his/her employer's policy may obtain an additional, secondary policy. Although not required, an individual pharmacist may choose to obtain additional coverage for several reasons. An employer may disclaim its responsibility if the situation is proven to be outside the scope of normal practice or protocol.[45] In some cases, the claim may exceed the employer's policy and the individual's personal, secondary policy would apply. Finally, an employer's policy covers the pharmacist's activity occurring at work whereas an individual policy would include coverage for work and non-work related advice and activities. Primary liability policies are also available for independent contractors and consultants.

Risk Management

Site-specific policies and procedures, clinic protocols, and collaborative practice agreements based on evidence-based medicine principles should be established to optimize patient outcomes and minimize risks. An attorney should write or review any agreement or contract for services before securing signatures. The basic elements to be addressed in a contract have been described.[46] Although the exposure for liability increases as pharmacists' practice activities and responsibilities expand, many techniques can be employed to minimize that risk. The key steps to managing risk include identifying, assessing, eliminating, minimizing, and transferring risk.[47, 48] A proactive approach should emphasize measures to eliminate, minimize, and transfer risk, which can be accomplished in a variety of ways. Examples include ensuring adequate credentialing, hiring qualified personnel, improving procedures and protocols, maintaining good patient and staff relations, and communicating and documenting activities well.[47, 48] Reasonable extrapolations to ambulatory care pharmacy practice would include obtaining the medical staff's endorsement of pharmacist involvement and clinical pharmacy protocols, clearly documenting all pharmacist interventions and communication in the patient's medical record, maintaining professional competence and achieving appropriate credentials, and evaluating pharmacist intervention and patient outcomes as part of the comprehensive quality improvement efforts. A worksheet to assist with identifying, evaluating, and addressing various liability risks is available.[46] The evolution of risk management and quality improvement processes in recent years has led to a logical interface between the two concepts. Integrating risk management and quality improvement is sensible and can enhance the effectiveness of both.[47, 48]

Section 7: Marketing and Promotion

Marketing includes researching customer needs and wants, developing strategies, maintaining customer records, delivering products and services, financing, promotion, pricing, and monitoring customer satisfaction.[49]

Preparing to Advertise

Being able to define the service in a way that is appealing to all customer groups is key to the marketing process. Therefore, services should be evaluated to identify the health needs and services currently available. It is important that the definition of the service includes how the service will be different from any other service available in the community and why the patient, health care provider, or third party payer should select the new service. The service has to meet the expectations of the customer to be a success.[7, 50]

Physicians and Other Health Care Providers

Once the benefits of the service have been defined, the marketing design needs to be molded around the groups to be marketed. To evaluate the opinions of health care professionals, insurers, and patients regarding the perceived need for and anticipated use of the proposed service, a simple questionnaire can be distributed to assess the best way to market the service. Gathering these opinions before investing in a new service can be helpful and cost-effective. The questionnaire can also ascertain whether a similar service existed in the past and how successful it was.[51] If the primary person making referrals to the service will be a physician, it should be determined which physicians should be targeted for marketing by specialty or subspecialty and special interests. Talking to other health care professionals may provide insight as to the demand for the service. For example, endocrinologists, internal medicine physicians, and primary care physicians would be the groups one would market to for a diabetes education service, as they are the ones who will refer potential patients.

Physicians will be evaluating the service on a more professional level. They may inquire about the educational background and specialty training of the pharmacist(s) providing the particular service, the disease-state management plans, and the outcomes that are expected.[49]

Establishing a relationship with other health care providers is essential in establishing or expanding any service. Providing physicians and other practitioners with additional services may enable them to better meet the needs of their patients. The ability of pharmacists to identify potential problems, such as drug adherence, can result in appropriate and timely interventions and build confidence with the health care provider, leading to requests for further pharmacist consultations.[52]

Patients

Research has demonstrated that patients are

often unaware of the services pharmacists are able to provide and are unlikely to appreciate the roles and responsibilities of pharmacists.[53] Therefore, the marketing plan for patients will need to be different from the marketing plan for health care providers or payers. Patients will be evaluating the service for value, convenience, and quality of care. Patients will want a guarantee that the service for which they are paying will meet their needs and expectations as well as being price competitive; therefore, extensive, straightforward education about a new service needs to be provided.[54]

Payers and Stakeholders

When promoting the service to payers, it is necessary to clearly describe how the new service will improve both outcomes and cost-effective care. It will be necessary to document decreased emergency department, hospital, or office visits; improved patient care or satisfaction; and/or reduced overall drug costs. Some managed care organizations contract health care services if the proposed service meets the payer's goals. The potential is there to have a steady flow of patients through their health care plan.

Knowledge of the key stakeholders is critical. These individuals have a vested interest in the success or failure of the proposed service and represent the real customers in the process. It is critical to know how success is defined for them with regard to both financial and nontangible benefits. From a financial perspective, understanding how they value cost-savings, enhanced revenues, and risk reduction is vital in planning the approach. In assessing nontangible benefits, consideration should be given to growth, new opportunities that may evolve from the service, and strategic positioning within the health care sector in which they operate.

Soliciting input from these key individuals is a critical step in the planning process. A new service should seek to solve a previously identified problem or improve an existing process, which can often be identified by conducting a needs assessment. This assessment can often identify areas of strength relative to areas of concern and can provide useful insight into what the customers perceive as "valuable" versus the proposed needs of various parties who will interact with the service. It can also assist with identification of how the current needs of a particular sector are addressed and how the new service can address those needs in a better way. It may also help with identifying legal restrictions, which may limit the scope of the service or the ability to provide the proposed service.

Public Advertising

Products can be marketed or promoted in several ways, including internal and external marketing.

Internal Marketing

Internal marketing is dependent on the staff. The staff needs to be knowledgeable about the new service so that when there are questions regarding pharmacy services, they are able to answer the questions and promote the benefits of the specialized service. It is also prudent for patients to see promotional items around the waiting areas. Another option is mailing out program information to current patients either with a particular disease state or to all patients to reach family members who may have the specific disease being targeted.[7, 50]

External Marketing

Because the intangible nature of pharmacy services makes it difficult for consumers to grasp what pharmacists do, patients who have used the service will be instrumental in promotion outside office walls.[49] They will be describing the service to their family, neighbors, and friends, which will certainly increase knowledge of the new service within the community. Other methods of promoting a service include broadcast (radio or television spots), print (newspaper advertisements, yellow pages, leaflets, posters, newsletter), Web page information, and volunteer screening for support groups (heart failure, diabetes) to help monitor disease states and educational programs for professional and consumer groups.[55, 56]

Evaluation of Advertising

To justify the cost of a marketing campaign, it will be necessary to evaluate the effect the campaign has on the customers. Piloting an advertising campaign using a sample of the targeted population (health care providers and patients) can provide positive or negative feedback regarding the current plan. Adjustments may need to be made to the original design to accommodate for focus areas that were inadvertently missed or not fully explained.[57]

Once the campaign is under way and the new service is operating, it is important to consider how to maintain the customer base (professionals and patients) that currently uses the service and how to expand to other potential customers. As part of a quality assurance follow-up, the number of visits and what profit was gained should be evaluated. It would be valuable to determine what parts of the service customers like best and build on those focus points.[50, 56] This can be done through questionnaires or surveys. From the responses, it can be determined what needs to be done to retain current customers and hopefully obtain ideas on how to reach other potential customers. Some ideas may include sending out newsletters regarding a new drug on the market (drug information) or making phone calls to follow-up on a patient visit in which changes were made to therapy. Anything that can personalize the service will separate it from other community programs.[57]

Section 8: Service Development and Exit Plan

Milestones for Service Development

A well-constructed strategic plan is the cornerstone of success in the business environment. The strategic plan describes the projected direction of the patient care pharmacy service within the scope of the overall organization and the best approach for achieving defined goals.[58] It is the essential starting point for determining whether or not there is a need to establish a new service.

Although marked in a variety of ways, milestones are broadly defined as indicators or events placed at key points in the life of a project or service, intended to measure achievement in the ongoing project or service.[59] The indicators must be measurable, realistic, and consistent with the strategic plan to ensure progress. Milestones are measured at interim stages rather than at completion of the project, and they are absolutely essential in the process of service development. Milestones developed in advance of the start of the service serve as points for reflection and evaluation while allowing for redirection and modification of the service if necessary. The milestones also serve as interim markers of progress to help ensure the success of the service both in the development process and as continuing measures of quality once the service is established.

Planning for Service Development

Planning for service development involves knowledge of the many factors that influence the patient outcomes. At the center of all of these factors lies an understanding of the process by which individuals[60] and systems[61] implement change. Change, whether viewed in a positive or negative light, is one of the most difficult aspects for many people to accept and work with initially.[62] A strong sense of consensus among contributing parties can be valuable in reducing some of the stresses associated with implementing change in the workplace, particularly with service development.

During the planning stages of service development, efforts to conduct background research can be a productive use of time and effort. The collective development of the business plan proposal is often the most productive means of initial planning and ensures that the interests of those likely to be affected by the plan are identified and addressed. Collective input should also serve as the foundation for acceptance and ensures that inordinate amounts of time are not spent on small details at the expense of momentum.

Group effort requires the selection of a qualified leader[63] who understands the business environment and who has sufficient background and experience in establishing and conducting the day-to-day activities of the proposed service. The leader should be able to establish clear goals and appropriate timelines, assign responsibilities, coordinate efforts of the group, and select group members who understand the goal to be achieved with the initiative. The leader should have well-defined strategies for implementation and be able to delegate when appropriate. The leader should be credible among administrators in the organization and should represent the interests of major stakeholders who stand to benefit or lose from the success or failure of a program or project. Finally, a good leader should be able to accept responsibility for successes and failures of the project at all points in development.

Planning Phases

The planning process involves multiple stages. A planning guide was recently published for the establishment of palliative care programs.[64] Although specific for palliative care, many of the core elements of the program development are applicable to other clinical services.

Assessment of the factors affecting project or service development status should include those

internal and external to the service. Internal factors would include core strengths, as well as deficiencies, as these drive priorities and processes for development. External factors are more difficult to control but should be included in the planning process. These factors include MTM services,[22] legal issues (which vary by locale), payers (whose benefit coverage varies substantially from one another), and similar services within the institution or organization that are in direct competition with the proposed service and from whom the service must be distinguished.

Service Development

Service development requires a keen understanding of the business culture into which the clinical service is being introduced, the major competitors in the marketplace, and the potential impact of the service in that system. Implicit in this process is the knowledge of the key decision-makers. These individuals can assist or impede the development of the service and its implementation. These decision-makers should have a clear understanding of how the proposed new service will benefit the organization and how it will fit into the overall strategic plan.

For ambulatory clinical pharmacy practice, market analysis should be done to evaluate model practices and implement ideas to assist in creating an excellent clinical practice. Other clinical pharmacy practitioners are often willing to help share their materials. Resources are available to assist pharmacists in setting up their own ambulatory clinical practices, including protocols and collaborative practice agreements from other clinics and institutions.[65]

The financial implications of the proposed service should be explored with the business unit of the institution where the service will operate. A proposed business plan should be developed to compare current and future costs because these can be used to determine the financial feasibility of the project and how the new service affects the organization financially. A well-constructed business plan can also increase the credibility of the project with regard to the proposed financial benefit. The business plan should identify not only current and future sources of funding, but also contingency plans for covering unexpected operating expenses.

Lines of authority within the system should be well established. The scope and impact of the proposed clinical service are vital to relating the interaction of the service to existing clinical programs. In addition, lines of responsibility within the larger system should also be clearly defined to ensure integration and completion of the interrelated aspects of the service within the institution.

Finally, criteria defining the success of the service should be established to systematically monitor progress. Key customers and decision-makers should be present to assure that all concerns regarding the proposed service are adequately addressed through an objective process.

Launching a Service

Once approval of the proposed plan and financial arrangements has been secured, the service can be launched. Personnel to assist with the implementation process should now be identified and a training plan should be developed to ensure a smooth transition and continuity of patient care. A new patient care service will have numerous new record-keeping processes and operating procedures. Strong administrative and clinical support will be essential in these early days as the risk for errors, omissions, and harm to a patient will likely be higher than usual due to the unfamiliarity of personnel with new processes.

Operation of the new service will need to be coordinated with other services in the health care organization that are involved with or affected by the service, such as laboratory or pharmacy dispensing services, and equipment needed to run the service, such as computer systems and communications networks. Integration of these systems will ensure a smooth transition period and reduce the likelihood of compromising care because of inefficient or ineffective system processes.

Providing the Service

Policies and procedures approved by the director or coordinator of the service and descriptions of how the service will operate should be in place from the start. These help ensure that guidance exists for consistent operation across most aspects of the service and should reflect the current business environment. Key information should be provided in sufficient detail to give an outside observer a relatively clear understanding of the structure, function, and basic operation of the service.

Assessing the Impact on Existing Services

During the early stages of operation, periodic monitoring of the new service's impact on existing services should be performed. At predefined intervals, careful evaluation of whether the service is performing at the projected levels should be considered.

Unplanned events and other influences that have an impact on the success of the program should be reviewed, and modifications should be made as necessary. The evaluation should consider system and process changes that have occurred as a result of the service as well as changes in predefined outcomes as quantifiable measures of success. Continuous quality improvement activities are often used to complete the evaluative process and should be conducted by individuals without a substantial stake in the service to improve objectivity.

Establishing a Timeline for Implementation

Timelines include dates by which particular milestones or objectives are expected to be accomplished. Timelines are often established concurrently with the milestones to provide consistency in expectations and improve accountability for the various elements being managed by different individuals. The timeline should establish a priority ranking for aspects of the project that require completion of specific tasks that are required for project or service development.

Many successful implementation plans use Gantt charts to structure a timeline for complex projects. A Gantt chart, developed in the 1910s by Henry Gantt, is a diagram that shows tasks and deadlines necessary for completing a project, and graphically represents how long a project should take, identifies necessary resources, and assists with planning for elements that must be completed in sequence to be positioned among those which can be completed at any time in the process.[66] Although proprietary programs such as Microsoft Project (Microsoft Corp., Redmond, WA) make the development of Gantt charts relatively easy, several free software computer programs are also available for download (Appendix 1).

The timeline may be modified as necessary after an interim analysis of progress to date and as unexpected obstacles are encountered in the process. The findings of the analysis may necessitate minor changes in focus or major redirection of the project to address issues and keep the project moving forward.

Reasonable expectations should also be established to ensure that the success of the new service is not undermined by too aggressive an approach. They should take into account both internal and external factors, which will markedly influence progress and direction of the new service. Periodic assessment should be performed to evaluate progress in meeting established objectives.

Expansion of Services

Clinical services that are well established and successfully managed should continue to grow over time. At some time in the process, consideration may be given to expansion of services, whether to cover additional therapeutic areas, or to meet the needs of a larger number of patients and customers within the same therapeutic area. Ideally, the need for expanded services should be quantified and documented because the simple desire to expand services may be insufficient for expansion. The expanded service must also be consistent with the strategic plan for the health care system.

Plans for Modification of the Business-Practice Model

The initial model developed for the service should include a fair degree of flexibility to address change, whether anticipated or unexpected. Change can appear in a variety of ways, including, but not limited to, customer needs, the regulatory environment, budgetary issues, administrative changes, and leadership changes. To address the potential impact of any of these changes, outcome assessments should be used to measure the relative success of the service and to guide modifications. The possibility of redirection of the service should always remain an option if undesired outcomes or previously unanticipated outcomes occur. The service should solicit input from customers with a vested interest in the service. Efforts should be directed to determining whether or not they are satisfied with the outcomes.

Exit Plan

The successful business model for a new patient care service must always consider the possibility of the need to cease provision of the service at some point in time. This decision may come in the middle of glowing success, overt

failure of the service, or a change in the overall direction of the organization where the service is being provided. The need to exit can be driven by a variety of factors, which are quite similar to those that drive modification of the service. Before an exit strategy is seriously considered, care must be taken to ensure that all initial processes related to the identified need for exit have been adequately tested. Exit strategies should be considered when recommended modifications do not address problems or deficiencies that have been identified or because of the potential effect of impending administrative changes. Although these problems may serve as initial indicators that the service may need to be discontinued, a separate set of clearly defined criteria must be developed as part of the self-assessment process to guide in the decision toward modification of the service or implementation of an exit strategy. Although it is difficult to entirely separate the financial aspects of the service from the personal investment of time and energy, financial viability is probably one of the most critical features of the evaluative process.

The professional staff of the service must also realize that the exit does not equate with failure of the service itself. Facility needs and priorities may simply change over time. In addition, administrative changes can alter priorities despite the apparent success of the service.

Communication is a key component of the exit strategy. Data justifying the proposed need to discontinue the service should be presented to the key administrative figures, key stakeholders, and all others with an implied or direct influence on the service. In addition, the exit plan must include a strategy for caring for the patients who receive their care through the service if the exit strategy ultimately becomes necessary. This strategy may include training for the providers within the facility who will assume the care of these displaced patients, as well as other resources made necessary by the shift in the delivery of patient care.

Section 9: Evaluation of Service Outcomes

The evaluation of service outcomes is an integral part of the overall business plan for clinical pharmacy services in the ambulatory care setting. In the current health care environment, clinical pharmacists need to continue to demonstrate the value of their services to ensure continued growth. In general, it is important to evaluate clinical outcomes, humanistic outcomes, and economic outcomes in an appropriate and organized manner. The timeline for outcomes assessment will depend on the service provided and the disease or problem addressed.

Clinical Outcomes

A number of clinical outcomes can be measured and assessed using generic and disease-specific tools. Examples of such outcomes might include monitoring specific laboratory parameters related to disease or problem (e.g., glycosylated hemoglobin level reduction in patients with diabetes mellitus or low-density lipoprotein cholesterol level reduction in patients with dyslipidemia) or physical assessment parameters (e.g., blood pressure in patients with hypertension). These measures may be compared to baseline, a group not exposed to the service, internal standards (specific health care system standards), and/or external standards (guidelines or benchmarking data). Ideally, data should be compared at specified time points (quality improvement) as well as to both internal and external standards.

In addition, the Institute for Clinical Systems Improvement has developed and validated 51 outcome instruments that can be used to evaluate patient outcomes after interventions by health care providers, including pharmacists.[67] Examples of these patient outcome measurements have been published previously.[2]

Other clinical performance measures for ambulatory care services are available from the AQA Alliance (formerly called the ambulatory care alliance).[68] The AQA Alliance is a joint effort between the American Academy of Family Physicians, the American College of Physicians, America's Health Insurance Plans, and the Agency for Healthcare Research and Quality. The mission of the AQA Alliance is to "improve health care quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring performance at the physician or group level..." Outcome measurements are valuable in assessing an ambulatory care clinical pharmacy service and include disease-related outcomes, as well as many drug-specific outcomes, such as the percentage of patients with persistent asthma who are prescribed inhaled corticosteroids and the percentage of patients with coronary artery disease who are prescribed a lipid-lowering agent. The AQA Alliance also provides

information on how to develop additional outcome measures. These outcome measures may be used to assess a population with a specific disease or as a research method to examine how process changes affect outcomes.[69] For example, in the case of the patient with diabetes, an external standard would be the American Diabetes Association (ADA) standards of care and the ADA–National Committee for Quality Assurance benchmarking data. It is imperative that clinical pharmacists have a working knowledge of the health-related quality of life instruments that are relevant to their services and are able to determine the appropriate methods to assess their interventions.

The Pharmacy Quality Alliance, a new collaborative initiative, has also been established.[70] It recently endorsed pharmacy quality measures, which can be used in a clinical pharmacy practice. Its mission is as follows:

To improve health care quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring performance at the pharmacy and pharmacist-levels; collecting data in the least burdensome way; and reporting meaningful information to consumers, pharmacists, employers, health insurance plans, and other healthcare decision-makers to help make informed choices, improve outcomes and stimulate the development of new payment models.[70]

Additional methods to determine effectiveness of clinical pharmacy interventions include examining whether a particular service resulted in a reduction of clinic visits, emergency department visits, or overall hospitalizations. These patient-oriented outcomes would be preferable to disease-oriented outcomes such as blood pressure reduction in a patient with hypertension or peak flow meter readings in a patient with asthma. Although these outcomes are important, they can be time intensive and costly to measure in the most objective manner.

Humanistic Outcomes

Perhaps the best method of assessing the impact of a service on a specific disease state or problem is health-related quality of life outcome measures,[2] which actually measure the impact of therapy on the disease process. Payers are now using these data in reimbursement policies. The National Quality Measures Clearinghouse (NQMC), sponsored by the Agency for Healthcare Research and Quality and the United States Department of Health and Human Services, is a database and Web site for information on specific evidence-based health care quality measures and measure sets.[71] The mission of NQMC is to provide practitioners, health care providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining detailed information on quality measures and to further their dissemination, implementation, and use in order to inform health care decision makers. Measures are submitted to the NQMC by a variety of national, state and local organizations, including health care systems, accreditation organizations, professional associations, research institutions and licensing boards.

Humanistic outcomes are as important as clinical outcomes and can add additional information to the decision process. It is helpful to determine whether patients are satisfied with their care and/or feel as though their quality of life has improved as a result of the service provided. Patient surveys and questionnaires, involving Likert scales and open-ended questions, can provide this information to the clinical pharmacist and may include both functioning and well-being surveys and satisfaction surveys. Satisfaction surveys, which tend to employ both ratings and objective information, are used primarily to inform or guide administrative decisions. Functioning and well-being surveys are more likely to be used at an individual patient level. More detailed information on measuring patient satisfaction and designing surveys can be found in the literature.[72]

Patient surveys are often institution and/or situation specific but may include statements such as "The pharmacist increased my knowledge of my problem/disease state"; "I am satisfied with the care I received from my pharmacist." Patients are then asked to rate these statements (5 [strongly agree] to 1 [strongly disagree]). To evaluate more thoroughly, it may be helpful to add open-ended questions to the survey as well, such as "What are you most happy/frustrated with?"; "What changes would you like to see?" It is important to note that pharmacists should test any newly created questionnaires before use to determine flaws and make necessary adjustments. These pilot instruments can be completed internally and/or externally in order to validate them. Development and validation of an instrument to measure patient satisfaction with pharmacy

services has been described in the literature.[73, 74] Clinical pharmacists involved in the Asheville Project used these surveys in their own humanistic assessments.[75]

Primary care providers and other health care professionals can also be surveyed after implementation of the service. It can be useful for the clinical pharmacist to be aware of individual provider satisfaction with a particular service, including ease of referral. As a result, clinical pharmacists can better prioritize their involvement and make necessary adjustments to current services.

Economic Outcomes

It has become increasingly necessary to demonstrate economic benefit to the institution or overall health care system. Essentially, there are four types of economic evaluations: cost effectiveness, cost benefit, cost minimization, and cost utility. A detailed review of each of these evaluations is beyond the scope of this paper and has already been described in the literature.[76, 77]

There have been reviews in the pharmacy literature of the economic benefit of clinical pharmacy services in the ambulatory care setting.[9, 78] In general, clinical pharmacists should be able to demonstrate that the overall cost savings to the health care system is greater than the initial and continued cost of the service. Examples of initial costs may include personnel, space, paperwork, laboratory costs, and devices purchased. These costs will obviously vary depending on the setting and individual situation and must be carefully evaluated before implementation. With regard to determining cost savings, it is necessary to look at both direct and indirect costs. Although emphasis is often placed on direct drug costs (e.g., switching from a more expensive to a less expensive drug; discontinuing unnecessary therapies), indirect costs may have long-term impact. For example, recommending a drug to prevent a future illness or health consequence may increase drug costs but may improve overall health outcomes (decreased clinic visits, emergency room visits, hospitalizations) and/or decrease adverse events, which will have economic benefits to the patient and health care system.

Documentation of clinical pharmacy interventions and of the economic value of these services is absolutely vital. Assignment of a specific dollar value to interventions is often difficult but may be achieved by using information already documented in the literature (e.g., a 1% reduction in glycosylated hemoglobin level results in significant cost avoidance of $685–950/year of mean total health care costs for patients with diabetes).[79] Alternatively, this may be achieved through use of software available through a particular health care system. Rxpertise (www.rxpertise.com), Assurance (www.medsmanagement.com), and Outcomes (www.getoutcomes.com) are examples of systems that attempt to assign cost savings for each individual intervention and that are used by various institutions around the country. Other documentation systems are available for community pharmacy, which may have some components of outcome documentation.[80]

Section 10: Financial Considerations for Business-Practice Model Development

A hallmark step in business model development involves the definition of what precisely constitutes a "service." Possibilities include a patient encounter, a consultation (written or otherwise), or perhaps even the dispensing of a prescription.[81] This service should be discrete, measurable, and "deliverable," so as to ensure that it can be billed or at least counted in some fashion.

Essentially two cost estimates are to be considered: direct and indirect costs. An explanation of these costs is summarized in Table 5.

Revenue Generation

Generation of revenue is a cornerstone of any viable service and the establishment of a revenue estimate is critical to business model development.[9, 82] Several factors should be evaluated continually to ensure a revenue stream that allows the business to remain fiscally sound and solvent. The payer mix should be known in order to analyze the source of the revenue. Different reimbursement structures include fee-for-service billing to private insurance, incident-to-billing under Medicare, payment for MTM services under Medicare part D, and (in some states) payment from state Medicaid programs.[38, 39] Other potential reimbursement may come directly from employers or self-paying patients. In some instances, the clinical pharmacist's salary may come from the managed care organization or health care system where the primary financial incentive is to increase cost-effective prescribing and improve health outcomes, rather than generate revenue. Revenue is sometimes also

Table 5. Direct and Indirect Costs to Be Considered

Costs	Examples
Direct costs	
Labor	Salary, fringe benefits, training, annual fees, certification fees, consultants (potential)
Minor equipment	Telephones, pagers
Capital equipment	Office equipment (copiers, chairs, desks, storage space), remodeling of existing space, fax machines, computers, software and online resources, laboratory equipment (e.g., point-of-care testing equipment)
Administrative	Relocation expenses of employees, recruitment, contract negotiations, marketing, compliance (e.g., licenses), malpractice insurance, billing, collections, office manager and staff
Miscellaneous	Travel for employees, continuing education reimbursement, interpreters, supplies and operational expenses (record keeping, photocopying, printing, postage, laboratory, telecommunications)
Indirect costs	
Overhead	
Physical space	Rent or lease

generated from honoraria payments from a college of pharmacy for precepting students during advanced practice experiences. It is important to keep track of payments received for services because billed charges may be substantially more than the amount paid.

One specific situation for special consideration is the case where a pharmacist in an ambulatory clinical practice is funded by a college of pharmacy. If the clinic or organization is not contributing to the pharmacist's salary, revenue generated may be routed back to the college of pharmacy, after administrative fees have been removed. If the college of pharmacy contributes half of the pharmacist's salary, a portion may still be sent back to the college of pharmacy. What happens to this money will be up to the discretion of the college of pharmacy and the clinical faculty member. It is important that a detailed practice plan be written that outlines the procedure.

Some other considerations include the prediction of patient volume or service volume to be delivered, establishment of a price per unit of service delivered, and an estimate of total revenue.[83]

The computation of net revenue is also important. Net revenue is calculated by subtracting the total cost of the operation (direct and indirect) from total revenue. When considering net revenue, it should be pointed out that both fixed costs (e.g., personnel salary, utilities) and variable costs (e.g., professional service fees, certain utilities) have a significant impact on net revenue. Fixed costs cannot be controlled per se, but financial restraint and discount purchasing can minimize variable costs.

Pro Forma Evaluation

Another significant measure in maintaining the viability of a service includes a pro forma evaluation.[84, 85] This evaluation should include a timetable for analysis and how far into the future the service will be considered. Evaluative criteria should include return on investment, the "break-even point," and the time to "break even." In other words, it should be determined whether the service is generating revenue or losing money, and how long it would take to not lose money.

Some other considerations include the potential for volume changes (increases and decreases) and their impact on costs. Fixed expenses should not change with small-to-moderate increases in volume. Variable expenses, however, will potentially change as volume changes. Certain expenses, termed "hybrid expenses," may change in the event of a sudden or dramatic change in volume (e.g., need to hire additional personnel).

Salary, fringe benefits, technology charges, and legal charges are other specific costs of concern.[9] Employees will expect periodic increases in wages, usually annually. Fringe benefits may be offered depending on the success of the services. For example, if net revenue exceeds expectations, all employees could be paid a "dividend" to boost morale and provide incentive for increased productivity. Technology, such as wireless Internet, may increase or decrease costs depending on its impact on productivity.

Cost Avoidance

Cost avoidance is an alternate financial model. This is especially true for a clinical pharmacist employed by a managed care organization or health care system. For example, it may be difficult to determine who financially benefits from decreasing unnecessary drug use as

pharmacy benefits are not always managed by health plans (e.g., pharmacy benefits managers).[81, 86] Health plans may not save money by a decrease in utilization. However, decreases in emergency visits, clinic visits (to physicians), and hospitalizations should decrease overall costs to the health plan. However, few services will actually reduce costs in today's health care environment. Rather, services generally decrease the rate of increase. In other words, costs may go up, but increased utilization of the services may blunt the rate of rise. Clearly, slowing the increase in costs has value, but it requires an estimate of expected inflation, not just "what if this intervention hadn't been made by this service" model to provide credibility.

Vigilance must be maintained by reviewing the operating statements (balances), the general ledger (what is coming in vs going out), and financial performance analysis. This analysis should be done at least quarterly with a semiannual and annual review. Because many pharmacists are not familiar with the financial aspect of service management, a consultant or accountant be necessary.

Conclusion

This document provides the framework necessary for pharmacy practitioners and administrators to develop a business-practice model for clinical pharmacy service development in the ambulatory setting. As ambulatory care practices continue to evolve, there will be increased knowledge of how to initiate and expand the services. This document is intended to serve as a basis to assist in the growth and development of clinical pharmacy services in the ambulatory environment.

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References

1. **American College of Clinical Pharmacy**. Home page. Available from http://www.accp.com. Accessed November 20, 2006.
2. **American College of Clinical Pharmacy**. Task force on ambulatory care clinical pharmacy practice: establishing and evaluating clinical pharmacy services in primary care. Pharmacotherapy 1994;14:743–58.
3. **Carter BL, Helling DK**. Ambulatory care pharmacy services: has the agenda changed? Ann Pharmacother 2000;34:772–87.
4. **Strauss SP**. The small business bible. Hoboken, NJ: John Wiley & Sons, Inc., 2005.
5. **Abrams R**. Six-week start-up: a step-by-step program for starting your business, making money, and achieving your goals! Palo Alto, CA: The Planning Shop, 2004.
6. **Cipolle RJ, Strand LM, Morley PC, eds**. Pharmaceutical care practice: the clinician's guide, 2nd ed. New York: McGraw-Hill, 2004.
7. **Eckel F**. Are we successfully marketing our profession? Top Hosp Pharm Manage 1985;5(1):86–8.
8. **Mintzer R**. Start your own business book. Avon, MA: Adams Media, 2002.
9. **Schumock GT, Butler MG, Meek PD, Vermeulen LC, Arondekar BV, Bauman JL, for the 2002 Task Force on Economic Evaluation of Clinical Pharmacy Services of the American College of Clinical Pharmacy**. Evidence of the economic benefit of clinical pharmacy services: 1996–2000. Pharmacotherapy 2003;23:113–32.
10. **McGlynn EA, Asch SM, Adams J, et al**. The quality of health care delivered to adults in the United States. N Engl J Med 2003:348:2635–45.
11. **Gurwitz JH, Field TS, Harrold LR, et al**. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003;289:1107–16.
12. **Gandhi TK, Weingart SN, Borus J, et al**. Adverse drug events in ambulatory care. N Engl J Med 2003;348:1556–64.
13. **Zhan C, Sangl J, Bierman AS, et al**. Potentially inappropriate medication use in the community-dwelling elderly: findings from the 1996 medical expenditure panel survey. JAMA 2001;286:2823–9.
14. **Hajjar ER, Hanlon JT, Artz MB, et al**. Adverse drug reaction risk factors in older outpatients. Am J Geriatr Pharmacother 2003:1:82–9.
15. **Bates DW, Cullen DJ, Laird N, et al**. Incidence of adverse drug events and potential adverse drug events: implications for prevention. JAMA 1995;274:29–34.
16. **Meredith S, Feldman PH, Frey D, et al**. Possible medication errors in home healthcare patients. J Am Geriatr Soc 2001;49:719–24.
17. **McDonnell PJ, Jacobs MR**. Hospital admissions resulting from preventable adverse drug reactions. Ann Pharmacother 2002;36:1331–6.
18. **Dennehy CE, Kishi DT, Louie C**. Drug-related illness in emergency department patients. Am J Health Syst Pharm 1996;53:1422–6.
19. **Budnitz DS, Pollock DA, Weidenbach KN, et al**. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858–66.
20. **Aspden P, ed**. Institute of Medicine report. Preventing medication errors: quality chasm series. Washington, DC: National Academy Press, 2006.
21. **American Pharmacists Association**. Evidence of the value of pharmacists. Available from www.aphanet.org. Accessed July 27, 2007.
22. **The Lewin Group**. Medication therapy management services: a critical review. J Am Pharm Assoc 2005;45:580–7.
23. **American Pharmacists Association and the National Association of Chain Drug Stores**. Medication therapy management in community pharmacy practiced: core elements of an MTM service, April 29, 2005. Available from http://www.aphanet.org. Accessed July 27, 2007.
24. **American Society of Health-System Pharmacists**. ASHP guidelines for obtaining authorization for documenting pharmaceutical care in patient medical records. Am J Hosp Pharm 1989;46:338–9.
25. **American Society of Health-System Pharmacists**. ASHP guidelines on documenting pharmaceutical care in patient medical records. Am J Health Syst Pharm 2003;60:705–7.
26. **Brock KA, Doucette WR**. Collaborative working relationships between pharmacists and physicians: an exploratory study. J Am Pharm Assoc 2004;44:358–65.
27. **Claxton KL, Wojtal P**. Design and implementation of a credentialing and privileging model for ambulatory care pharmacists. Am J Health Syst Pharm 2006;63:1627–32.
28. **Schumock GT**. How to develop a business plan for clinical pharmacy services: a guide for managers and clinicians. Kansas

City, MO: American College of Clinical Pharmacy, 2001.
29. **American Society of Health-System Pharmacy**. ASHP statement on the pharmacist's role in primary care. Am J Health-Syst Pharm 1999;56:1665–7.
30. **American Society of Health-System Pharmacy**. ASHP guideline: minimum standard for pharmaceutical services in ambulatory care. Am J Health Syst Pharm 1999;56:1744–53.
31. **Hammond RW, Schwartz AH, Campbell MJ, et al**. Collaborative drug therapy management by pharmacists—2003. Pharmacotherapy 2003;23(9):1210–25.
32. **Keely JL, for the American College of Physicians–American Society of Internal Medicine**. Pharmacist scope of practice. Ann Int Med 2002;136:79–85.
33. **American Pharmacists Association**. States with some form of collaborative drug therapy management (CDTM): November 2005. Available from http://www.aphanet.org. Accessed July 27, 2007.
34. **American Society of Health-System Pharmacists**. Status of collaborative drug therapy management in the United States, March 2004. Am J Health Syst Pharm 2004;61:1609–10.
35. **Punekar Y, Lin SW, Thomas J III**. Progress of pharmacist collaborative practice: status of state laws and regulations and perceived impact of collaborative practice. J Am Pharm Assoc 2003;43:503–10.
36. **Knapp KK, Okamoto MP, Black BL**. ASHP survey of ambulatory care pharmacy practice in health systems—2004. Am J Health Syst Pharm 2005;62:274–84.
37. **U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.** Medicare prescription drug, improvement and modernization act of 2003. Available from http://www.cms.hhs.gov. Accessed July 27, 2007.
38. **Minnesota Department of Human Services**. Available from http://www.dhs.state.mn.us/. Accessed July 24, 2007.
39. **North Carolina Department of Human Services**. Available from http://www.dhhs.state.nc.us/dma/Forms/mtmpinstructions.pdf. Accessed July 24, 2007.
40. **Bush J**. The HIPAA privacy rule: three key forms. Fam Pract Manag 2003;10(2):29–33.
41. **US Department of Labor, Occupational Safety and Health Administration**. Bloodborne pathogens and needlestick prevention: OSHA standards. Available from http://www.osha.gov/SLTC/bloodbornepathogens/standards.html. Accessed July 24, 2007.
42. **U.S. Department of Health and Human Services, Centers for Disease Control and Prevention**. Current CLIA regulations. Available from http://www.cdc.gov/clia/regs/toc.aspx. Accessed July 24, 2007.
43. **Council on Credentialing in Pharmacy**. Available from http://www.pharmacycredentialing.org. Accessed July 24, 2007.
44. **Almquist DD**. Liability insurance coverage for nontraditional services. Am J Hosp Pharm 1992;49:2124.
45. **Williams KG**. Liability for expanded responsibilities. Am J Health Syst Pharm 1997;54:1152, 1157.
46. **Baker KR**. Practitioner risks and malpractice concerns. In: How to bill for clinical pharmacy services, 3rd ed. Kansas City, MO: American College of Clinical Pharmacy, 2001.
47. **Darr K**. Risk management and quality improvement: together at last—part 1. Hosp Top 1999;77(1):27–31.
48. **Darr K**. Risk management and quality improvement: together at last—part 2. Hosp Top 1999;77(2):29–35.
49. **Holdford DA**. Marketing for pharmacists. Washington, DC: American Pharmacists Association, 2003.
50. **Stahl DA**. Developing and marketing ambulatory care programs. Nurs Manage 1984;15(5):20–4.
51. **Dedrick SC**. Marketing outpatient pharmacy services. Top Hosp Pharm Manage 1985;5(1):73–7.
52. **Smith JE, Sheaffer SL**. Marketing clinical pharmacy services. Top Hosp Pharm Manage 1985;5(1):53–62.
53. **Chewning B, Schommer JC**. Increasing clients' knowledge of community pharmacists' roles. Pharm Res 1996;13:1299–304.
54. **Bernard M**. Overview of marketing for the pharmacist. Top Hosp Pharm Manage 1985;5(1):1–7.
55. **Levine N**. Physician marketing: a word of caution [editorial]. Dermatology Times 2000;21:5.
56. **Segal R, Smith DP**. Pharmacist's beliefs and values about advertising patient oriented services. J Health Care Marketing 1986;6(1):35–41.
57. **Klegon DA, Slubowski MA**. Marketing ambulatory care centers: assessment, implementation, evaluation. J Amb Care Manage 1985;8:18–27.
58. **Acton Consulting Limited**. Glossary: strategic planning. Available from http://www.consultacton.com/01GetReady/. Accessed July 24, 2007.
59. **Information Technology for Management**. Glossary: milestones. Available from http://www.wiley.com/college/turban/glossary.html. Accessed July 24, 2007.
60. **Dixon J**. Evaluation criteria in studies of continuing education in the health professions: a critical review and a suggested strategy. Eval Health Prof 1978;1:47–65.
61. **Glanz K, Lewis FM, Rimer BK, eds**. Health behavior and health education: theory, research, and practice, 2nd ed. San Francisco, CA: Jossey-Bass, 1996.
62. **Flower J**. The five fundamentals of dealing with change. Available from http://www.well.com/user/bbear/change2.html. Accessed July 24, 2007.
63. **Vaknin S**. What doth a leader make? Available from http://samvak.tripod.com/leader.html. Accessed July 24, 2007.
64. **Von Gunten CF, Ferris FD, Portenoy RK, Glajchen M, eds**. CAPC manual: how to establish a palliative care program. New York, NY: Center to Advance Palliative Care, 2001. Available from http://64.85.16.230/educate/content/development/phase1.html. Accessed July 24, 2007.
65. **Blair MM, Blake EW, Harris IM, eds**. Ambulatory care new practitioner survival guide. Kansas City, MO: American College of Clinical Pharmacy, 2004.
66. **Smartdraw.com**. Microsoft Smartdraw® Gantt chart and timeline center. Available from http://www.smartdraw.com/tutorials/gantt/tutorial1.htm?exp=gan. Accessed July 24, 2007.
67. **Institute for Clinical Systems Improvement**. Available from http://www.icsi.org. Accessed July 24, 2007.
68. **AQA Alliance**. Available from http://www.aqaalliance.org. Accessed July 24, 2007.
69. **Bungay KM, Wagner AK**. Comment: assessing the quality of pharmaceutical care. Ann Pharmacother 1993;27:1542–3.
70. **Pharmacy Quality Alliance**. Home page. Available from http://www.pqaalliance.org. Accessed July 24, 2007.
71. **National Quality Measures Clearinghouse**. Available from http://www.qualitymeasures.ahrq.gov. Accessed July 24, 2007.
72. **Bungay KM**. Methods to assess the humanistic outcomes of clinical pharmacy services. Pharmacotherapy 2000;20(10 pt 2):253S-8.
73. **MacKeigan LD, Larson LN**. Development and validation of an instrument to measure patient satisfaction with pharmacy services. Med Care 1989;27:522–36.
74. **Larson LN, MacKeigan LD**. Further validation of an instrument to measure patient satisfaction with pharmacy services. J Pharm Mark Manage 1994;8:125–39.
75. **Cranor CW, Christensen DB**. The Asheville project: factors associated with outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc 2003;43:160–72.
76. **Willett MS, Bertch KE, Rich DS, Ereshefsky L**. Prospectus on the economic value of clinical pharmacy services. A position statement of the American College of Clinical Pharmacy. Pharmacotherapy 1989;9:45–56.
77. **Schumock GT**. Methods to assess the economic outcomes of clinical pharmacy services. Pharmacotherapy 2000;20(10 pt 2):243S-52.
78. **Schumock GT, Meek PD, Ploetz PA, Vermeulen LC**. Economic evaluations of clinical pharmacy services—1988–1995. Publications committee of he American College of Clinical Pharmacy. Pharmacotherapy 1996;16:1188–208.
79. **Wagner E, Sandhu N, Newton K, et al**. Effect of improved glycemic control on health care costs and utilization. JAMA 2001;285:182–9.
80. **American Pharmacists Association**. MTM documentation systems. Available from http://www.aphanet.org. Accessed July

24, 2007.
81. **Dix A**. Clincal management: change the script. Health Serv 2005;115:26–8.
82. **Snella KA, Sachdev GP**. A primer for developing pharmacist-managed clinics in the outpatient setting. Pharmacotherapy 2003;23:1153–66.
83. **Schlosberg C**. The medicare prescription drug, improvement and modernization act and the impact on care of people with chronic illness: benefit design and implementation issues. Care Manag J 2004;5:113–21.
84. **Kuo GM, Buckley TE, Fitzsimmons DS, Steinbauer JR**. Collaborative drug therapy management services and reimbursement in a family medicine clinic. Am J Health Syst Pharm 2004;61:343–54.
85. **Jameson J, VanNoord G, Vanderwoud K**. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. J Fam Pract 1995;41:469–72.
86. **Strandberg LR**. Pharmacy benefits management and ambulatory pharmacy services. Pharm Pract Manage Q 1996;15:19–26.

Appendix 1. Resources for Development of a Business-Practice Model

Ambulatory care clinics and institutional ambulatory care

ACCP Task Force on Ambulatory Care Clinical Pharmacy Practice. ACCP white paper: establishing and evaluating clinical pharmacy service in primary care. Pharmacotherapy 1994;14(6):743–58.

Blair MM, Blake EW, Harris IM, et al, eds. Ambulatory care new practitioner survival guide. Kansas City, MO: American College of Clinical Pharmacy, 2004.

ASHP guideline: minimum standards for pharmaceutical services in ambulatory care. Am J Health Syst Pharm 1999;56:1744–53.

Ables AZ, Baughman OL. The clinical pharmacist as a preceptor in a family practice residency training program. Fam Med 2002;34:658–62.

Barner JC, Brown CM, Shepherd M, Chou J, Yang M. Provision of pharmacy services in community health centers and migrant health centers. J Am Pharm Assoc 2002;42:713–22.

Bazaldua O, Ables AZ, Dickerson L, et al. Suggested guidelines for pharmacotherapy curricula in family medicine residency training: recommendations from the Society of Teachers of Family Medicine Group on Pharmacotherapy. Fam Med 2005;37(2):99–104.

Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. Am J Hosp Pharm 1994;51:772–7.

Britton ML, Lurvey PL. Impact of medication profile review on prescribing in a general medicine clinic. Am J Hosp Pharm 1991;48:265–70.

Carmichael JM, Alvarez A, Chaput R, DiMaggio J, Magallon H, Mambourg S. Establishment and outcomes of a model primary care pharmacy service system. Am J Health-Syst Pharm 2004;61:472–82.

Chen J, Britten N. "Strong Medicine": An analysis of pharmacist consultations in primary care. Fam Pract 2000;17:480–3.

Dickerson LM, Denham AM, Lynch T. The state of clinical pharmacy practice in family practice residency programs. Fam Med 2002;34:653–7.

Knapp KK, Okamoto MP, Black BL. ASHP survey of ambulatory care pharmacy practice in health systems—2004. Am J Health Syst Pharm 2005;62:274–84.

Kuo GM, Buckley TE, Fitzsimmons DS, et al. Collaborative drug therapy management services and reimbursement in a family medicine clinic. Am J Health-Syst Pharm 2004;61:343–54.

Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. JAMA 2006;296:2563–71.

Taylor CT, Byrd DC, Krueger K. Improving primary care in rural Alabama with a pharmacy initiative. Am J Health-Syst Pharm 2003;60:1123–9.

Yanchick JK. Implementation of a drug therapy monitoring clinic in a primary-care setting. Am J Health Syst Pharm 2000;57(suppl 4):S30–7.

Community practice

Bernsten C, Bjorkman I, Caramona M, et al. Improving the well-being of elderly patients via community pharmacy-based provision of pharmaceutical care: a multicentre study in seven European countries. Drugs Aging 2001;18:63–77.

Carter BL, Chrischilles EA, Scholz, D, Hayase N, Bell N. Extent of services provided by pharmacists in the Iowa Medicaid pharmaceutical case management program. J Am Pharm Assoc 2003;43:24–33.

Chrischilles EA, Carter BL, Lund BC, et al. Evaluation of the Iowa Medicaid pharmaceutical care management program. J Am Pharm Assoc 2004;44:337–49.

Cranor CW, Christensen DB. The Asheville project: factors associated with outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc 2003;43:160–72.

Grainger-Rousseau TJ, Miralles MA, Hepler CD, Segal R, Doty RE, Ben-Joseph R. Therapeutic outcomes monitoring: application of pharmaceutical care to community pharmacy. J Am Pharm Assoc 1997;NS37:647–61.

Harris WE, Rivers PH, Goldstein R. The potential role of community pharmacists in care management. Health Soc Care Community 1998;6:196–203.

Linville C. Wyoming's PharmAssist program is helping residents improve their health and cut medication costs. America's Pharmacist 2004;126:26–9.

Miller LG, Scott DM. Documenting indicators of pharmaceutical care in rural community pharmacies. J Managed Care Pharm 1996;2:659–66.

Rupp MT, DeYoung M, Schondelmeyer SW. Prescribing problems and pharmacist interventions in community practice. Med Care 1992;30:926–40.

Sturgess IK, McElnay JC, Hughes CM, Crealey G. Community pharmacy based provision of pharmaceutical care to older patients. Pharm World Sci 2003;25(5):218–26.

Appendix 1. Resources for Development of a Business-Practice Model (continued)

Description and development of services

American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy practice: core elements of an MTM service (version 1.0). J Am Pharm Assoc 2005;45:573–9.

ASHP guidelines for obtaining authorization for documenting pharmaceutical care in patient medical records. Am J Hosp Pharm 1989;46:338–9.

ASHP guidelines on documenting pharmaceutical care in patient medical records. Am J Health Syst Pharm 2003;60:705–7.

Brock KA, Doucette WR. Collaborative working relationships between pharmacists and physicians: an exploratory study. J Am Pharm Assoc 2004;44:358–65.

Ferro LA, Marcrom RE, Garrelts L, et al. Collaborative practice agreements between pharmacists and physicians. J Am Pharm Assoc 1998;38:655–66.

Hammond RW, Schwartz AH, Campbell MJ, et al, for the American College of Clinical Pharmacy. Collaborative drug therapy management by pharmacists—2003. Pharmacotherapy 2003;23(9):1210–25.

Heitz RM, Van Dinter M. Developing collaborative practice agreements. J Pediatr Health Care 2000;14:200–3.

Pharmacy Access Partnership. Collaborative practice agreements. Available from www.go2ec.org/CollabPracticeAgreements.htm. Accessed July 24, 2007.

Zillich AJ, McDonough RP, Carter BL, Doucette WR. Influential characteristics of physician/pharmacist collaborative relationships. Ann Pharmacother 2004;38:764–70.

Financial impact

Benrimoj SI, Langford JH, Berry G, et al. Economic impact of increased clinical intervention rates in community pharmacy: a randomized trial of the effect of education and a professional allowance. Pharmacoeconomics 2000;18(5):459–68.

Cranor CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc 2003;43:173–84.

Dobie RL, Rascati KL. Documenting the value of pharmacist interventions. Am Pharm 1994;NS34(5):50–4.

Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults: the IMPROVE study. Pharmacotherapy 2000;20(12):1508–16.

Farris KB, Kumbera P, Halterman T, Fang G. Outcomes-based pharmacist reimbursement: reimbursing pharmacists for cognitive services, part 1. J Manag Care Pharm 2002;8(5):383–93.

Galt KA. Cost avoidance, acceptance, and outcomes associated with a pharmacotherapy consult clinic in a Veterans Affairs medical center. Pharmacotherapy 1998;18(5):1103–11.

Hatoum HT, Witte KW, Hutchinson RA. Patient care contributions of clinical pharmacists in four ambulatory care clinics. Hosp Pharm 1992;27:203–6,208–9.

Jameson J, VanNoord G, Vanderwoud K. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. J Fam Pract 1995;41:469–72.

Knapp KK, Katzman H, Hambright JS, Albrant DH. Community pharmacist interventions in a captivated pharmacy benefit contract. Am J Health Syst Pharm 1998;55:1141–5.

The Lewin Group. Medication therapy management services: a critical review. J Am Pharm Assoc 2005;45:580–7.

McMullin ST, Hennenfent JA, Ritchie DJ, et al. A prospective, randomized trial to assess cost impact of pharmacist-initiated interventions. Arch Intern Med 1999;159:2306–9.

Smith DH, Fassett WA, Christensen DB. Washington State CARE project: downstream cost changes associated with the provision of cognitive services by pharmacists. J Am Pharm Assoc 1999;39:650–7.

Snella KA, Trewyn RR, Hansen LB, Bradberry JC. Pharmacist compensation for cognitive services: focus on the physician office and community pharmacy. Pharmacotherapy 2004;24:372–88.

Helpful business-oriented Web sites for starting a new business and identifying customers

www.USChamber.com: Resources from both the national and local chambers for business development

www.TSNN.com: Searchable database of trade shows worldwide

www.SBA.gov/sbdc: Small business development centers offer low-cost help

http://adage/americandemographics: *American Demographics* is a fee-for-service monthly magazine that offers information on consumer trends and analysis

www.hoovers.com: Offers fee-for-service business and industry data, sales, marketing business development, and other information on public and private companies

www.Entrepreneur.com/FormNet: Offers forms to analyze a business

www.fedstats.gov: Main portal for government statistics

www.census.gov: Free demographic information and access to all U.S. census data

http://quickfacts.census.gov/qfd/: Information on the state or county level census

www.census.gov/econ/census02: Economic census, compiled every 5 years; gathers business activity information by industry and subsectors of industry compiled down to a ZIP code

Medicare resources

CMS: www.cms.hhs.gov/

ACCP: www.accp.com/position.php#commentaries

APhA: www.aphanet.org/AM/Template.cfm?Section=APhA_Resources_Medicare

ASHP: www.ashp.org/

Appendix 1. Resources for Development of a Business-Practice Model (continued)

Clinical Laboratories Improvement Act resources
CDC: http://www.cdc.gov/clia/regs/toc.aspx
CMS: www.cms.hhs.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html

Occupational Safety and Health Administration resources
OSHA Bloodborne Pathogens Facts Nos. 1–6: www.osha.gov/OshDoc/data_BloodborneFacts/Health Insurance Portabilty and Accountability Act resources
Department of Health and Human Services: www.hhs.gov/ocr/hipaa
American Academy of Family Physicians: www.aafp.org/hipaa
Sample Forms: www.aafp.org/fpm/20030200/29theh.html
Manual: www.aafp.org/x20716.xml
American Medical Association: www.ama-assn.org/ama/pub/category/4234.html
U.S. Department of Health and Human Services, National Institutes of Health, Privacy Rule: http://privacyruleandresearch.nih.gov/
Bush J. The HIPAA privacy rule: three key forms. *Fam Pract Manag* 2003;10(2):29–33.
Kibbe DC. 10 steps to HIPAA security compliance. *Fam Pract Manag* 2005;12(4):43–9.

Credentialing and privileging for pharmacists resources
Council on Credentialing in Pharmacy: www.pharmacycredentialing.org
Board of Pharmaceutical Specialties: www.bpsweb.org
Commission on Certification in Geriatric Pharmacy: www.ccgp.org

Gantt charts for service implementation timelines: programs available for download
http://associate.com/gantt
http://www.mindtools.com/pages/article/newPPM_03.htm

Appendix 2. Professional Pharmacy Organizations

Organization	Web Site	Purpose and Goals
AACP (American Association of Colleges of Pharmacy)	www.aacp.org	Represents pharmaceutical education
AAPT (American Association of Pharmacy Technicians)	www.pharmacytechnician.com	Provides continuing education and services to pharmacy technicians, represents members' interests to the public and other health care organizations
ACA (American College of Apothecaries)	www.acainfo.org	Research and education resource center that provides pharmacists with information regarding issues affecting the pharmacy profession; ACA also provides a support line, specialty practice education program, and pharmacy-related publications
ACCP (American College of Clinical Pharmacy)	www.accp.com	Supports and promotes clinical pharmacy practice, research, and education
AFPE (American Foundation for Pharmaceutical Education)	www.afpenet.org	Supports pharmacists to further their studies in advanced pharmacy, in industry, association work, academia, and other areas of professional practice
AMCP (Academy of Managed Care Pharmacy)	www.amcp.org	Professional society, dedicated to promoting the development and application of pharmaceutical care and to ensure appropriate health care outcomes for all patient care
APhA (American Pharmacists Association)	www.aphanet.org	Provides professional information and education for pharmacists and advocates improvement of health care through the provision of comprehensive pharmaceutical care
ASAP (American Society for Automation in Pharmacy)	www.asapnet.org	Aids members in applying computer technology into pharmacies; ASAP includes independent pharmacies, hospital pharmacies, colleges of pharmacy, state and national associations, and government agencies
ASCP (American Society of Consultant Pharmacists)	www.ascp.com	Pharmacy association for consultant pharmacists specializing in long-term care; the association provides members with leadership, education and resources for the practice of pharmacy in senior care
ASHP (American Society of Health-System Pharmacists)	www.ashp.org	Represents pharmacists who practice in health maintenance organizations, long-term care facilities, home care, and other community care systems

Appendix 2. Professional Pharmacy Organizations (continued)

Organization	Web Site	Purpose and Goals
ASPEN (American Society for Parenteral and Enteral Nutrition)	www.nutritioncare.org	Involved in the provision of nutritional therapies; prepares standard guidelines for the use of nutrition support and professional practice
ASPL (American Society for Pharmacy Law)	www.aspl.org	Furthers the legal knowledge of pharmacists, students of law, attorneys, government, and other professions interested in issues affecting pharmacy and drugs
BPS (Board of Pharmaceutical Specialties)	www.bpsweb.org	Trains and certifies pharmacists in a specialized field
CCGP (Commission for Certification in Geriatric Pharmacy)	www.ccgp.org	National certification program for pharmacists who want to specialize in geriatric pharmacy practice
CCP (Council of Credentialing in Pharmacy)	www.tcpf.org	Provides leadership, standards, and public information as well as coordinating the profession's voluntary credentialing programs
CPF (Community Pharmacy Foundation)	www.tcpf.org	Assists community pharmacists in achieving targeted therapeutic goals and fostering improvements in patient care
ICPT (Institute for the Advancement of Community Pharmacy)	www.advancepharmacy.org	Supports educational initiatives, research projects, and programs to advance community pharmacy practice in the United States
NCPA (National Community Pharmacists Association)	www.ncpanet.org	Represents pharmacy owners, managers, and employees of independent community pharmacies across the United States
NCPDP (National Council for Prescription Drug Programs)	www.ncpdp.org	Creates and promotes data interchange standards in industry, provides information and resources to education industry, and support its members
NIPCO (National Institute for Pharmacist Care Outcomes)	www.nipco.org	National accrediting organization for pharmacist care education and training, leading to the pharmacist care diplomate credentialNPhA (National
www.npha.net Pharmaceutical Association)	Represents the interests and needs of minorities in all	practice settings
NPTA (National Pharmacy Technician Association)	www.pharmacytechnician.org	An organization for pharmacy technicians