

Independent MTM Pharmacist



Module 11

MEDICATION THERAPY MANAGEMENT SERVICES

Developing a Practice as an Independent MTM Pharmacist



Professional education monograph series for pharmacists from APhA



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Learning Objectives

After reading this monograph, the pharmacist will be able to:

1. Describe the professional role and business model of a pharmacist working as an independent medication therapy management (MTM) pharmacist practitioner.
2. Explain aspects of business planning strategies, including an analysis of a business venture's strengths, weaknesses, opportunities, and threats.
3. Describe federal and state pharmacy laws and regulations and state and local business laws and regulations that should be reviewed when starting a new venture as an independent MTM pharmacist practitioner.
4. Describe potential liability issues pertaining to pharmacists as MTM practitioners and list safeguards to consider prior to business initiation.
5. Access tools and resources available for pharmacist practitioners to build and provide MTM services in an independent practice.

ACPE Activity Type: Application-Based

MTM Presents New Opportunities

The inclusion of medication therapy management (MTM) as a requirement for prescription drug plans in the Medicare Modernization Act of 2003 helped promote the application of pharmacists' clinical expertise to patient care by including payment provisions for pharmacists.

Five years later, a growing number of patients and third-party payers are recognizing the value of pharmacists' knowledge and the education they provide during MTM encounters.¹ Today, many pharmacists provide MTM services using a systematic and consistent core elements model framework (medication therapy review, personal medication record, medication-related action plan, intervention and/or referral, and documentation and follow-up).²

In addition to Medicare prescription drug plans, several Medicaid programs, self-insured employers, and self-paying patients currently compensate pharmacists providing MTM services in a number of settings. These settings include community pharmacies, ambulatory care clinics, long-term care settings, hospitals, and hospices.¹

Pharmacists who have implemented services report many benefits, including increased patient satisfaction, improved patient care, and increased professional satisfaction.¹ However, a number of barriers have prevented more widespread MTM implementation. In a recent survey, 186 pharmacists who were not currently providing MTM services reported that the most important reason for not implementing these services was lack of time.¹

Pharmacists are using a variety of systems and models to implement MTM services. As the practice of pharmacy continues to evolve, some pharmacists are exploring new professional opportunities by providing MTM services as a separate, independently owned practice. There are emerging opportunities for pharmacists with the desire to begin providing MTM services on their own or expand the services that they already provide to other settings.

For those pharmacists interested in being an independent MTM pharmacist practitioner, there may be some uncertainty of how to get services started or what steps they will need to take to support the development of a successful venture. Oftentimes, one of the biggest concerns when starting a new business is "not knowing what you don't know."

If you would like to explore opportunities to provide MTM services outside the structure of a traditional practice setting, this monograph will help you learn strategies for starting your independent practice, identify laws and regulations that you must comply with as an MTM provider, and analyze potential challenges so you can be prepared and develop a well thought out plan before providing MTM services to patients.

This monograph addresses issues that are specific to providing MTM services as an independent practitioner. Additional training programs are available from the American Pharmacists Association (APhA) that offer in-depth discussion of several other issues that pertain to developing and providing MTM services. The APhA MTM Resource Center at www.pharmacist.com/mtm contains a broad range of materials that can assist you as you prepare to start your own practice, including training in MTM service delivery, an MTM Self-Assessment Tool, and detailed guidance on writing business plans and documenting services.

Defining Your MTM Practice

Once you have decided that you want to explore opportunities to develop your own independent MTM practice, you will need to establish the parameters of the business. (The specific opportunities that you are able to pursue may be limited by your state practice act.) Some questions to reflect on when defining your service include:

- What unmet MTM needs exist in your community?
- How much time do you plan to commit to your MTM practice?

What's in a Job Title?

As you begin to develop and market your MTM practice, you will need to select a job title to define yourself. Some MTM providers simply refer to themselves as an "MTM pharmacist" or "MTM provider" and use this title to introduce themselves to patients, prescribers, and other involved parties. Others select a short phrase to describe themselves, such as "clinical pharmacist who performs MTM services." You might choose to use your name and credentials, followed by a tag line such as "providing education to patients and their health care team to optimize medication use," or "providing medication information, assessments, and medication-related risk management."

Some pharmacists have considered calling themselves "MTM consultants," because they are providing MTM in a consultant role. However, the term "consultant" should be used carefully, because it has a specific meaning within pharmacy and is often used synonymously with those practitioners who provide services such as medication regimen reviews (MRRs) within a long-term care facility.

For example, many professional liability insurance policies have not specifically distinguished between MTM services and consultant pharmacy, and may charge higher rates for pharmacists who describe themselves as consultant pharmacists. Furthermore, state pharmacy practice acts may specifically describe activities for consultant pharmacists. Consultant pharmacists are governed by specific laws and regulations.

Other possibilities for a title would be "independent MTM pharmacist," or "independent pharmacist practitioner." However, be cautious when using the term "independent," because many in the pharmacy community regard "independent" as indicative that the pharmacist is the owner of the pharmacy in which he or she operates. Finally, take care if you choose to use the words "stand-alone service" to describe your business. By definition, MTM services should stand alone from the requirements associated with dispensing services, and this terminology will not allow you to differentiate yourself.

Your Turn: What job title will you give yourself?

- Will you choose to provide specialized services such as disease state education in addition to general MTM services?
- Where will you provide services?
- What payment opportunities exist?
- What fee structure and billing methods will you employ?

Writing a mission statement for your practice is a useful strategy for helping you better define your vision and goals for the service. Your mission statement should be two or three sentences that describe who you are, the nature of the services you will provide, and the intended consumers of your services. It may also mention your core values and your desired public image. Having a mission statement can be useful in your marketing activities, because it provides a succinct message about the practice. Furthermore, a mission statement can serve as a guidepost as your business matures to help you assess whether you are progressing toward your professional goals, or whether adjustments to either your business or your goals are necessary.

A SWOT analysis should be performed as part of the process to define your MTM practice. A SWOT analysis is a general tool that can be applied to diverse settings to analyze internal/personal Strengths and Weaknesses and place them in context of external Opportunities and Threats. The SWOT analysis will help you define both your current skills and needs along with the external environment in which you plan to provide the service. An example of a SWOT analysis for

starting an MTM practice is shown at www.pharmacist.com/mtm/swot.

Your Turn: Conduct a SWOT analysis of your strengths and weaknesses along with the opportunities and threats for starting your MTM service.

Carving Out Time

As noted earlier, time constraints have been cited by pharmacists as the most important barrier to MTM service delivery. As you begin thinking through the development of your independent MTM practice, it will be essential to determine how much time you want to devote to providing services and identify areas of your schedule you will cut back to allocate this time to your independent MTM practice.

Many pharmacists starting their own businesses choose to provide MTM services part-time, either with or without reducing hours at their current employer. Developing an independent MTM practice as a supplement to other employment has several benefits, such as allowing you to maintain a source of steady income and benefits (e.g., health insurance) and providing a financial cushion as you determine the long-term financial viability of your service. However, some pharmacists may opt to begin their independent MTM practice as a full-time venture. This model allows pharmacists to devote all their professional efforts to the development of their practice, but is generally advisable only for pharmacists who feel comfortable that they will be able to generate solid, consistent demand for their services, and have cash reserves to sustain themselves financially during slow periods.

It may be difficult to predict the number of patients who will utilize services provided by your practice, and many current independent MTM providers report that patient case levels are inconsistent from month to month. Starting a part-time practice can help as you grow your business and allows more flexibility to adjust to changing market conditions.

If you plan to provide MTM services part-time, you will need to decide whether you will scale back on your current work hours. Consider whether you will provide your services in the evening, on weekends, or during a selected day of the week, and the benefits and drawbacks of each approach. For example, if you provide your services in the evenings, will it allow you to maintain a reasonable balance between your professional life and your personal life? If you provide your services only one day a week, how will you manage issues that require follow-up? Also consider the potential scheduling needs of your patients. If you intend to target your marketing efforts toward patients who are retired, they may prefer daytime appointments, whereas patients who hold 9-to-5 jobs may prefer evening appointments. Finally, as you review your scheduling options, remember that you will

need to allocate time to manage the paperwork and other administrative tasks associated with the business.

After you plan a schedule for providing services in your practice, you may want to start allocating this time to your business development and marketing efforts. This strategy will allow you to devote specific periods of time to growing your business and to determine whether your planned time commitments will be feasible with your other responsibilities.

If you plan to maintain full- or part-time employment while starting your own part-time MTM business, carefully review your contract with your current employer to ensure that it does not prohibit you from such ventures. If it does, it may be possible to renegotiate your terms of employment to allow you to start your own MTM practice without conflict.

Determining the Scope of Services to Provide

The nature of the services you choose to provide is an important factor. Will you solely offer general MTM services following the core elements model described by APhA and the National Association of Chain Drug Stores Foundation, or will you offer additional specialized services in specific disease state areas?² Also, consider the needs of your community. For example, is there a large population of patients with diabetes who might benefit from a service that specializes in managing the medication needs of such patients?

Are potential payers likely to be interested in specific activities or comprehensive services? As you consider this aspect of developing an independent MTM practice, assess your current clinical strengths and weaknesses as well as your career goals. Determine whether you will need additional training to prepare yourself for the roles that you envision in your career goals.

Location, Location, Location

Another critical consideration will be the location for provision of services. Numerous possibilities for locations exist, including setting up a home office, annexing space in a pharmacy, renting space in a physician's office, visiting senior centers, or providing services on-site at employers. Some MTM providers also make house calls. In fact, you can provide MTM just about anywhere that you can meet privately with a patient and bring the necessary equipment and paperwork. (Community centers or public libraries may have private rooms that you can reserve for this purpose.)

You may even be able to provide services in other pharmacies. For example, other pharmacies in your region might be willing to contract with you to provide MTM services on their premises for patients enrolled in their Medicare Part D programs.

Finally, consider whether you will want your practice to be based in one location or to be portable. If your

service is portable, it may increase access for more patients, but may pose more logistical challenges.

Your Turn: Use **WORKSHEET—PART A** on page 7 to help map out your vision of the service.

Distinguishing MTM Services From a Medication Regimen Review Performed by a Consultant Pharmacist

According to the American Society of Consultant Pharmacists, "a consultant pharmacist is a pharmacist who is paid to provide expert advice on the use of medications by individuals or within institutions, or on the provision of pharmacy services to institutions."³ Although this definition is appropriately broad, the responsibilities and scope of practice of a "consultant pharmacist" are further defined by state practice acts and federal regulations.

The traditional role of a consultant pharmacist is to provide a medication regimen review (MRR) for long-term care facility residents, as required by the Centers for Medicare and Medicaid Services.⁴ This review is distinct from one performed during MTM services in several ways. The MRR requires that the drug regimen of each nursing facility patient be reviewed at least monthly by a licensed pharmacist, who then reports any "irregularities," which must then be acted upon.⁵ Such services usually involve chart reviews and may not require direct consultations with patients. Today, the role of consultant pharmacists has expanded, and many provide MRRs in diverse practice settings.³

Patients in long-term care facilities may receive MTM services, and MTM services may be provided by consultant pharmacists. However, in this case, the consultant pharmacist activities must be separate and distinct, and the two processes must be billed separately. (For example, a chart review cannot be billed as an MTM service; consultant pharmacists need to make available separate and distinct services if they want to provide both MRR and MTM.)

Although MTM is similar to MRR, patient education is an essential focus of MTM and the patient generally is more involved in implementing the action plan.

Developing a Business Model

Now that you have defined a vision for your independent MTM practice, you will need to begin filling in the details of your plan to make your vision a reality. One of the most crucial steps to developing any professional practice is to establish a financially viable business plan. To do so, you will need to determine your costs and track projections for providing the service so you can establish fees that will make your service sustainable.

Costs for Providing MTM Services

A fundamental step in establishing a business model is determining how much money you will need to bring in to cover your expenses and make a fair profit. Start by reviewing all the costs associated with initiating and providing your services, including:

- Computer hardware and software, including a documentation and billing system and information technology support

- Rent or mortgage for office space and storage
- Utilities (phone, fax, Internet, electricity, water, sewer, other)
- Remodeling (e.g., for a home office)
- Legal fees
- Accountant fees
- Office supplies and equipment, including a filing system for patient records
- Postage
- Patient supplies (i.e., testing equipment)
- Marketing costs
- Additional liability insurance
- Mileage (where applicable)
- Support staff (e.g., billing assistant)

See **TOOLS AND RESOURCES** for links to worksheets to help you assess the costs of starting and running your service and additional guidance on business planning and related issues.

Finances for Starting Your Business

Even if you intend to maintain regular employment as a source of income while beginning your independent MTM practice, you may require a loan to manage start-up costs. These costs include lawyer fees, setting up a home office, documentation and billing systems, marketing, and the mileage for driving to potential clients.

Estimate the costs associated with starting your practice, and determine whether you will need a loan to cover these costs. If you plan to take a loan, you will likely need to write a business plan, which will detail the expected costs of service and revenue projections. Several resources are available to assist you with this process, including those made available through APhA and the U.S. Small Business Administration (see **TOOLS AND RESOURCES**).

Many business owners recommend the development of an informal business plan even if it is not required to secure a loan. Reviewing business model worksheets that are available in a range of resources, including those in the **TOOLS AND RESOURCES** section, can help you think through and plan for the various factors that will affect the financial success of your independent MTM practice.

Establishing Fees

An important part of planning for your business will be estimating the amount of compensation you will receive for your services. Compensation may come through contracts with third-party payers (e.g., Medicare Part D plans, self-insured employers, other commercial insurance, Medicaid [in select states]) and from out-of-pocket payments from patients. It is essential to determine the level of compensation necessary for your services to generate a fair profit before you begin contracting with payers.

Consider the number of patients you would need to treat to “break even” (i.e., cover your start-up and over-

head costs before producing any net income). For example, if your overhead costs were \$500 per month, you would need to see five patients per month at \$100 each to cover those costs (not accounting for the taxes you would pay on the income). And, if you take out a \$10,000 loan to start your business, you would have to make payments of roughly \$200 for 5 years to pay off that loan (loan rates and terms may vary), requiring another two patients per month to cover costs.

Treating more patients will help you amortize (i.e., spread out) your start-up and overhead costs. Therefore, if you provide services to only a few patients each month, it may be difficult to be profitable.

After estimating the overhead expenses to provide your service, and adding this to an hourly rate for your income, you will be better able to determine a fair hourly rate for your services. Be sure to account for the taxes you must pay on your income and the administrative time spent on the provision of services outside the actual encounter when determining a profitable fee.

Have this rate in mind when you enter into contract negotiations with third-party payers. (It will be helpful if you have data showing that the payers’ expected cost savings will exceed the amount of money you ask them to invest in your services.) Also consider that you will only be able to charge fees that the market will bear. If your costs are too high, you may need to investigate more efficient means for delivering services. On the other hand, if you contract with Medicare and/or Medicaid, you are prohibited from charging others a lower rate. The Lewin Group report, commissioned by APhA, provides additional guidance for establishing pharmacists’ fees for MTM services.⁶

Finally, many pharmacists want to expand their patient care services to reap intangible benefits, such as increased professional satisfaction derived from addressing patient needs and the ability to develop more meaningful relationships with patients. In fact, in a recent national survey of pharmacists providing MTM services, patient needs were listed as the most important reason for implementing services.¹ These are real benefits associated with MTM, and pharmacists should be commended for seeking them. Nevertheless, it is essential to ensure that your revenues will exceed your expenses and provide a viable income, or you will not be able to attain these benefits for long.

Contracting to Provide Services

Once you have determined a rate for your services that will allow your practice to be financially viable, you will need to identify payers and establish contracts. Consider all potential opportunities to be compensated for providing services in your community. Are many individuals in your community covered through Medicare Part D or a state Medicaid program that provides MTM services? Are there employers open to exploring the benefits MTM provides? Do the residents of your community

have the resources to pay out of pocket for services? (Keep in mind that potential patients and others are likely to need education about the benefits of MTM before they are willing to pay for services.)

Some payers, such as Medicare Part D plans and Medicaid, offer a standard contract. Payment rates offered through such programs vary widely and are generally not negotiable. Some are based on the amount of time spent with the patient, while others offer a flat fee per encounter. You may need to start providing MTM services to get a good sense of the amount of time required to assess the profitability of a fee-per-encounter payment system. Keep in mind that service delivery is likely to become more efficient as you gain experience. However, do not be afraid to turn down contracts that will not allow you to generate a fair profit.

Contracting with small to midsized employers generally allows more room for negotiation. Be prepared to offer your own draft contract for services that can be adapted to meet company needs. Know beforehand which aspects of your contract you are willing to negotiate. For example, will you charge based on the amount of time spent with patients, by the visit, or by the number of patients with a certain disease state who enroll in the program? When will payment for services be received? What types of documentation must accompany the invoice? The contract should also specify how patients will be identified for the program. It may also be wise to ask the company to provide credit references and call those references to assess the company's payment history.

Carefully review all contracts to familiarize yourself with the terms of the agreement. For example, some contracts include language describing the types of insurance coverage you must carry. Clauses about indemnification, which specify legal responsibilities, are common and should be fully understood, or clarified as needed. Ensure you know both your rights and responsibilities under any contract, and have it reviewed by a lawyer, before signing anything.

Financial arrangements are generally more straightforward for patients who pay out of pocket for services. However, determine ahead of time whether you are willing to allow patients to pay for services in installments, and if so, how you will manage accounts that become past due. You may choose to accept credit cards, which can help reduce the need to establish payment plans and lower the risk of incurring bad debt. If you choose this option, be sure to include credit card fees when calculating your overhead.

Implementation Strategies

After defining the vision for your independent MTM practice and figuring out the financial aspects, it will be time to develop the infrastructure for providing your services. This will include procuring and/or developing a

documentation system to manage the service, and generating sources of patient referrals. A number of materials available from APhA at www.pharmacist.com give detailed guidance on the elements of establishing such an infrastructure. Here, we will focus on some of the specific issues facing the development of an independently run MTM practice.

Documentation and Materials

Regardless of the size and nature of your practice, you will need a comprehensive documentation system. Documentation is essential for developing a record of services provided, tracking outcomes, and performing quality assurance activities. (For a review of documentation for MTM, see APhA's continuing education program *Documenting Pharmacy-Based Patient Care Services*.)

Options are available for using either a paper-based or electronic documentation system. Paper-based systems have the advantage of requiring less up-front expenditures, but tend to be less efficient in the long run. Electronic systems tend to have greater up-front costs but may be more cost effective over time. They may allow for more efficient management of patient records and many furnish additional functions such as outcomes tracking, features for communicating with other health care providers, integration with billing and other accounting functions, and Health Insurance Portability and Accountability Act (HIPAA) compliance support, thereby reducing the amount of administrative time necessary.

If you plan to provide services in multiple locations, you need to determine which materials will be available in each location and those that must be transported. Web-based documentation systems may be of particular benefit for pharmacists caring for patients at multiple locations.

Collecting clinical and economic outcome data as part of your documentation process can help you market your services to current and potential patients as well as payers. (Some payers may request that you track specific outcomes.) Regardless of the outcomes tracked, it is essential to identify them early in the process so all necessary data are collected during service delivery.

You must ensure that your entire system is HIPAA compliant, and may want to seek legal counsel to guide the development of HIPAA policies and procedures and supporting paperwork, such as consent forms for patients to sign and business associate agreements that will govern your relationships with other entities. Furthermore, if you plan to work out of your home, your record-keeping system and backup storage also need to comply with HIPAA, including its security requirements.

In the event that you decide to discontinue the service or close your business, you still must maintain records for several years in case you are ever audited. For example, federal law requires that records be maintained for 10 years after a claim is submitted to Medicare Part D plans. Check with your state board of pharmacy and/or

lawyer to determine if your state has more stringent requirements.

You will need to maintain your own accounting system that will, among other things, manage billing and maintain records for taxes and potential future audits. If your pharmacy documentation software does not support these features, off-the-shelf software programs designed for self-employed individuals are available to manage many aspects of the financial records of your service (e.g., Quicken, Quickbooks) and associated taxes (e.g., TurboTax, TaxCut). Keep in mind that as an independent contractor your income is not subject to withholding. You will need to make quarterly estimated tax payments on income from your MTM practice—and make sure that you set aside an appropriate amount each month for taxes. (There may be a few exceptions in individual circumstances.)

Marketing Your MTM Practice

A targeted survey of third-party MTM payers reported that lack of patient awareness of the benefits of MTM services is the single most important barrier to expansion of MTM service provision.¹ Additional research shows that as patients gain exposure to MTM services, they are more likely to recognize the value of MTM, have a favorable opinion of the services, and desire the services for themselves.^{1,7,8} Therefore, marketing efforts to support your MTM practice should address patients as well as employer groups, health care providers, and payers.

If you maintain other employment while developing and running your MTM practice, determine which, if any, marketing activities are permissible while performing your job functions. Check with your supervisor in advance to clarify the pharmacy's policy and ensure that you obtain a written confirmation of any allowed mention of your MTM practice. It may also be prudent to have your lawyer review any information you plan to provide while at another employer to ensure that you do not run afoul of antitrust and anti-kickback laws.

As you develop your marketing materials, keep in mind that an essential aspect of a strong marketing campaign is disseminating a clear message. Identify and emphasize the key features of your MTM practice that are most likely to appeal to your market (e.g., reduce emergency room visits, reduce medication costs, improve patient care, bolster patient empowerment) and ensure that the message is clear and consistent throughout your marketing materials. Finally, be persistent—MTM services remain a new concept for many, and you may need to continually reinforce your message to garner support and referrals.

MARKETING TO PATIENTS AND PHYSICIANS

Many different strategies can be used for marketing MTM services to patients and physicians. For example,

are there physicians in your community who will likely refer patients to your service? Will you promote yourself at health fairs or local community meetings? Such strategies may help you identify patients who will pay out of pocket for MTM services, or might have third-party coverage.

As you strive to grow a referral base, think about offering “meet the pharmacist” nights at local senior centers and other community groups or other free public relations activities that may help increase awareness of the value of MTM and provide a source of referrals. Setting up an informational booth at shopping malls, community fairs, and other areas with heavy foot traffic also may be beneficial.

Word-of-mouth communication can be an important source of patient referrals. However, make sure that any activities you use to encourage referrals do not violate the antikickback statute, which makes it illegal to solicit or receive remuneration for the referral of a patient who receives benefits through a government health care program, such as Medicare or Medicaid. (For example, you cannot have a referral contest in which you give a prize to the person who generates the most referrals.) You will need to be particularly sensitive to this risk if you sometimes practice within a physician's office.

Another option is to identify patients through Medicare Part D and Medicaid programs. Some national plans help to identify Medicare Part D patients for MTM services, however many have specific requirements that may be difficult for individual MTM service providers to meet. State programs that identify patients who are eligible through Medicaid vary. One option for providing services to patients eligible for MTM through Medicare is to contract with other pharmacies in your area that are not yet providing these services. Such pharmacies may not have the human resources available to meet all of their MTM needs but may be willing to contract with outside pharmacists to handle their MTM cases.

SMALL TO MIDSIZED EMPLOYERS

Marketing to local employers has been used as a successful business strategy by many pharmacists who provide MTM services. Consider the small to midsized employers in your community, and seek out those who make a commitment to health and wellness. Identify the key decision makers at the company (e.g., human resource manager, health plan coordinator). Go to regional meetings of small businesses and use the forum as an opportunity to network. Attend meetings of groups of business leaders, such as Rotary clubs, and the local chamber of commerce. Such networks may contribute contacts with small business owners who might be interested in contracting with you to provide your services to their employees.

When you market to employers, emphasize that MTM services not only improve clinical outcomes, but can also reduce absenteeism and lead to a more produc-

tive workforce with improved morale. (MTM services have been shown to reduce both direct health care costs and the number of sick days per year for employees enrolled in the programs.⁹⁻¹¹)

Your Turn: Use **WORKSHEET—PART B** to help guide your marketing plan.

Laws and Regulations

As a practicing pharmacist, you are already familiar with many of the laws and regulations that affect the practice of pharmacy. However, before beginning an MTM business venture you need to make certain that all aspects of your MTM practice and business comply with federal, state, and local laws and regulations. It is generally wise to have a lawyer review your business to ensure that you are complying with such laws and regulations.

You should also review your state practice act to be sure that all aspects of the service you plan to provide are permissible. It may be most practical to first consult with your state pharmacy association's government affairs group to gain insight on the board's current interpretation of various aspects of the act. (Some state pharmacy boards have chosen to remain silent on this issue.) Consider contacting your board of pharmacy to inquire whether your planned MTM activities are within the practice act and requesting a response in writing.

The legal status of your practice is another important factor to consider. You may want to incorporate your service, establish a limited liability company, or act as a sole proprietor. Some of these options allow you to separate your personal assets from your business' assets in the event that your business is ever sued or declares bankruptcy. Many online resources provide guidance regarding the pros and cons of each of these options; you may also choose to ask a lawyer and/or certified public accountant for guidance. Most likely, you will need to apply for a federal Employer Identification Number for tax purposes.

You will need to comply with the relevant laws and regulations associated with being an employer if you decide to have any employees, such as an office assistant to help manage paperwork and billing. (Many Internet resources offer guidance in this area.) Again, it may be judicious to have a lawyer oversee any employment opportunities that you offer.

Pharmacists who plan to perform point-of-care testing must comply with standards established by the Occupational Safety and Health Administration, and must register if planning to perform Clinical Laboratory Improvement Amendments (CLIA)-waived tests.⁹

Finally, some third-party payers, particularly those funded through government health programs, may require you to participate in training to address various issues, such as HIPAA, waste, fraud, abuse prevention efforts, and/or their billing and documentation requirements, as a condition of their contract. You should

familiarize yourself with these laws and regulations as well as federal antitrust and anti-kickback statutes.

Managing Liability

It is essential that pharmacists consult with a pharmacy liability insurance company before starting a new practice, and purchase additional coverage as necessary. General professional liability insurance may not cover MTM services, and insurance companies may not currently have a standard policy designed to cover the specific services that you intend to provide.

As MTM service provision becomes more recognized and established, insurance companies may develop standard MTM policies to offer to pharmacists. Until policies become more standardized, it may be wise to have a lawyer review your liability coverage to ensure that all the activities you plan to perform are covered. If necessary, you can also work with a lawyer to assist you in drafting language for a new policy to propose to an insurance liability company. (Colleagues or your state pharmacy association may be able to provide suggestions or recommendations for identifying a lawyer with expertise in this area.) Although this requires an added step, it will protect you against learning that you are not insured for the activities you are performing after a claim has already been filed.

If you have liability coverage through an employer and plan to provide outside services, you will require separate liability coverage for providing those services. In addition, if you plan to provide services in an office space you rent or own, you may want to have general liability insurance to cover claims relating to the property, such as slip and fall claims.

Your Turn: Does your current professional liability insurance cover the provision of MTM services? If you're not certain, be sure to contact your insurance company, and have a lawyer review your policy independently.

In addition to ensuring that you are practicing within your capabilities and state practice act, attention to communication skills may reduce liability risk. Claims data show that health care providers with good patient assessment and communication skills are less likely to be sued.¹⁰

Good communication skills help prevent misunderstandings and can foster better relationships with patients, making them less likely to sue in the event of an adverse outcome. Warmly greeting the patient, asking open-ended questions, listening attentively to the patient, and treating the patient the same way you would want your parents to be treated by their health care team are general guidelines that can help.¹⁰ Effective communication and collaboration with prescribers is not only beneficial for patient care, but may be mutually protective in liability management.

Other liability pitfalls may surround patient assessment. Although the pharmacist's role in patient

Part A: Defining the Practice

1. How much time do you plan to dedicate to developing your MTM practice and providing MTM services?

2. How will you make room in your current schedule for this time commitment?

3. What services do you plan to provide? Do you intend to start with some of these services and then expand?

4. Where do you plan to provide services?

5. Which groups or entities do you anticipate will be the payers for your MTM service?

6. What are your plans for developing a documentation system?

Part B: Developing Your Marketing Plan

1. List three prescribers in your community who are prospective sources of patient referrals, and describe a plan to market your MTM service to them.

2. List three small businesses or business leader organizations in your region that might be interested in MTM services for their employees, and describe a plan to contact them.

3. List three community groups or locations (e.g., senior center, health fairs) where you could market your services, and describe a plan to provide a presentation to the group.

Tools and Resources

MTM business development is an emerging field with new resources steadily being made available. The following is a sampling of publicly available materials that you may find useful.

MTM and Pharmacy Resources

Internet Resources

American Pharmacists Association
MTM Resource Center
<http://www.pharmacist.com/mtm>

State Association and Pharmacy Board Links
<http://www.pharmacist.com>; select "Government Affairs," then "State Resources"

Department of Health and Human Services
HIPAA Web site
<http://www.hhs.gov/ocr/hipaa/>

Healthcare Providers Service Organization
Risk Management Articles
<http://www.hpso.com/resources/articles-index.jsf>

National Association of Boards of Pharmacy
<http://www.nabp.net>

MTM Business Planning Spreadsheets

The following links allow you to download functional MS Excel worksheets to assess various business scenarios. These worksheets may be modified and incorporated into business plans as needed.

Start-Up Costs
<https://www.pillhelpworks.com/share/MTMStartCosts.xls>

MTM Case Load Projections
<https://www.pillhelpworks.com/share/MTMCaseProj.xls>

Revenue Projections
<https://www.pillhelpworks.com/share/MTMProjShort.xls>

Recommended Reading

American College of Clinical Pharmacy; Harris IM, Baker E, Berry TM, et al. Developing a business-practice model for pharmacy services in ambulatory settings. *Pharmacotherapy*. 2008;28:285.

Berger BA. *Communication Skills for Pharmacists*. 3rd ed. Washington, DC: American Pharmacists Association; 2009.

Hagel HP, Rovers JP, eds. *Managing the Patient-Centered Pharmacy*. Washington, DC: American Pharmacists Association; 2002. Includes guidance for performing a SWOT analysis.

Hogue MD, Bluml B, eds. *The Pharmacist's Guide to Compensation for MTM Services*. Washington, DC: American Pharmacists Association; 2008.

Holdford DA. *Marketing for Pharmacists*. 2nd ed. Washington, DC: American Pharmacists Association; 2007.

Millonig M. *101 MTM Tips for the Pharmacist*. Washington, DC: American Pharmacists Association; 2008.

Schumock GT, Stubbings J. *How to Develop a Business Plan for Pharmacy Services*. Lenexa, KS: American College of Clinical Pharmacy; 2007.

Small Business Resources

Internal Revenue Service

Limited Liability Company Web page

<http://www.irs.gov/businesses/small/article/0,,id=98277,00.html>

SCORE—Counselors to America's Small Business

Provides educational resources on developing small businesses and a network of entrepreneurs who offer free mentoring.

<http://www.score.org/index.html>

U.S. Small Business Administration

<http://www.sba.gov>

Includes "How to Write a Business Plan."

http://www.sba.gov/idc/groups/public/documents/sba_homepage/pub_mp32.pdf

assessment is more limited than that of health care professionals who diagnose patients, it is important to ensure that your patient assessment skills are appropriate for the patient population(s) you will be treating and the services you provide.

Finally, maintaining thorough professional documentation will be essential should you ever face a lawsuit, audit, or similar investigation.

Your Turn: How would you rate your communication skills? If you think they may be a bit rusty, it might be a good time to participate in some training courses. Good communication skills are useful when working with patients and can help you foster business and professional relationships.

Summary

There are many opportunities for pharmacists who want to provide MTM services, and these opportunities continue to expand. Pharmacists should carefully assess their options for providing MTM services as an independent venture and research the many aspects of developing their business with a solid plan for professional success.

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4. American Society of Consultant Pharmacists. Guidelines for medication therapy management services in long-term care facilities. March 2007. Available at: <http://www.ascp.com/resources/policy/upload/ASCP-MTMGuidelines-3-3-07.pdf>. Accessed September 3, 2008.
5. Centers for Medicare and Medicaid Services. State Operations Manual. Appendix PP – Guidance to Surveyors for Long Term Care Facilities. Revised August 1, 2008. Available at: http://cms.hhs.gov/manuals/Downloads/som107op_pp_guidelines_tcf.pdf. Accessed September 3, 2008.
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7. Truong HA, Layson-Wolf C, Rodriguez de Bittner M, et al. Perceptions of patients on medication therapy management (MTM) services pertaining to Medicare Part D. Presented at: American Pharmacists Association Annual Meeting; March 19, 2006; San Francisco, CA.
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9. American College of Clinical Pharmacy; Harris IM, Baker E, Berry TM, et al. Developing a business-practice model for pharmacy services in ambulatory settings. *Pharmacotherapy*. 2008;28:285.
10. Healthcare Providers Service Organization. *HPSO Risk Advisor*. Pharmacist edition. 2007. Available at: http://www.hpso.com/pdfs/newsletters/2007/HPSO07_Pharm.pdf. Accessed September 3, 2008.

CE Assessment Questions

Instructions: For each question, circle the letter corresponding to the correct answer on the CE Examination Form. **Please review all of your answers to be sure you have marked the proper letter.** There is only one correct answer to each question.

1. The leading reason cited by pharmacists in a recent survey for not implementing MTM services is:

- a. Patients do not really need the service.
- b. Inadequate time.
- c. Physician resistance.
- d. Dispensing activities are more professionally rewarding.

2. The term "consultant pharmacist" is most likely to be used to describe a pharmacist who:

- a. Performs MRRs in long-term care facilities.
- b. Provides MTM services.
- c. Has halted clinical activities to pursue writing and speaking engagements.
- d. Provides information and recommendations to prescribers.

3. In business planning, the term "SWOT" stands for:

- a. Sustainable, whole, organic, and timeless.
- b. Supervision, work performance, organization, and time management.
- c. Strengths, weaknesses, opportunities, and threats.
- d. Selling, wholesale, openings, and transactions.

4. One benefit to maintaining employment while starting an MTM side venture is that:

- a. It will allow greater schedule flexibility.
- b. Your professional insurance through your employer will cover your MTM service.
- c. You can store all the patient records from your MTM service at your employer's facility.
- d. It ensures a continuous income and associated benefits.

5. Which of the following statements is true?

- a. If you provide MTM services in a home office, your patient records are not subject to HIPAA regulations.
- b. You may be able to contract with other pharmacies to provide MTM services in their facility.
- c. Liability insurance companies have standard contracts for MTM service providers.
- d. If you maintain part-time employment, you do not need to pay income taxes on your MTM service.

6. A primary distinction between MTM services and an MRR is that:

- a. Patient education is an essential component of MTM services but not MRRs.
- b. Adverse events are not addressed during MTM services.
- c. Patients in long-term care facilities are only allowed to receive an MRR.
- d. Patients who have Medicare receive MTM services, while patients who have Medicaid receive MRRs.

7. Which of the following statements is true?

- a. Contracts for providing MTM services through state Medicaid programs are generally open to negotiation.
- b. Pharmacists should ask all self-paying patients to purchase annual packages of services.
- c. Pharmacists may provide a draft contract for the terms of MTM service provision to small employers.
- d. Health care providers are prohibited from accepting credit card payments for services.

8. Third-party payers report that an important barrier to expansion of MTM services is:

- a. Lack of data showing the value of the MTM services.
- b. Lack of patient awareness of the benefits of MTM.
- c. Pharmacists are not interested in providing MTM.
- d. Resistance to implementation of MTM services by prescribers.

9. A good strategy for marketing MTM services directly to patients is:

- a. Conducting a referral contest with prizes for patients who generate the most referrals.
- b. Copying the patient records from your current employer to use for a direct mail campaign.

- c. Having an educational booth at health fairs and senior centers.
- d. Providing a \$10 gift card to anyone who refers a patient.

10. Which of the following might be a good choice for connecting with small businesses that are interested in MTM services?

- a. State pharmacy association meetings.
- b. Chamber of commerce activities.
- c. Setting up a booth at shopping malls.
- d. Holistic health fairs.

11. State boards of pharmacy have the authority to:

- a. Determine whether MTM services are included in state practice acts.
- b. Grant waivers to HIPAA requirements.
- c. Provide liability insurance.
- d. Dictate contract terms for providers of MTM services.

12. If a patient slips and falls while visiting an office (not in your home) where you provide MTM services, any liability claims would typically be addressed by which type of insurance?

- a. Professional liability insurance.
- b. Homeowners insurance.
- c. General liability insurance.
- d. The patient would be covered by his or her health insurance and would not have standing (i.e., be allowed) to sue you.

13. A recommended strategy for reducing the risk of lawsuits is to:

- a. Require all patients to sign a waiver absolving you of any responsibility for malpractice.
- b. Make a commitment to developing and maintaining good communication skills.
- c. Require background checks on all patients to determine whether they have a history of liability claims.
- d. Tape-record all patient encounters.

14. Amortizing start-up costs for a business means to:

- a. Refinance a mortgage to use home equity for funding business development.
- b. Default on payment.
- c. Spread out payments on a loan.
- d. Add a clause to your life insurance to pay off start-up costs.

15. A contract with a small business should include which of the following issues?

- a. A guarantee of clinical outcomes.
- b. A statement establishing whether fees will be charged based on time spent with the patient or a flat fee per encounter.
- c. The SWOT analysis for the MTM service.
- d. A description of actions that will be performed if "irregularities" are discovered in patients' medication regimens.

CE Credit

To obtain 1.5 hours of continuing education credit (0.15 CEUs) for "Medication Therapy Management Services: Developing a Practice as an Independent MTM Pharmacist," complete the assessment exercise, fill out the CE Examination Form at the end of this publication, and return that page to APhA. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before December 1, 2011, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is 202-000-08-235-H03-P.

"Medication Therapy Management Services: Developing a Practice as an Independent MTM Pharmacist" is a home-study continuing education program for pharmacists developed by the American Pharmacists Association.



American Pharmacists Association
Improving medication use. Advancing patient care.

CE EXAMINATION FORM

Medication Therapy Management Services: Developing a Practice as an Independent MTM Pharmacist

To receive **1.5** contact hours of continuing education credit (**0.15 CEUs**), please provide the following information:

1. Type or print your name and address in the spaces provided.
2. Mail this completed form for scoring to:
American Pharmacists Association—CE Exam
P.O. Box 791082
Baltimore, MD 21279-1082
3. CE processing is free for APhA members. If you are not an APhA member, please enclose a \$15 handling fee for grading the assessment instrument and issuing a Statement of Credit.

A Statement of Credit will be awarded for a passing grade of 70% or better. If you fail the exam, you may retake the exam once. If you do not pass the second time, you may no longer participate in this continuing pharmacy education program. Please allow 6 weeks for processing. Pharmacists who complete this exercise successfully before **December 1, 2011**, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is: **202-000-08-235-H03-P**.

PARTICIPANT INFORMATION

NAME _____

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CITY _____ STATE _____ ZIP _____

E-MAIL _____

WORK PHONE _____

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How long did it take you to read the continuing education program and complete this test? _____ Hours _____ Minutes

My signature certifies that I have independently taken this CE Examination:



Florida pharmacists: If you need your CE participation recorded in the State of Florida's CE Broker tracking system, please provide your Florida license number: _____

CE ASSESSMENT QUESTIONS—ANSWERS

Please circle your answers (one answer per question).

- | | | | |
|------------|------------|-------------|-------------|
| 1. a b c d | 5. a b c d | 9. a b c d | 13. a b c d |
| 2. a b c d | 6. a b c d | 10. a b c d | 14. a b c d |
| 3. a b c d | 7. a b c d | 11. a b c d | 15. a b c d |
| 4. a b c d | 8. a b c d | 12. a b c d | |

PROGRAM EVALUATION

PLEASE ANSWER EACH QUESTION.

	EXCELLENT			POOR	
1. Overall quality of the program	5	4	3	2	1
2. The program was relevant to pharmacy practice	5	4	3	2	1
3. Value of the content	5	4	3	2	1

PLEASE ANSWER EACH QUESTION MARKING WHETHER YOU AGREE OR DISAGREE.

	Agree	Disagree
4. The program met the stated learning objectives:		
• Describe the professional role and business model of a pharmacist working as an independent medication therapy management (MTM) pharmacist practitioner.	<input type="checkbox"/>	<input type="checkbox"/>
• Explain aspects of business planning strategies, including an analysis of a business venture's strengths, weaknesses, opportunities, and threats.	<input type="checkbox"/>	<input type="checkbox"/>
• Describe federal and state pharmacy laws and regulations and state and local business laws and regulations that should be reviewed when starting a new venture as an independent MTM pharmacist practitioner.	<input type="checkbox"/>	<input type="checkbox"/>
• Describe potential liability issues pertaining to pharmacists as MTM practitioners and list safeguards to consider prior to business initiation.	<input type="checkbox"/>	<input type="checkbox"/>
• Access tools and resources available for pharmacist practitioners to build and provide MTM services in an independent practice.	<input type="checkbox"/>	<input type="checkbox"/>
5. The program increased my knowledge in the subject area.	<input type="checkbox"/>	<input type="checkbox"/>
6. The program did not promote a particular product or company.	<input type="checkbox"/>	<input type="checkbox"/>

Impact of the Activity

The information presented (check all that apply):

7. Reinforced my current practice/treatment habits Will improve my practice/patient outcomes Provided new ideas or information I expect to use
 Enhances my current knowledge base
8. Will the information presented cause you to make any changes in your practice? Yes No
9. How committed are you to making these changes? (Very committed) 5 4 3 2 1 (Not at all committed)
10. Do you feel future activities on this subject matter are necessary and/or important to your practice? Yes No

Follow Up

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

- Yes, I am interested in participating in a follow-up survey. No, I am not interested in participating in a follow-up survey.

You also can go to <http://www.pharmacist.com> and take your test online for instant credit.