Abstract

Objectives: To review recent changes to federal and state laws and regulations that affect the provision of pharmacists’ patient care services, and to discuss effects of these changes on the practice of pharmacy.

Data sources: Information from government sources and entities engaged in advocacy to support provider status for pharmacists, including APhA, the National Association for State Pharmacy Associations, the Patient Access to Pharmacists’ Care Coalition, and additional references cited by primary sources.

Study selection: At the author’s discretion based on the relevance of the information presented.

Summary: Pharmacists’ patient care services have been proven to improve patient outcomes and reduce health care costs. However, access to these services is limited by barriers that include laws and regulations restricting pharmacists’ scope of practice and opportunities to receive payment for services. Provider status activities that promote patient access to pharmacists’ patient care services are crucial to addressing these barriers and optimizing the pharmacist’s role in the health care system. Changes to federal and state laws and regulations in recent years include expanding pharmacists’ scope of practice and payment opportunities. However, more work remains to be done, and ongoing advocacy is necessary to support efforts to expand patient access to pharmacists’ services. As pharmacy practice evolves, issues such as credentialing and privileging, access to electronic health records, and liability coverage should be considered by pharmacists.

Conclusion: Changes to federal and state laws and regulations are increasing opportunities for pharmacists to provide patient care services. Ongoing provider status activities are necessary to support the current momentum to advance the practice of pharmacy.

Pharm Today. 2016;22(7):64–76

Accreditation information
Provider: American Pharmacists Association
Target audience: Pharmacists
Release date: July 1, 2016
Expiration date: July 1, 2019
Learning level: 2

ACPE number: 0202-0000-16-132-H04-P
CPE credit: 2 hours (0.2 CEUs)
Fee: There is no fee associated with this activity for members of the American Pharmacists Association. There is a $25 fee for nonmembers.

The American Pharmacists Association (APhA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education (CPE). The ACPE Universal Activity Number assigned to this activity by the accredited provider is 0202-0000-16-132-H04-P.

Advisory board: Ryan M. Burke, PharmD, Associate Director, Practice Initiatives; Anne Burns, BPharm, Assistant Vice President, Professional Affairs; Stacie Maass, BPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs; and James A. Owen, PharmD, BCPS, Vice President, Practice and Science Affairs, American Pharmacists Association.

Disclosures: Ryan M. Burke, PharmD; Anne Burns, BPharm; Stacie Maass, BPharm; and James A. Owen, PharmD, BCPS, declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria. APhA’s editorial staff declare no conflicts of interest or apparent conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For complete staff disclosures, please see the APhA Accreditation Information section at www.pharmacist.com/education.

Development: This home-study CPE activity was developed by the American Pharmacists Association.

Learning objectives
■ Discuss what is meant by “provider status” for pharmacists.
■ Describe federal and state provider status legislation and regulation affecting the pharmacy profession.
■ Provide an update on the status of efforts to recognize pharmacists and their services at the federal, state, and private-sector levels.
■ Explain how compensation for pharmacists’ services can affect patient care and pharmacists’ practices and opportunities.
Preassessment questions

Before participating in this activity, test your knowledge by answering the following questions. These questions will also be part of the CPE assessment.

1. Which of the following is a significant barrier to expanded provider status for pharmacists?
   a. There is a lack of opportunities for payment.
   b. Patients do not need services.
   c. Physicians do not want to collaborate.
   d. Pharmacists lack necessary training.

2. Which of the following is true about payment to pharmacists through Medicare Part B, as of May 2016?
   a. Payments that would normally be covered through Part B are covered through Part A for pharmacists.
   b. Pharmacists can only receive payment through Part B for providing services to patients in medically underserved areas.
   c. Pharmacists cannot directly receive payment through Part B for patient care services because their services are not listed as a covered service in the Social Security Act.
   d. Only some states allow pharmacists to receive payment directly through Medicare Part B.

3. Which of the following types of indirect Medicare Part B billing may only be used for services provided in physicians’ offices?
   a. Incident-to billing
   b. Transitional care management
   c. Chronic care management
   d. Immunization administration

4. Which of the following descriptions best defines credentialing?
   a. Documented evidence of professional qualifications
   b. The process by which an organization or institution obtains, verifies, and assesses an individual’s qualifications to provide patient care services
   c. Permission or authorization granted by a health care institution to a health care provider to render specific services
   d. The process by which a health care organization, having reviewed an individual care provider’s credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization

5. Which of the following statements is true about the role of pharmacists’ patient care services in accountable care organizations (ACOs)?
   a. Pharmacists who provide patient care services through ACOs may bill Medicare Part B directly for their services.
   b. Because ACOs receive financial incentives for quality, ACOs may contract with pharmacists who improve performance on quality measures, even if services cannot be directly billed.
   c. In current practice, pharmacists’ roles in ACOs are generally limited to consultative practice for population health management rather than direct patient care.
   d. Public and private ACOs use a common set of quality measures, which streamlines the selection of interventions that pharmacists can provide.

Pharmacists as providers

Pharmacists have the knowledge and skills to provide a wide range of patient care services, such as those shown in Table 1. A substantial and growing body of evidence demonstrates that when pharmacists provide such services in a wide variety of practice settings, patient outcomes improve, and costs are reduced.

Pharmacists’ delivery of such services has expanded dramatically over the past decade. Findings from APhA’s 2015 environmental scan of patient care services provided by pharmacists found that pharmacists are increasingly providing a wide range of patient care services to manage chronic diseases and improve overall health. These services include:

- Medication management (88%)
- Disease state education (84%)
- Immunizations (63%)
- Medication adherence services (60%)
- Disease state management (58%)
- Care transition services, including medication reconciliation (42%)
- Health and wellness screenings (34%)
- Smoking cessation (34%)
- Nutrition and weight loss (13%)
- Other (6%)

These patient care services are delivered in many different practice settings, including both community-based settings (e.g., independent, mass merchandiser, national chain, regional chain, and supermarket pharmacies) and integrated health organization settings (e.g., acute care/inpatient hospitals, ambulatory care clinics, health-system outpatient settings, long-term care, integrated delivery systems, and physician offices).

However, some consider pharmacists to be “the most overtrained and underutilized profession in America” because barriers to widespread availability of pharmacists’ services remain. These barriers include laws, regulations, and policies that limit pharmacists’ scope of practice and opportunities for payment. Provider status efforts are working to change this situation to expand patients’ access to services.

Findings from the 2015 survey confirmed the need to address financial and regulatory challenges facing pharmacists, such as updating and contemporizing pharmacy practice acts and other statutes to facilitate pharmacists’ new roles. Perhaps more importantly, survey findings indicated that sources of revenue must be developed and expanded to support access to these services and fully realize their value for the health care system.

Provider status activities are those that promote patient access to pharmacists’ patient care services by addressing barriers at all levels. Numerous programs and entities at federal, state, and private levels have the potential to adopt policies that can increase patient access to pharmacists’ patient care services.

Advocacy to support provider status activities is crucial for expanding opportunities for pharmacists. The Pharmacists Provide Care campaign (www.pharmacistsprovidecare.com)
services. The passage of the Affordable Care Act (ACA) in expanding Medicare beneficiaries’ access to pharmacists’ management (MTM) programs. This law was a step toward prescription drug plans to establish medication therapy management, such as diabetes, cardiovascular disease, and respiratory disease.

The Medicare Modernization Act of 2003 created the Medicare Part D drug benefit and included requirement for prescription drug plans to establish medication therapy management (MTM) programs. This law was a step toward expanding Medicare beneficiaries’ access to pharmacists’ services. The passage of the Affordable Care Act (ACA) in 2010 further expanded opportunities for pharmacists. The ACA established incentives for improving quality while controlling costs, thereby creating indirect avenues for payment to pharmacists who are able to demonstrate the value of services. Value-based programs that may provide opportunities for pharmacists include patient-centered medical homes (PCMHs) and accountable care organizations (ACOs) (see sidebar).

### Table 1. Examples of pharmacists’ patient care services

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic disease management and education</td>
<td>Helping patients improve the management of their condition(s) and optimize the benefits of their medications and health outcomes. Goal setting, monitoring, medication management services, and coaching help improve conditions such as diabetes, cardiovascular disease, and respiratory disease.</td>
</tr>
<tr>
<td>Medication management</td>
<td>Conducting a comprehensive review of a patient’s medications for appropriateness, effectiveness, safety, and adherence, and providing ongoing monitoring, as needed. The goal is to optimize medication use and health outcomes.</td>
</tr>
<tr>
<td>Health and wellness</td>
<td>Providing patients with immunizations, blood pressure checks, point-of-care testing (e.g., cholesterol and glucose), weight management, tobacco cessation counseling, and other preventive services.</td>
</tr>
<tr>
<td>Transitions of care</td>
<td>Managing medications and coordinating information with other health care professionals to assist patients in transitioning smoothly between health care settings and prevent negative events, such as hospital readmissions.</td>
</tr>
</tbody>
</table>

Source: Reference 1.

has been a central component of APhA’s strategy to promote federal provider status efforts. Through this initiative, APhA has organized more than 20,000 supporters who have sent more than 40,000 letters to Members of Congress. State- and local-level advocacy, largely driven by state pharmacy associations, is another key component of overall provider status efforts. A list of all state associations, along with contact information and websites, is available at www.naspa.us/statepharmacy.html.

**Federal pathways to provider status**

Many successes have occurred at the federal level to support provider status for pharmacists, including both legislative and regulatory developments.

**Federal legislative activities**

The Medicare Modernization Act of 2003 created the Medicare Part D drug benefit and included requirement for prescription drug plans to establish medication therapy management (MTM) programs. This law was a step toward expanding Medicare beneficiaries’ access to pharmacists’ services. The passage of the Affordable Care Act (ACA) in

A**COs, quality, and pharmacists**

ACOs are health care models that vary widely and can involve single or multiple insurers, independent physician practices, health systems, and pharmacies and/or providers that share risk and are accountable for quality metrics and achieving cost thresholds. The ACA authorized two Medicare ACO initiatives: the Pioneer ACO demonstration and the Medicare Shared Savings Program. Development of these ACOs has coincided with the development of many non-Medicare ACOs in the private sector in numerous markets. In addition, a few state Medicaid programs have developed ACOs, and more are expected to be developed.

The Medicare Pioneer ACO and the Medicare Shared Savings Program share a common set of 33 quality metrics, 12 of which are directly related to medications, as well as other measures that can be influenced by pharmacists, such as health promotion and education. Commercial and Medicaid ACOs use a variety of quality metrics with little standardization among them. Currently, at least two accrediting agencies offer ACO accreditation: URAC (formerly known as the Utilization Review Accreditation Commission) and the National Committee for Quality Assurance. Both agencies include medication-related quality metrics in their accreditation requirements.

ACOs engage pharmacists in both population health management and direct patient care services to support performance on quality measures. For example, population health management services might include a pharmacist reviewing the ACO’s entire patient panel to identify patients at risk for medication-related problems, assist in the development and management of best practices, and help assess, measure, and improve medication-related quality metrics.

Regarding direct patient care, pharmacists provide a variety of services focused on improving care transitions, medication adherence, medication management, and chronic disease management. Because chronic diseases are managed primarily through appropriate medication use, pharmacists often collaborate with other health care team members to manage the patient’s chronic conditions. Pharmacists may deliver medication management to targeted patients to identify and resolve medication problems and collaborate with the health care team to establish and attain medication-related goals. Collaborative practice agreements between pharmacists and prescribers may be used to facilitate efficient delivery of these services.

In addition, ACA established the Center for Medicare and Medicaid Innovation (CMMI) at CMS, which has awarded grants for innovative practice models that include advanced pharmacist practices. The Department of Health & Human Services (HHS) has outlined specific goals for the move to value-based payment.

However, while many recognize pharmacists’ ability to affect quality and value, one of the greatest barriers to expanding access to pharmacists’ services is that pharmacists are excluded from receiving payment through Medicare Part B. (Outpatient health care services, including those of physicians and other recognized health care providers, are cov-
CMS has expanded eligibility for postdischarge medication reconciliation; all beneficiaries who are members of Medicare Advantage are now eligible for this service.

In addition, in September 2015, CMS announced plans for a new model aimed at testing methods of optimizing medication use among Medicare Part D beneficiaries. The Part D Enhanced Medication Therapy Management model aims to determine whether adding incentives and options to create innovative programs will help to attain the overall objectives of MTM programs that focus on optimizing medication use and improving care coordination. CMS will begin testing the model in 2017.

CMMI has provided Health Care Innovation Awards to study compelling new ideas to deliver better health, improved care, and lower costs for people enrolled in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP), particularly those with complex health care needs. Award recipients provide services to a wide range of patient populations, from children to seniors, across the care continuum. Several organizations received Health Care Innovation Awards for projects that involve pharmacists in the delivery of patient care services. Each project is monitored for measurable improvements in quality of care and savings generated over a 3-year period.

In January 2015, HHS announced that it is testing and expanding new value-based payment models that can improve health care quality and reduce total health care costs. This initiative includes a shift toward increasing accountability for both quality and total cost of care and a greater focus on population health management as opposed to payment for specific services. This focus on value can yield a multitude of practice opportunities for pharmacists because of the potential impact on outcomes and cost.

**Transitioning to value-based payments.** In 2011, Medicare made almost no payments to providers through alternative payment models such as ACOs, but by 2015, approximately 20% of Medicare payments went to such models. HHS has already seen a combined cost savings of $417 million to Medicare as a result of existing ACO programs, and HHS expects these models to continue the current slowdown in health care spending.

In January 2015, HHS set a goal of tying 30% of traditional Medicare payments to alternative payment models (e.g., ACOs) by the end of 2016 and tying 50% of payments to such models by the end of 2018. In addition, HHS set a goal of tying 85% of all traditional Medicare payments to quality or value by 2016 and 90% by 2018 through programs such as the Hospital Value-Based Purchasing and the Hospital Readmissions Reduction Program.

To expand the reach of these goals beyond Medicare, HHS has established the Health Care Payment Learning and Action Network. Through this program, HHS will help private payers, employers, consumers, providers, states and state Medicaid programs, and other partners expand alternative payment models into their programs. Following this announcement, many of the largest private insurance plans in the country
stated that they also intended to transition up to 75% of their business to value-based payment models by 2020.5,6

Pause and reflect
■ What changes in pharmacy practice do you anticipate will occur as Medicare expands use of alternative payment models and ties increasing percentages of traditional payments to quality and value?

Options to bill for services provided to Medicare beneficiaries. Although pharmacists cannot bill Medicare Part B directly as providers, there are other options for pharmacists to receive compensation for their services (e.g., incident-to billing). There are specific—and in some cases, extensive—criteria for Medicare billing that pharmacists should carefully review when exploring whether to use these options (see the information on the CMS Medicare web page for pharmacists at www.cms.gov/center/pharmacist.asp for the most up-to-date billing requirements).

CMS contracts with regional Medicare Administrative Contractors (MACs) to process claims, enroll health care providers in the Medicare program, and educate providers about requirements for billing Medicare. Because MACs may interpret CMS requirements differently, it is important to both understand information from CMS and verify billing requirements with the regional MAC. More information about MACs, including links to contact information, can be found at www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors.html.

Medicare billing opportunities for pharmacists’ services. In recent years, CMS has allowed certain pharmacists’ services to be billed by physicians and other qualified non-physician practitioners (NPP) to Medicare Part B. Specific services that may be billed under the physician or NPP include the following:
■ Incident-to physician services in physician-based practices or hospital outpatient clinics: physicians may bill for nonphysician services by using incident-to codes, and pharmacists who provide chronic disease management, medication management, and other patient care services at physicians’ offices can have their services

<table>
<thead>
<tr>
<th>Table 2. Examples of state legislative changes in 2014 and 2015 that affect provider status</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
</tbody>
</table>
| **Indiana** SB 358 (2015) | • Allows nurse practitioners and physician assistants to sign collaborative practice agreements with pharmacists  
• Defines medication therapy management |
| **Kentucky** HB 377 (2015) | • Allows multiple pharmacists, practitioners, and patients to be included on one agreement |
| **Maryland** HB 716 (2015) | • Allows nurse practitioners and physician assistants to sign collaborative practice agreements with pharmacists (in addition to dentists, physicians, podiatrists, and midwives)  
• Allows pharmacists to initiate therapy |
| **North Dakota** SB 2173 (2015) | • Allows nurse practitioners to sign collaborative practice agreements with pharmacists (in addition to physicians)  
• Expands to pharmacists beyond institutional settings |
| **California** SB 493 (2014) | • Created an avenue for community practice pharmacists to enter into a collaborative agreement by obtaining the designation of Advanced Practice Pharmacist |
| **Minnesota** HB 2402 (2014) | • Adds the ability for pharmacists to initiate therapy  
• Allows multiple pharmacists and multiple prescribers to be included in one agreement  
• Allows nurse practitioners and physician assistants to sign collaborative practice agreements with pharmacists |
| **Tennessee** SB 1992/ HB 2139 (2014) | • Allows multiple pharmacists and multiple prescribers to be included in one agreement |
| **Wisconsin** SB 251 (2014) | • Very broad language that says “a pharmacist may perform any patient care service delegated to the pharmacist by a physician.” |

**Laws affecting payment to pharmacists**

- **North Dakota** SB 2320 (2015) • Adds MTM as a covered benefit in Medicaid
- **Washington** SB 5557 (2015) • Requires that pharmacists be included in Washington state insurance networks and be eligible to bill for services within their scope of practice.
- **Minnesota** SF 825 (2015) • Expands medication therapy services covered by Medicaid to recipients taking prescriptions to treat or prevent one or more chronic medical conditions.

Source: Reference 16.
billed using these codes when specific criteria are met. In January 2014, a letter from CMS affirmed the use of incident-to billing codes by pharmacists. More information about incident-to billing can be found at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0441.pdf.

- Transitional care management (TCM) as part of a team-based bundled payment: pharmacists may be part of the team providing care that is billed using TCM codes. According to CMS, licensed clinical staff under the physician's direction may furnish specific services, including medication management and assessing and supporting adherence to treatment regimens. Although pharmacists cannot bill using these codes directly, they can provide the services in conjunction with a physician who bills for the service. The TCM codes are most typically used following patient discharge from an acute care facility. More information about TCM code requirements can be found at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Transitional-Care-Management-Services-Fact-Sheet-ICN908628.pdf.

- Annual wellness visit (AWV): the Medicare AWV may be provided by a physician or “a medical professional (including a health educator, registered dietitian, nutrition professional, or other licensed practitioner), or a team of such medical professionals who are working under the direct supervision of a physician.” Pharmacists may act as one of the health professionals who are on the team providing the wellness visit. Several activities are covered as part of the AWV, including a review of the patient’s medication use as well as assessment of other risk factors. More information about AWV code requirements can be found at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AWV_chart_ICN905706.pdf.

- Chronic care management (CCM): in 2015, CMS began covering CCM services for non-face-to-face care coordination for Medicare beneficiaries with multiple chronic conditions. This service requires at least 20 minutes of clinical staff time directed by a physician or qualified health professional per calendar month. CMS permits clinical staff to provide the CCM service incident-to the services of the billing physician (or other appropriate practitioner) under the general supervision (rather than direct supervision) of the physician or other qualified practitioner. Additional information can be found at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.

### State pathways to provider status

Each state provides its own legislative and regulatory opportunities for advancing the pharmacy profession. At the state level, expanding access to pharmacists’ patient care services includes efforts to designate pharmacists as providers, enabling payment to pharmacists for services, and expand pharmacists’ scope of practice. In recent years, states have passed and/or implemented legislative and regulatory changes affecting these areas. Some states have also passed laws and regulations that address other aspects of pharmacy practice, such as credentialing and privileging. The momentum at the state level continues, with similar numbers of pieces of legislation being considered in 2016 compared with 2015.

Several states that have expanded pharmacists’ scope of practice report both improved patient outcomes and overall cost savings. For example, Ohio’s largest Medicaid managed care organization opted to cover MTM services for all beneficiaries. In the program’s first year, it had a $1.35:$1.00 return on investment (ROI) in drug cost savings alone. Total savings, including avoided hospitalizations, emergency department visits, and other unnecessary health care consumption, yielded an ROI of $4.40:$1.00.

In response to these and similar findings, the National Governors Association released a report in 2015 that addressed the inclusion of pharmacists as members of integrated health care teams. The report highlights numerous states that have expanded pharmacists’ scope of practice, integrated pharmacists into chronic care delivery teams, and developed team-based models of care that include pharmacists. The report concludes that “states should consider engaging

| Table 3. Elements that may be included in a collaborative practice agreement |
|-------------------------------|---------------------------------------------------------------|
| **Element** | **Specific activities** |
| Services/authority | • Modify therapy  
• Initiate therapy  
• Physical assessment  
• Order labs  
• Interpret labs  
• Perform lab tests |
| Requirements | • Continuing education requirements  
• Pharmacist qualifications  
• Liability insurance |
| Restrictions | • Disease state  
• Site of practice  
• Mediations |
| Individuals involved | • Number of pharmacists  
• Number of prescribers  
• Number of patients  
• Types of prescribers  
• Relationship between patient and prescriber  
• Pharmacist-to-prescriber ratio |
| Procedural requirements | • Patient involvement  
• Approval and reporting of agreements  
• Length of time for agreements  
• Payment provisions  
• Documentation  
• Physician review |

Source: Reference 16
in coordinated efforts to address the greatest challenges pharmacists face: restrictions in CPAs [collaborative practice agreements], recognition of pharmacists as health care providers to ensure compensation for direct patient care services, and access to health [information technology] systems.”

Recently passed state laws that may expand access to pharmacists’ services are listed in Table 2. Several of these laws address multiple challenges that pharmacists face. For example, Oregon passed provider status–related legislation for pharmacists in June 2015. H.B. 2028 took effect immediately when it was signed into law. This law:

- Clarifies that pharmacists can be paid for clinical services by both private and public third-party payers
- Expands existing laws related to CPAs to make them less restrictive
- Authorizes the development of statewide protocols for various clinical services, including smoking cessation and travel medicine

Pharmacists should contact their state pharmacy associations for additional guidance on laws and regulations in their state.

### Pause and reflect

- Are you familiar with laws and regulations pertaining to pharmacists’ scope of practice and payment opportunities in your state?
- What changes do you believe are necessary to improve access to pharmacists’ services in your state?

### CPAs and state-based protocols

The types of patient care services that pharmacists may perform are determined by state practice regulations, which vary among states. CPAs are used in many states to expand the depth and breadth of services the pharmacist can provide to patients and the health care team. Elements that may be included in a CPA are shown in Table 3. CPAs create a formal relationship between pharmacists and physicians or

### Table 4. Consensus recommendations for collaborative practice agreement (CPA) elements

<table>
<thead>
<tr>
<th>Type of provision</th>
<th>In state laws and/or regulations</th>
<th>At the practice level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>• Any practitioner with prescriptive authority may collaborate with pharmacists using a CPA. • CPAs may be between single or multiple pharmacists and single and multiple prescribers. • CPAs may apply to single or multiple patients or patient populations.</td>
<td>• CPAs should specify which patient(s) and/or patient population(s) can receive services under the agreement. • Depending on the complexity of the services being provided under a CPA, it may be appropriate for the pharmacist to have additional credentials or training beyond what is required for licensure. • CPAs should specify which pharmacist(s) may provide services under the CPA. A pharmacist’s practice setting should not be a barrier to his or her ability to enter into a CPA.</td>
</tr>
<tr>
<td><strong>Authorized services</strong></td>
<td>• The initiation and modification of drug therapy may be authorized under a CPA with a prescriber.</td>
<td>• In some situations, use of an evidence-based protocol can ensure optimal care when pharmacists are initiating or modifying drug therapy and may be included in the CPA, though they may not be needed or appropriate in others.</td>
</tr>
<tr>
<td><strong>Requirements and restrictions</strong></td>
<td>• All prescription drugs, including controlled substances, may be included within pharmacists’ collaborative practice authority. • CPAs should be maintained by the pharmacist(s) and collaborating prescriber(s) and be available on request or inspection.</td>
<td>• Pharmacist(s) and prescriber(s) may specify the level of patient involvement in the CPA. Depending on the level of service, elements such as informed consent, written consent, or opt-out provisions may be appropriate, as determined by the parties to the agreement. • Agreements should not be required to be sent to or approved by a state regulatory board or other agency; such requirements create unnecessary paperwork burden and slow the efficiency of care delivery. • Collaborating practitioners are encouraged to review and/or renew their CPAs within a timeframe that is clinically appropriate. • Collaborating practitioners should conform to evidence-based guidelines and the agreed-upon process of care with regard to documentation requirements and the collaborating practitioner’s responsibility for review of services provided under the agreement. • Practitioners may consider liability insurance provisions and the appropriateness of articulating these in their voluntary agreement. • It is the professional duty of all health professionals to stay current in the clinical areas in which they practice. If individual practitioners determine that continuing education requirements are appropriate for their clinical arrangement, they may be specified in the agreement.</td>
</tr>
</tbody>
</table>

Source: Reference 16.
other providers and identify specific functions that pharmacists can perform under certain conditions. These functions may include initiating, modifying, or discontinuing therapy and ordering laboratory tests. There is substantial variation among states on what is allowed. For example, some states limit CPAs to one physician and one pharmacist, while other states allow multiple physicians and pharmacists to enter into a CPA (Table 3).

Recent legislative activity in several states has expanded scope of practice by loosening restrictions on CPAs and/or developing statewide protocols. Statewide protocols are being used more frequently for public health concerns such as immunizations and naloxone, smoking cessation, hormonal contraceptives, and travel medications. Statewide protocols expand pharmacists’ ability to deliver services because they are designed to allow all qualified pharmacists within the state to practice under a single protocol, but they cannot be customized by individual pharmacists. These protocols expand authority but do not require a pharmacist to have a formal agreement with a prescriber and are usually developed by a state agency such as the public health department, state board of pharmacy, and/or state board of medicine. These protocols do not require the pharmacist to identify and have a formal relationship with a prescriber.

National resources to support CPA development include those from CDC, which were developed in collaboration with the APhA Foundation, and those from the National Alliance of State Pharmacy Associations (NASPA). Materials created by CDC and the APhA Foundation to promote development of CPAs include resources designed for pharmacists, other providers, payers, and decision makers. NASPA released recommendations for elements of collaborative practice authority that should be included in state pharmacy practice acts and regulations and those elements that should be left to the individual agreements between pharmacists and prescribers (Table 4). Pharmacists’ scope of practice, the practice of pharmacy, or the provision of pharmacists’ patient care services can also be affected by other entities, including a state’s attorney general or insurance commissioner. For example, some states’ attorneys general are affecting pharmacists’ scope of practice or permissible services by interpreting that “initiate” and “prescribe” are not interchangeable terms in statutes and regulations. In addition, in some cases, state insurance commissioners who oversee insurance laws and regulations covering state-governed plans have interpreted “administer” to apply only to vaccinations and not to other injectable medications, thereby limiting coverage of pharmacists’ services.

**Recognition as providers**

As with Medicare Part B, whether or not pharmacists are defined as providers may affect whether they are able to obtain payment for their services from other public (e.g., Medicaid) and private third-party payers. As of January 2016, at least 39 states designate pharmacists as providers either in statute or regulation, and at least 9 consider pharmacists to be providers in their state Medicaid programs. However, being listed as a provider in state laws and regulations is not a guarantee of payment.

**Success story: California.** In 2013, California passed S.B. 493, which established that pharmacists in the state are considered health care providers and expanded their scope of practice. The law also created a new practitioner title for pharmacists—Advanced Practice Pharmacist (APP)—and provides additional authorities to pharmacists who receive the APP credential.

These provisions allow all pharmacists to
- Furnish self-administered hormonal contraceptives pursuant to a statewide protocol
- Furnish prescription nicotine replacement products for tobacco cessation pursuant to a statewide protocol
- Furnish prescription travel medications recommended by CDC

To earn recognition as an APP, pharmacists must fulfill two of the following criteria:
- Earn certification in a relevant area of practice, such as ambulatory care, critical care, oncology pharmacy, or pharmacotherapy.
- Complete a postgraduate residency program.
- Have provided clinical services to patients for at least 1 year under a CPA or protocol with a physician, APP-credentialed pharmacist, collaborative drug therapy management (CDTM) pharmacist, or health system.

Pharmacists who earn the APP recognition are authorized to
- Perform patient assessments
- Order and interpret tests related to drug therapy
- Refer patients to other health care providers
- Initiate, adjust, and discontinue drug therapy pursuant to an order by a patient’s treating prescriber in accordance with established protocols
- Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

The California Pharmacists Association website provides a detailed summary of authorities granted to pharmacists under the new law. North Carolina and New Mexico have similar practitioner titles with expanded scope of practice for pharmacists.

**Payment for pharmacists’ services**

As of January 2016, some type of payment for pharmacists’ services is available on a relatively broad basis in at least 31 states. Of these states, 20 provide some payment for services to Medicaid enrollees (including directly from the Medicaid department, Medicaid managed-care organizations, or a CMMI grant), 14 provide payment for provision of MTM to Medicaid beneficiaries, and 6 provide payment for delivery of MTM services to state employees.

**Success story: Washington state.** In May 2015, the state of Washington passed S.B. 5557, which requires commercial and private health care plans in Washington to enroll pharmacists in their provider networks. The law clarified that the state’s Every Category of Health Care Providers law applies
to pharmacists and closed previous loopholes that allowed insurance companies to exclude pharmacists from their networks. The law also created an advisory committee to determine credentialing, privileging, billing, and payment processes.

Although many states consider pharmacists to be providers and allow payment, this is the first law that specifically requires third-party payers to provide compensation for pharmacists’ services. The state’s Medicaid and public employee health plans also intend to participate (although they are not required to by law).

The law does not require insurance plans to include all pharmacists in their networks, and it does not require coverage for all services provided by pharmacists. Covered services must be within the pharmacist’s scope of practice. The new law did not make any changes to pharmacists’ scope of practice or change requirements for pharmacists to have CPAs.

Similar to other providers, pharmacists must go through credentialing and privileging processes to be compensated for their services. Pharmacists practicing in organizations that have credentialing processes already in place could start participating in January 2016. The program will go into effect for community clinics and pharmacies in 2017. Health systems that have internal credentialing are now able to bill for pharmacists’ services at full evaluation and management payment codes rather than relying on other mechanisms such as incident-to billing to receive compensation.

Effect of provider status on pharmacy practice: Emerging Issues

As the practice of pharmacy evolves to incorporate more advanced patient care services, many operational and infrastructure issues must be addressed, including the use of credentialing and privileging, electronic health records (EHR), and liability.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Credential</td>
<td>Documented evidence of professional qualifications</td>
<td>Academic degrees, state licensure, residency certificates, and certification, such as certified diabetes educator or certified asthma educator</td>
</tr>
<tr>
<td>Credentialing</td>
<td>The process of granting a credential</td>
<td>A state board of pharmacy granting a practitioner a license to practice, or the Board of Pharmacy Specialties granting a pharmacist a specialty certification in oncology</td>
</tr>
<tr>
<td></td>
<td>The process by which an organization or institution obtains, verifies, and assesses an individual’s qualifications to provide patient care services</td>
<td>Obtaining and verifying an individual’s certificate of completion from a postgraduate pharmacy residency program or assessing the clinical experience and preparation for specialty practice</td>
</tr>
<tr>
<td>Privileging</td>
<td>The process by which a health care organization, having reviewed an individual health care provider’s credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization</td>
<td>Granting a practitioner permission for pharmacokinetic dosing in hospitals, ordering laboratory tests, monitoring and adjusting specific medications</td>
</tr>
</tbody>
</table>

**Credentialing and privileging**

Credentialing and privileging processes are increasingly being required before pharmacists are allowed to provide a service or be compensated for it. While a pharmacy license is intended to indicate that a pharmacist has entry-level competencies, credentials that demonstrate additional competencies may be required for providing more advanced patient care services. A range of processes are used for credentialing and privileging. A helpful resource to review when identifying credentials that are available for pharmacists to earn, and that may be required for various roles, is the Council on Credentialing in Pharmacy’s “Certifications for Pharmacists” document, available at www.pharmacycredentialing.org/Files/CertificationPrograms.pdf. The list is not exhaustive, and new certifications may have been created since it was published.

Definitions related to credentialing and privileging are shown in Table 5. These processes are used within many health care organizations to ensure the capabilities and competence of health care professionals, including pharmacists. Credentialing of pharmacists is done by organizations to assess whether the pharmacist has the qualifications for a position in the organization and to verify the pharmacist’s credentials. Credentialing is often done by the human resources department of the organization as part of the hiring process and may be updated periodically.

Privileging is a separate process that involves providing a pharmacist with permission to perform specific services within the organization. Privileging is often determined by a

---

**Pause and reflect**

- What changes in pharmacy practice have you experienced in recent years?
- What changes do you expect to see in the next few years?
committee of health care providers based on credentials and an assessment of the health care practitioner’s capabilities. While credentialing is a standard process used by organizations for pharmacists, privileging is an emerging practice, especially as the scope of services delivered by pharmacists becomes more complex and diversified.  

Many organizations already have credentialing and privileging processes in place for other health professionals and will be able to incorporate pharmacists into existing processes. Pharmacists may need to educate individuals responsible for these processes to help them understand pharmacist credentials and patient care services. Pharmacists should be prepared to provide the necessary documentation required for the credentialing and privileging programs in their organization.

Electronic health records
Implementation and effective use of EHR systems is critical as pharmacists embrace new roles and expand on patient care service delivery. EHR systems, when effectively and appropriately implemented, can support safe, effective, and efficient medication use, continuity of care, and population health management, as well as facilitate efficient electronic documentation and communication among all practitioners and with payers. EHR systems and health information exchanges (HIEs) help facilitate the exchange of relevant information among patients’ health care providers and contribute to improvements in overall care to patients.

Significant work has been undertaken to support the development of EHR systems that fully integrate pharmacists. However, challenges with system access, implementation, use, and interoperability and exchange of clinical information remain. The Pharmacy Health Information Technology Collaborative advocates for systems that meet pharmacists’ needs. In addition, the Health Information Exchange (HIE) is a national initiative that is increasingly being used to share health information across different members of multidisciplinary care teams. More information about these initiatives is available at www.pharmacyhit.org and www.healthit.gov/HIE.

Liability
Liability is another issue that must be considered as pharmacists’ services expand. Pharmacists should be aware of the potential for expanded liability associated with additional practice activities and the potential impact on their liability insurance coverage needs and cost.

Conclusion
In recent years, there has been increasing support for the role of the pharmacist and pharmacists’ patient care services at the federal and state levels and by private third-party payers. Barriers facing increased access to pharmacists’ patient care services include laws and regulations that restrict pharmacists’ scope of practice and those that limit payment opportunities. Recent years have seen important legislative and regulatory changes that address these and other barriers; however, ongoing advocacy efforts are necessary to sustain this momentum and continue to advance the profession.

References
16. National Alliance of State Pharmacy Associations. Pharmacist col-


CPE assessment
This assessment must be taken online; please see “CPE information” in the sidebar on page 74 for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. Which of the following pharmacist’s activities would be considered a provider status patient care service?
   a. Educating a patient about adverse events
   b. Disease state management
   c. Patient counseling at the point of dispensing
   d. Diagnosing chronic conditions

2. Which of the following is a significant barrier to expanded provider status for pharmacists?
   a. There is a lack of opportunities for payment.
   b. Patients do not need services.
   c. Physicians do not want to collaborate.
   d. Pharmacists lack necessary training.

3. Which of the following is a federal law that allowed for the coverage of a pharmacist-provided service for qualifying Medicare patients?
   a. Medicare Modernization Act of 2003
   b. Medicare Access and CHIP Reauthorization Act of 2015
   c. Medication Therapy Management Empowerment Act
   d. Pharmacy and Medically Underserved Areas Enhancement Act

4. Which of the following is true about payment to pharmacists through Medicare Part B, as of May 2016?
   a. Payments that would normally be covered through Part B are covered through Part A for pharmacists.
   b. Pharmacists can only receive payment through Part B for providing services to patients in medically underserved areas.
   c. Pharmacists cannot directly receive payment through Part B for patient care services because their services are not listed as a covered service in the Social Security Act.
   d. Only some states allow pharmacists to receive payment directly through Medicare Part B.

5. Which of the following organizations is a collaboration of stakeholder groups including pharmacy associations that focuses on supporting provider status legislation as its primary purpose?
   a. Council on Credentialing in Pharmacy
   b. National Alliance of State Pharmacy Associations
   c. National Association of Boards of Pharmacy
   d. Patient Access to Pharmacists’ Care Coalition

6. Which of the following is proposed federal legislation that would expand the pool of patients eligible for MTM services through Medicare Part D?
   a. Medication Therapy Management Empowerment Act
   b. Pharmacy and Medically Underserved Areas Enhancement Act
   c. Medicare Opportunities Act
   d. Social Security Modernization Act

7. Which of the following measures related to the provision of MTM is used as a measure that affects star ratings for Medicare Part D plans?
   a. Adherence to chronic medications for the treatment of depression
   b. Comprehensive medication review completion rate
   c. Percentage of patients who receive targeted MTM visits
   d. Hospital readmission rates

8. What percentage of traditional Medicare payments does HHS plan on tying to alternative payment models (e.g., ACOs) by the end of 2018?
   a. 25%
   b. 40%
   c. 50%
   d. 75%

9. Which of the following types of indirect Medicare Part B billing may only be used for services provided in physician’s offices?
   a. Incident-to billing
   b. Transitional care management
   c. Chronic care management
   d. Immunization administration

10. Which of the following types of Medicare billing codes is most likely to be used when caring for patients who have recently been discharged from an acute care facility?
   a. Incident to billing codes
   b. Transitional care management codes
   c. Chronic care management
   d. Annual wellness visit codes

11. According to the findings in the National Governors Association’s 2015 report on pharmacists’ services, states that have expanded access to pharmacists’ patient care services have found which of the following outcomes?
   a. Improved patient outcomes and increased costs
   b. Improved patient outcomes and neutral costs
   c. Neutral patient outcomes and decreased costs
   d. Improved patient outcomes and decreased costs
12. Which state passed a law in 2013 establishing a new practitioner title called the Advanced Practice Pharmacist?
   a. California  
   b. Washington  
   c. North Carolina  
   d. Maryland

13. Which state passed a law in 2015 requiring that private third-party payers compensate pharmacists for providing patient care services?
   a. Wisconsin  
   b. Washington  
   c. Tennessee  
   d. Florida

14. Which of the following states passed a law in 2015 that added MTM services as a covered benefit to the state Medicaid program?
   a. Kentucky  
   b. Pennsylvania  
   c. Nevada  
   d. North Dakota

15. Which of the following is a requirement for pharmacists to receive compensation from third-party payers for patient care services in Washington state?
   a. Undergo a credentialing and privileging process  
   b. Obtain full access to electronic health records  
   c. Earn the designation of Advanced Practice Practitioner  
   d. Enter into a collaborative practice agreement with a prescriber who has privileges with the payer

16. Which of the following statements about collaborative practice protocols is true?
   a. Statewide protocols are increasingly used to address public health concerns.  
   b. All CPAs in a state must provide pharmacists with the same authorities.  
   c. Most legislation in recent years has tightened CPA restrictions.  
   d. Pharmacists are free from liability if they follow the requirements specified in the CPA.

17. Consensus recommendations for the development of CPAs include which of the following elements in state laws and/or regulations?
   a. Which patients can receive services under the agreement  
   b. The level of patient involvement, including informed consent and opt-out provisions  
   c. Requirements for liability insurance  
   d. Initiation and modification of drug therapy may be authorized under a CPA with a prescriber

18. Which of the following medication classes can be dispensed under statewide protocol in some states?
   a. Hormonal contraceptives  
   b. Statins  
   c. Diuretics  
   d. Intranasal corticosteroids

19. Which of the following descriptions best defines credentialing?
   a. Documented evidence of professional qualifications  
   b. The process by which an organization or institution obtains, verifies, and assesses an individual’s qualifications to provide patient care services  
   c. Permission or authorization granted by a health care institution to a health care provider to render specific services  
   d. The process by which a health care organization, having reviewed an individual care provider’s credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization

20. Which of the following statements is true about the role of pharmacists’ patient care services in ACOs?
   a. Pharmacists who provide patient care services through ACOs may bill Medicare Part B directly for their services.  
   b. Because ACOs receive financial incentives for quality, ACOs may contract with pharmacists who improve performance on quality measures, even if services cannot be directly billed.  
   c. In current practice, pharmacists’ roles in ACOs are generally limited to consultative practice for population health management rather than direct patient care.  
   d. Public and private ACOs use a common set of quality measures that streamlines the selection of interventions pharmacists can provide.