



2017 House of Delegates

Report of the Policy Committee

- ❖ Patient Access to Pharmacist-Prescribed Medications
- ❖ Pharmacists' Role within Value-Based Payment Models
- ❖ Pharmacy Performance Networks

Committee Members

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2016–2017 APhA Policy Committee Report

Patient Access to Pharmacist-Prescribed Medications

The committee recommends that the association adopt the following statements:

1. APhA asserts that pharmacists' patient care services and related pharmacist prescribing are beneficial to improving patient access to care, patient outcomes, and community health and align with coordinated, team-based care.
[Refer to Summary of Discussion Items 2, 3.]
2. APhA supports increased patient access to care through pharmacist prescriptive authority models including, but not limited to, collaborative practice agreements and statewide protocols.
[Refer to Summary of Discussion Items 3, 4, 5, 6, 7, 8.]
3. APhA opposes requirements and restrictions impeding patient access to pharmacist-provided patient care services and related pharmacist prescribing that do not improve quality, safety, and efficiency.
[Refer to Summary of Discussion Items 9, 10, 11, 12.]
4. APhA urges prescribing pharmacists to coordinate care with patients' other health care providers through appropriate documentation, communication, and referral.
[Refer to Summary of Discussion Items 3, 13, 14, 15, 16]
5. APhA advocates that medications and services associated with prescribing by pharmacists must be covered and compensated in the same manner as other prescribers.
[Refer to Summary of Discussion Items 17, 18.]
6. APhA supports the right of patients to fill pharmacist-prescribed medications at a pharmacy of their choice.
[Refer to Summary of Discussion Item 19.]

Summary of Discussion

1. The committee discussed the use of the terms *initiate*, *furnish*, and *prescribe* and the way *initiate* and *furnish* may create barriers to payment to pharmacists for prescriptive authority and appropriate reimbursement for the medication (if not prescribed). In some states, the term *initiate* does not have the same legal meaning as *prescribe* and also may be unfamiliar to patients. The committee agreed that using a term other than *prescribe* would not be beneficial to describe a patient care function that is already being performed by other health care professionals.
2. The committee discussed how the focus and intent of statement 1 is access to the pharmacists who are able to prescribe and those associated services as opposed to focusing on only access to medications.
3. The committee agreed that circumstances exist where pharmacist prescribing is not appropriate because pharmacists are not being formally trained as diagnosticians. The committee also discussed specific cases where a diagnosis would not be required, such as preventive care, travel medicine, immunizations, etc.
4. The committee reviewed all existing forms of pharmacist prescriptive authority models. The committee discussed including standing orders in the policy statement itself, but chose not to keep this item in the statement because it does not explicitly belong in the area of prescribing practices.
5. The committee discussed the need for prescriptive authority models that do not limit pharmacists' role in prescribing practices.
6. The committee discussed the education and training related to pharmacist prescribing and did not intend to identify any special training measures beyond the curriculum for the Doctor of Pharmacy degree.

7. The committee referenced the document “Pharmacist Collaborative Practice Agreements: Key Elements for CPA Legislative and Regulatory Authority,”¹ when discussing the current landscape of prescriptive authority models. This document was developed by the Collaborative Practice Workgroup, which was convened by the National Alliance of State Pharmacy Associations.
8. The committee specifically included the term *models* because it is used by the Center for Medicare and Medicaid Innovation and also encompasses existing models while including potential future models.
9. The committee reviewed potential forms of restrictions such as practice setting, additional education requirements, specific prescribers, specific pharmacists, or specific patients and chose the verb *oppose* to highlight the importance of advocating against these types of legislative barriers and administrative restrictions.
10. The committee acknowledged that a legitimate reason for requirements or restrictions on pharmacist prescribing practices may exist. However, the committee agreed that any requirements and restrictions should be evidence based and not be arbitrary and also should not impede patient access. The committee initially chose the term *unsubstantiated* in place of *arbitrary*, but chose not to use *unsubstantiated* because *arbitrary* was clearer.
11. The committee discussed the importance of having statement 3 as guidance for state-level implementation. The committee intends to support the removal of legislative, regulatory, or policy barriers, such as practice restrictions or limitations on which and how many prescribers may collaborate with pharmacists under a CPA, that would limit patient access to medications prescribed by pharmacists.
12. The committee discussed the importance of pharmacists in their respective states working with state boards of pharmacy, state pharmacy associations, and other state-level legislative and regulatory bodies to advance pharmacists’ role as prescribers in a state scope of practice act.

13. The committee further reviewed situations where a diagnosis may already exist (diabetes, etc.) and commented that the medications associated with conditions already being treated can be appropriately managed by pharmacists, but that such management should be performed in coordination with patients' other health care providers.
14. The committee reviewed the full spectrum of coordinated care and discussed the importance of monitoring and follow-up after the actions of prescribing.
15. The committee recognized that a pharmacist may be the health care system entry point for many patients, and pharmacists should be aware of potential situations that necessitate referral. The committee also discussed the importance for a patient to visit not only with a pharmacist but also with other members of the health care team when appropriate.
16. The committee discussed that coordination of care applies not only to prospective communication but also to retrospective communication with other members of the health care team.
17. The committee discussed that when a pharmacist issues a prescription, the pharmacist is then recognized as the prescriber on record and also recognized for coverage and compensation in the same way as other prescribers.
18. The committee reviewed existing billing codes used by prescribers and asserted that pharmacists should be able to use those same billing codes for pharmacist-prescribed medication and service.
19. The committee reviewed the APhA **2011 Potential Conflicts of Interest in Pharmacy Practice** policy statement when discussing issues related to conflicts of interest. The committee decided to further emphasize patients' autonomy to choose where they may fill their prescriptions in addition to existing policy on the subject.

20. The committee reviewed existing Washington State Administrative Code, specifically the definition of pharmacy practice (item 28 under the **RCW 18.64.011: Definitions** section) and **WAC 246-863-100, Pharmacist prescriptive authority—Prior board notification of written guideline or protocol required.**
21. The committee reviewed Oregon legislation (Oregon Revised Statutes, Chapter 689, Pharmacists; Drug Outlets; Drug Sales—Miscellaneous, 689.683 Prescription and dispensation of certain contraceptives; rules; insurance coverage) regarding hormonal contraceptive assessment, prescribing, dispensing, and referral by a pharmacist.
22. The committee discussed the importance of education and training but believes that pharmacists' current education prepares them for the authority to prescribe. The committee also reviewed the APhA **1975 Pharmacist's Responsibility for Continuing Competence** policy statement, which highlights the importance of pharmacists retaining their level of competence throughout their career.
23. The committee discussed that pharmacists should inherently understand that they have the professional responsibility to practice within their level of education and training as mentioned in the pharmacists' code of ethics.
24. The committee discussed the importance of sharing these practices with consumers and the public, but it assumed that information sharing would occur on the practice, state, and national level once approval of authority was obtained.

Reference

1. Collaborative Practice Workgroup, National Alliance of State Pharmacy Associations. *Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority*. 2015. Available at: <http://naspa.us/wp-content/uploads/2015/07/CPA-Workgroup-Report-FINAL.pdf>. Accessed August 8, 2016.

Patient Access to Pharmacist-Prescribed Medications

Background Paper Prepared for the 2016–2017 APhA Policy Committee

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Issue

Many states across the country have expanded the role of the pharmacist through statewide protocols, collaborative practice agreements (CPAs), or legislative and regulatory changes that allow a pharmacist to assess, monitor, modify, initiate, and dispense specific medications. While the various activities that are often included under the scope of “prescribing” can include selecting, initiating, monitoring, continuing, modifying, and administering, this paper will focus on the initiation of therapy. Authority to initiate therapy can vary widely from state to state.

These innovative practice models have begun to gain even more traction recently due to increased attention directed toward various public health issues—for example, patient access to naloxone for treatment of opioid overdose. Naloxone is not the only type of medication for which pharmacists can provide additional services. Smoking cessation products, hormonal contraception medications, and international travel medications have also become more accessible to patients because many states are using pharmacists more extensively and equipping them with the authority to assess, monitor, modify, initiate, and dispense these medications. Enabling pharmacists to expand their roles on the health care team by enhancing their ability to provide patients with access to necessary medications and expanded health care services is essential to maximizing the value of our nation’s health care system.

Summary of Key Concepts

- A national shortage in the number of primary care professionals is resulting in many medically underserved populations and limiting patients’ access to health care services.
- Pharmacists are highly qualified, trained, and accessible health care professionals who improve patient outcomes through the services they provide.
- Pharmacists are key members of health care teams, which is increasingly apparent as treatment and payment models shift toward coordinated care.

- Many states have begun allowing pharmacists to initiate certain medications through statewide protocol implementation and legislative or regulatory changes that permit or encourage CPAs and standing orders.
- Pharmacists are in a position to address unmet public health needs by providing care for chronic disease states, addressing public health initiatives, and offering preventive care services.
- Communication with patients' primary health care providers and documentation of services delivered are essential to ensuring the highest quality of care for patients.
- Practicing within the appropriate scope and identifying patient situations that necessitate referral are fundamental elements involved in the various prescriptive authority models.
- Several stakeholders and organizations outside the pharmacy profession have developed guidance documents referencing expanded roles for pharmacists and supporting broad collaborative authority.

Background

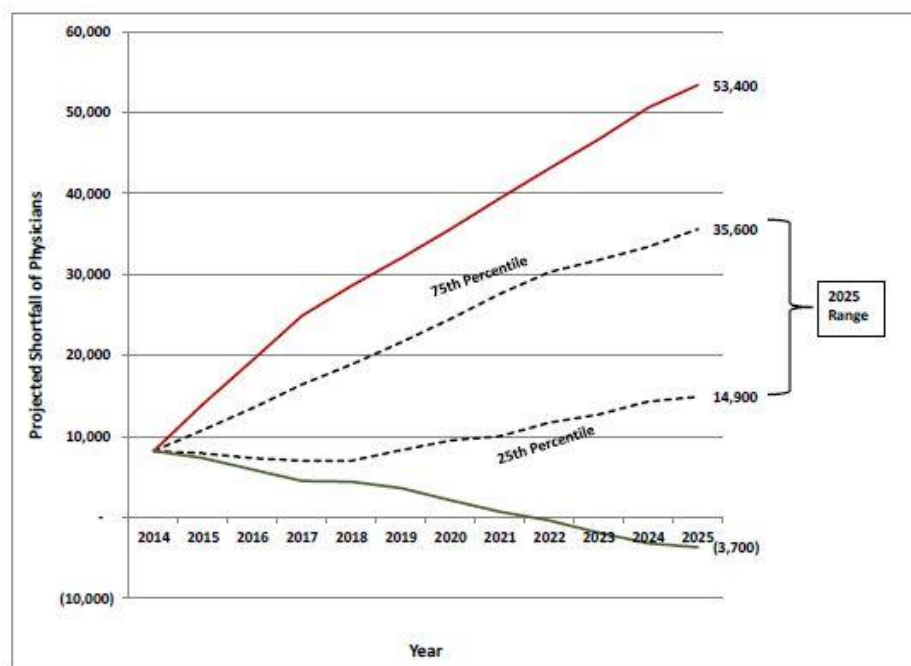
Introduction

Although the overall physician-to-population ratio in the United States has increased steadily over the past several decades, a growing trend toward physician specialization has not allowed for improvement in meeting the demand for primary care.¹ This reallocation of health care providers has left many patient populations without adequate and timely access to appropriate care. The need for appointments and the general lack of convenience pose additional barriers for patients attempting to gain access to care. Expanded implementation of prescriptive authority models that facilitate increased patient access to pharmacist-initiated medications is a viable solution to address this critical deficiency in patient access to primary care services.

Although pharmacists continue to expand the health care services they can deliver, shortages in the total number of physicians and in the number of primary care physicians are projected to worsen.² Immediate physician shortages highlight a greater need for health care stakeholders to routinely evaluate and assess our nation's pool of available resources. In 2015, the Association of American Medical Colleges (AAMC) committed to developing annual reports on physician supply-and-demand projections for this reason. The 2016 annual report published by AAMC reiterated and expanded on previous findings—an increasing deficit in physician supply in regard to physician demand.² Reports are driven by the most current research practices and by key trends in the profession that are most likely to affect the future supply and demand of physicians. Figure 1 depicts the projected shortfall of primary care physicians by 2025. Because the report weighs multiple potential supply-and-demand scenarios, projecting a specific number

with certainty is impossible. Instead, the projected shortfall is provided as a range that AAMC believes to be the most adequate representation of the primary care physician deficit by 2025—a projected deficit of 14,900 to 35,600 primary care physicians.

Figure 1. Total Projected Shortfall of Primary Care Physicians, 2014–2025

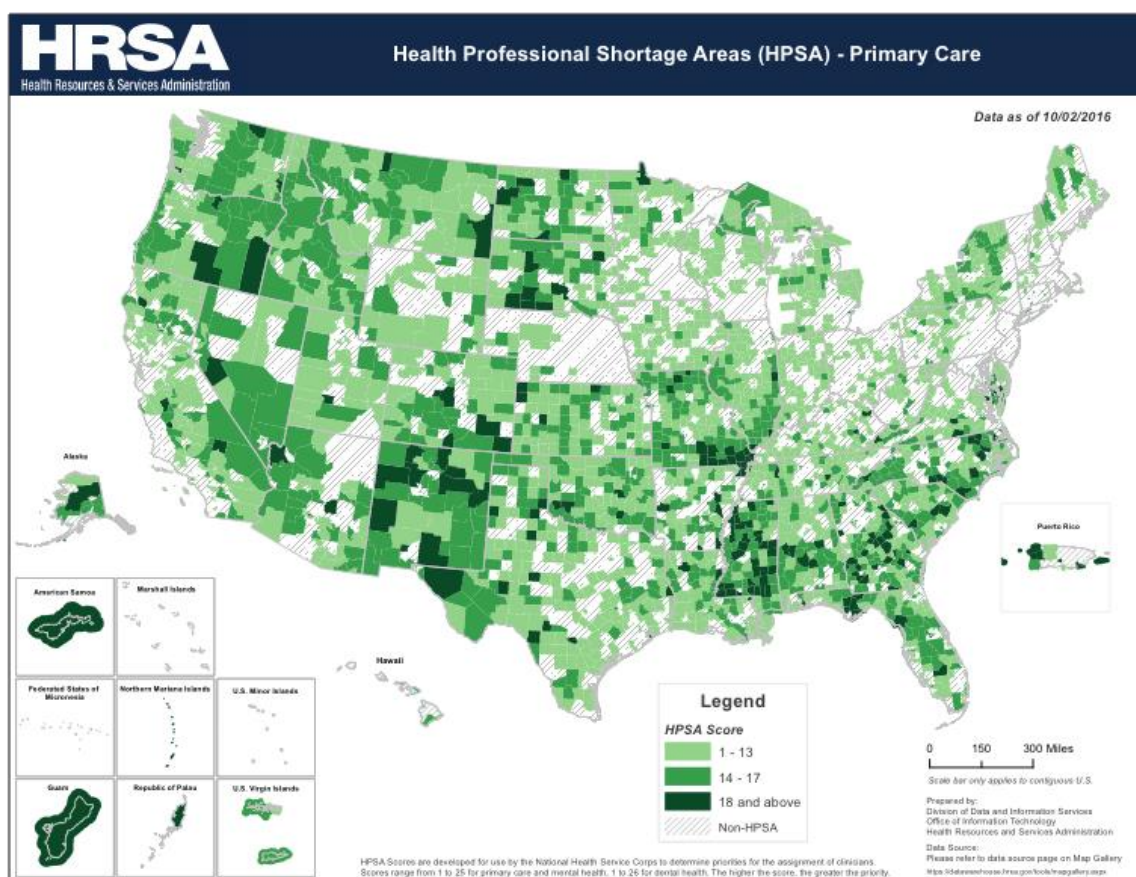


Source: (Dall et al., 2016)²

To supplement this research projecting the growing physician deficit, physician census data are also readily available. Data collected by the Federation of State Medical Boards (FSMB) document the number of licensed physicians per state, individual state population figures, and physicians per capita (per 100,000 population). The most recent data indicate a physician shortage in the near future. The authors of the census report also reference several studies to indicate that the future demands for primary care may be met by more active utilization of non-physician clinicians.³ The data also allow for the determination of whether a state can be classified as a health professional shortage area (HPSA). Shortage designation criteria are established by the Health Resources and Services Administration (HRSA), an agency of the United States Department of Health and Human Services (HHS). In general, classification as a primary care HPSA is based on a physician-to-population ratio of 1:3,500.⁴ A population in excess of 3,500 individuals per primary care physician would thus qualify as an HPSA. In 2014, approximately 6,100 areas in the United States were designated as primary care HPSAs.⁵

Figure 2 demonstrates the prevalence of HPSAs across the United States. HPSA scores indicate a priority for the assignment of clinicians in the corresponding area. The complete scoring process and criteria involved are accessible on the Health Resources and Services Administration website. The higher the score (and darker the shade of green), the greater the priority for clinician assignment. As evidenced in the data and Figure 2, a sizable percentage of the country is experiencing a shortage of primary care physicians.

Figure 2. Health Professional Shortage Areas (HPSA) – Primary Care



Source: (HRSA, 2016)⁵

Terminology

Several different terms are used in the marketplace to describe the initiation of medication therapy by a pharmacist. Commonly used terms include *prescribe*, *initiate*, and more recently, with respect to medications provided through state-based protocols, *furnish*. Traditionally, the majority of the profession has used the term *initiate* to describe pharmacist-prescribing activities. However, broad language should be encouraged to avoid restricting or limiting the services pharmacists can provide. When language

related to prescribing is used, it is important to emphasize to other providers that the pharmacist is working with the providers, not independent of them, to improve patient outcomes. As states continue to embrace prescriptive authority models, careful consideration should be given to addressing and describing terminology to avoid further segmentation or contribution to barriers impeding nationwide uptake.

Coordinated Care Approach

Over the past several years, the health care sector has seen several related trends emerge. These trends have begun to place focus on value-based patient care models rather than volume-based patient care models.⁶ As a result, many health care providers, prescription drug plans, and other stakeholders are now being guided and assessed by performance metrics. These metrics are evaluated on the basis of predetermined quality measures. This shift toward a value-based health care system is furthermore facilitating a shift within the various practice settings toward a more team-based, interdisciplinary care approach.⁷ The overall impact of these shifts has allowed for a natural progression toward a coordinated care model, with the patient's holistic health being at the forefront.

As health care practitioners are now being directly assessed on the quality of care they provide, hospitals and other providers are beginning to express a greater appreciation for health care teams.⁷ The changing landscape of the health care environment has affected not only the way that providers approach the facilitation and delivery of patient care, but also the roles and responsibilities of patients and other health care professionals within these models. Through patient-centered, team-based care models, patients are becoming more engaged in the decision-making process related to their health care and receiving more transparent information about the quality of care delivered by their providers. As a result of this increased transparency, patients are better equipped to select providers and health plans that will best suit their individual health care needs.

Changes in the health care landscape are also providing opportunities for pharmacists to play a greater role in the delivery of care services to patients. Pharmacists are increasingly being integrated into health care teams for their medication expertise and their focus on wellness and prevention and chronic disease management.

Coordinated, team-based care is often referred to as collaborative care and can serve as the foundation for more formal agreements and protocols that expand the types of services pharmacists can deliver. Many states have passed legislation allowing pharmacists to initiate certain medications under various prescriptive authority models, an expansion in scope of practice that allows pharmacists to take on additional patient care responsibilities. As the health care arena continues to progress in the direction of coordinated care, pharmacists will need to be vigilant in the documentation of services delivered and the

communication of this information to appropriate members of the health care team. Pharmacists should also refer patients to their primary care physician (if assigned) whenever deemed appropriate.

Prescriptive Authority Models

Pharmacist initiation of medications and pharmacist prescriptive authority models have been in place for years, steadily gaining traction since the 1970s. The Indian Health Service (IHS) was one of the first groups to institute the idea of coordinated care. Pharmacists were granted post-diagnostic prescriptive authority that allowed them to provide certain prescription legend drugs without a physician prescription.⁸ The Department of Veterans Affairs (VA) implemented a similar directive in 1995, allowing pharmacists prescriptive authority with the scope of practice established by local VA facilities.⁹ At the state level, Washington was the first state to pass legislation granting pharmacists collaborative prescriptive authority in 1979. “Today, 49 states and the District of Columbia enable pharmacist prescriptive authority under CPAs, standing orders, or statewide protocols.”¹⁰

Collaborative practice agreements are formal agreements in which a licensed provider makes a diagnosis, supervises patient care, and refers the patient to a pharmacist under a protocol or agreement that allows the pharmacist to perform specific patient care functions. The terminology used for CPAs can vary from state to state and may include collaborative drug therapy management agreement, collaborative pharmacy practice agreement, consult agreement, physician-pharmacist agreement, standing order or protocol, or, simply, physician delegation.

The term *statewide protocol* refers to a state regulatory framework under which qualified pharmacists are authorized by an empowered state body to initiate a specified medication or category of medications. Each protocol specifies the conditions under which a pharmacist may initiate and the general procedures that must be followed, while allowing the pharmacist to exercise clinical judgment in product selection. Generally, protocols are used to address patient care needs that do not require a diagnosis (i.e., preventive care) or for which a diagnosis already exists or can be easily obtained (i.e., through the use of a rapid diagnostic test).

A *standing order* is an order issued by a specific prescriber that can be carried out by other health care providers. Standing orders do not require an agreement with a collaborating provider. They may be used in several different settings and for different purposes. In institutional settings, standing orders are commonly incorporated into the general operations. Although standing orders have uses at the organizational level (typically in institutions, such as long-term care facilities and hospitals), they may also be implemented at the state level. A statewide standing order is typically issued by a state health official (or department) or attorney general. Statewide standing orders allow the designated individuals and/or others who meet the criteria to carry out an order throughout the entire state.¹¹

*Patient-Specific Collaborative Practice Agreements*¹⁰

Patient-specific CPAs are formal relationships between participating patients, a provider or group of providers, and a pharmacist or group of pharmacists. Notably, some states allow pharmacists to enter into CPAs with nurse practitioners and/or physician assistants. Patient-specific CPAs are more restrictive than population-specific CPAs in terms of the patients served by the agreement, limiting services to either a single patient or group of patients, only patients who are under the care of the collaborating provider(s), or patients receiving only post-diagnostic follow-up services. Currently, 19 states restrict collaborative practice to these patient-specific limitations.¹⁰

Patient-specific CPAs often are used by pharmacists to manage chronic disease states, such as diabetes, hypertension, and dyslipidemia.¹² Terms are negotiated between the provider(s) and the pharmacist(s). The pharmacist often then is able to initiate new medications, adjust medication therapies, and/or order laboratory tests.

*Population-Specific Collaborative Practice Agreements*¹⁰

Population-specific CPAs, in contrast with patient-specific CPAs, are regulated by broad inclusion criteria. Under this prescriptive authority model, patients who meet the inclusion criteria are eligible to receive services regardless of whether they are under the care of the collaborating provider(s) participating in the agreement. Population-specific CPAs have a collaborating prescriber, such as a medical director at a department of health, but that collaborating prescriber may not be the patient's personal physician. Currently, 17 states allow population-specific CPAs. By default, these states also allow patient-specific CPAs, because providers could also restrict certain agreements to specific patients or groups of patients.

Population-specific CPAs often are used by pharmacists to provide prevention and wellness services and to address certain acute conditions. They may also be used to manage chronic disease states. Under this model, pharmacists may administer certain vaccines pursuant to predetermined inclusion criteria. In several states, pharmacists are working under the terms of population-based CPAs to initiate an influenza medication after performing a flu test. Documentation of delivered services and communication with providers are imperative for pharmacists choosing to practice under these models.

*Statewide Protocols*¹⁰

Statewide protocols and unrestricted category-specific prescribing are both examples of autonomous prescribing models. Though pharmacists are still collaborating with providers to deliver services, autonomous prescribing allows for alternative models of care. One of the primary differences between statewide protocols and population-specific CPAs is that statewide protocols do not require pharmacists to practice under the delegation of functions by a specific provider or set of providers, as seen in Table 1.

An empowered state body, not a prescriber, establishes statewide protocols. The two models are similar, however, in that both are designed to facilitate delivery of care to populations, rather than individual patients.

Statewide protocols often address broad public health initiatives or are used to treat conditions that do not require a specific diagnosis. Typically, they are established by a public health department or state board of pharmacy. Statewide protocols issued to date have focused narrowly on specific medications or classes of medications. Examples of medications initiated by pharmacists under such protocols include tobacco cessation products, hormonal contraceptives, immunizations, and opioid reversal agents. The prescription opioid epidemic is a recent example of a public health initiative that has led many states to pass legislation allowing pharmacists to furnish naloxone. Currently, 19 states have passed statewide protocols for the issuance of naloxone.¹³ In addition, statewide protocols also exist for tuberculosis testing and travel medications.¹⁴ Many states with protocols in place also require patient counseling and education, some form of continuing pharmacist education component, and communication with the patient's primary care provider.

Unrestricted Category-Specific Prescribing¹⁰

Unrestricted category-specific prescribing models afford pharmacists autonomous prescribing authority and do not require the supervision of a collaborating provider or a state organization or agency.

Medications that may be prescribed under this model do not require a specific diagnosis. This model includes a very narrow spectrum of medications, including immunizations, epinephrine autoinjectors, fluoride supplements, and opioid reversal agents.

Unrestricted category-specific models of prescribing do not dictate certain protocols for pharmacists to follow. Instead, they often reference prevailing treatment guidelines or professional association recommendations. For example, pharmacists in Idaho may prescribe dietary fluoride supplements if they follow the recommendations set by the American Dental Association (ADA).¹⁵ This model is the least restrictive for pharmacists because changes in parameters associated with authority, such as changes to treatment guidelines, likely will not necessitate any type of statute or regulatory change.

Table 1. Side-By-Side Comparison of Collaborative Practice Agreements and Statewide Protocols

Collaborative Practice Agreement	Statewide Protocol
Individual agreement is negotiated between prescriber(s) and pharmacist(s).	Standardized agreement applies to any willing and qualified pharmacist in the state.

Pharmacist(s) must identify collaborating physician(s).	A pharmacist is not required to identify a collaborating physician.
The agreement applies to a pharmacist or group of pharmacists specifically defined in the agreement.	The protocol could apply to all pharmacists in the state who meet the requirements of the protocol.
The agreement can be patient-specific, disease state-specific, or patient population-specific, depending on state regulations and the conditions of the agreement.	Rather than being specific to the patient, pharmacist, or provider, the protocol defines the patient populations eligible for services, as well as the minimum qualifications needed by pharmacists to participate.
49 states and the District of Columbia allow CPAs.	25 states have established protocols in place. ¹⁴
Services may be broad and may address a variety of conditions, both acute and chronic.	Protocols tend to focus on discreet services or conditions, such as dispensing naloxone, hormonal contraception, or smoking cessation therapies.
Pharmacist authority under the agreement may or may not be protocol-driven.	Pharmacist authority is protocol-driven.
Authority provided in the agreement is at the discretion of the collaborating practitioner(s), based on local clinical needs.	A pharmacist follows a protocol that is usually developed by a state board of pharmacy, board of medicine, board of public health, or that is jointly developed.
Parameters are modifiable on the basis of negotiations with the collaborating practitioner(s).	Parameters are not modifiable by individual pharmacists.

(Adapted from: Adams AJ, 2016)¹⁶

Education and Training

As of 2004, the Accreditation Council on Pharmacy Education (ACPE) requires that all students attending schools of pharmacy complete a Doctor of Pharmacy (PharmD) degree in order to be eligible to become a licensed pharmacist.¹⁷ ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education.¹⁸ The PharmD degree program encompasses rigorous educational curricula and clinical training requirements. Schools of pharmacy are required to meet specific standards established and outlined by ACPE in order to achieve and maintain ACPE accreditation.

As of 2015 (implemented in July 2016), ACPE accreditation standards have been updated to reflect the evolving role of pharmacists in team-based care settings. The standards have been refined to ensure that graduating students are prepared to achieve advanced clinical outcomes and collaborate with other health care providers to deliver the highest quality of patient care. Graduates are now assessed on key elements, such as foundational science knowledge, patient-centered and population-based care, medication use systems management, and health and wellness prevention and intervention strategies.¹⁸

The accreditation standards also require that graduates receive the skills training and professional development necessary to deliver care effectively. Curricula include skills training in areas such as problem solving, interprofessional collaboration, cultural sensitivity, and communication, as well as professional development in the areas of leadership, self-awareness, and innovation.¹⁸ Thus, PharmD program graduates receive the education, training, and professional skills needed to provide high quality patient care in concert with other members of the health care team. As the health care landscape continues to change and needs continue to shift, routine refinement of accreditation standards should remain a priority to ensure that pharmacists' skills and training are aligned with the contemporary health care system.

In addition to the ACPE accreditation requirements that must be met by PharmD programs, some states require pharmacists to complete some form of additional training before entering into CPAs or administering protocols. To date, the majority of statewide protocols adopted require pharmacists to complete continuing education (CE) programs before engaging in the protocol. The training and/or practice designation requirements to enter into CPAs, however, vary widely from state to state.¹⁹

In some states, such as Minnesota and Washington, pharmacists are permitted entry into CPAs without any additional education or training beyond that of a PharmD program.^{20,21} Other states, such as California and North Carolina, require pharmacists to obtain an advanced practice designation before they are eligible to enter into CPAs.¹⁷ Pharmacists seeking recognition in California as an “advanced practice pharmacist (APP)” must fulfill at least two of the following qualifications: earn certification in a relevant area of practice, complete a postgraduate residency, or have provided clinical services to patients for at least one year under a CPA or protocol with another practitioner. Similarly, pharmacists seeking recognition in North Carolina as a “clinical pharmacist practitioner (CPP)” must meet certain criteria and receive approval from both the state pharmacy and the state medical boards.¹⁷ Still, other states allow pharmacists entry into CPAs without an advanced practice designation but with additional training.

Documentation and Communication

Two key components involved in the different prescriptive authority models are documentation of delivered services and communication with the collaborating provider(s). Though many states have laws

explicitly outlining what should be documented, appropriate documentation should be standard practice.²² Comprehensive access to electronic health records (EHRs) and other health information technology (HIT) can aid pharmacists in this process. Although documentation of services delivered can be completed through paper charting or electronic software systems, EHR access may allow pharmacists to view nurse and physician notes, patient vitals and laboratory results, care plans, and other important information needed to deliver patient care.¹² In addition, it assists pharmacists in communicating patient care activities to other members of the health care team. Pharmacist access to EHRs may also potentially help reduce hospital or long-term care readmission rates, facilitate enhanced medication reconciliation, and improve quality measures and patient outcomes.^{23,24}

Identifying the appropriate documentation and record keeping requirements in any CPA or protocol is recommended to ensure that all participating parties meet the standards of expectation. Delivered services may be documented by use of a Subjective, Objective, Assessment, and Plan (SOAP) note or forms tailored specifically to the patient care service being provided. Structured electronic documents, such as the pharmacist e-care plan, are being developed to standardize documentation formats that will be shared electronically between health care professionals and organizations as part of the EHR infrastructure.

Effective communication among team members is at the core of the coordinated care approach. Efficient communication strategies allow health care team members to build trust with one another and to deliver care in a more cohesive fashion. Information may be exchanged via email, fax, telephone, text messaging, live conversation, and so on.²⁵ Similar to the previously mentioned documentation requirements, some states also have specific regulations regarding communication, such as the scope of information and the time frame in which it is communicated. When necessary, pharmacists practicing under prescriptive authority models should communicate therapeutic interventions with the patient's collaborating primary care provider. In addition, any other relevant patient information or changes in any of the patient's conditions should also be communicated. Appropriate and efficient communication will facilitate continuity of care, build trusting relationships, and contribute to meeting quality metrics.

Referral

In addition to routinely communicating with the primary care provider and documenting all patient interactions and therapy changes, pharmacists should also be diligent in ensuring that patients are referred back to the physician in any situations that necessitate referral. CPAs may include a visit protocol, which pharmacists may use to guide their interactions with patients. Algorithms for treatment may also be included in the agreement. Alternatively, other agreements may simply advise referencing and following evidence-based guidelines.

Pharmacists are responsible for ensuring that they are practicing within the scope of the CPA and/or statewide protocol being administered. For example, if a pharmacist is managing a patient's blood pressure according to a treatment algorithm defined in a CPA, that algorithm likely has a step recommending referral if the patient's blood pressure continued to remain uncontrolled. The pharmacist would also want to refer if he or she suspected some underlying cause of hypertension, if the patient's hypertension appeared resistant, or if some new symptom or complication suddenly presented that was outside the scope of the pharmacist's expertise and/or the CPA.

Although patient referral because of situations beyond the scope of the agreement is important, the pharmacist should also encourage the patient to see the collaborating provider routinely, however often the physician deems necessary. The time frame for routine referral should be discussed between the pharmacist and collaborating provider prior to the development of the CPA. The time frame for routine referral will likely vary among agreements, and may depend on such factors as physician preference, condition(s) being managed, and care setting.

Supporting Organizations

While numerous pharmacy organizations and associations have published literature on the expanding role of pharmacists in patient care, it is important to note that there is also additional support from outside stakeholders. As research data and study results continue to become more readily available, a growing number of stakeholders have begun to acknowledge the impact pharmacists can make when integrated into health care teams. Studies have demonstrated improved medication adherence, increased health care savings, and higher quality care overall.^{26,27}

One such advocate for the profession, the National Governors Association (NGA), recently published a resource on pharmacist integration into health care teams. In an evolving health care landscape, NGA recognizes the importance of leveraging the third-largest group of health care practitioners to bridge some of the chasms facing the health care system today. NGA highlights medication management and chronic disease management as high priority areas in need of pharmacists' services.¹⁷ The resource also identifies potential barriers impeding pharmacist integration, as well as viable solutions. Examples of different state CPAs are provided, and the resource encourages quality review and process improvement in terms of state board of pharmacy approval. States are encouraged to identify the most significant challenges impeding pharmacist integration and to examine other states' existing practice models for potential solutions.

Similar to NGA, the National Center for Chronic Disease Prevention and Health Promotion of the Centers for Disease Control and Prevention (CDC) published a resource to assist pharmacists in generating CPAs

and promoting team integration. The resource identifies specific strategies and measures that pharmacists can leverage to develop rapport with other health care practitioners and stakeholders involved.¹²

Barriers

Variability in the implementation, scope of practice, and patients and populations served in the prescriptive authority models creates a challenging atmosphere for broad-scale national uptake. Though all pharmacists receive the same education through PharmD programs, some states still restrict participation in CPAs to certain practice settings. As discussed earlier, significant variability also exists among states regarding the designation and training requirements related to entry into CPAs. These interstate regulatory discrepancies prevent chain pharmacies operating in multiple states from implementing expanded health care services at a national level.²²

Concerns from other health care providers and a lack of financial resources to support pharmacists providing care under these models pose additional challenges. Pharmacists can play an active role by educating other health care practitioners about the services patients can receive through these models. In addition to the barriers created by concerns from other providers, financial challenges exist because clear guidance or understanding as to whether pharmacists receive payment for the initiation of medications is lacking currently. As pharmacist prescriptive authority models continue to become more prevalent, focus should be directed toward the development of standardized guidelines related to payment for pharmacists' services, and potentially the establishment of payment methodologies that recognize and compensate for "degree of efforts" and contributions to the patient's overall care outcomes.

Conclusion

As the most accessible health care practitioners to patients in the United States, pharmacists are conveniently positioned to bridge many of the gaps in the health care system today. In addition to the vast number of areas and populations that are already classified as medically underserved, projections estimate that the nationwide shortage in the number of primary care physicians will continue to worsen. As the degree requirements, education, and training for pharmacists have progressively evolved over the years, the patient assessment skills and health care services that pharmacists are able to provide have also expanded.

Trends in the health care sector toward value-based patient care models are creating additional opportunities for pharmacists to practice in team-based settings through a coordinated care approach. These opportunities further allow pharmacists to demonstrate their value and the impact they can make as members of the health care team. The pharmacist-physician relationship is extended through CPAs, which expand pharmacists' authority to initiate, modify, and discontinue medication therapy and also order

laboratory tests to manage chronic disease conditions and, in some cases, certain acute conditions. Autonomous prescribing models addressing public health initiatives, such as statewide protocols, are also increasing patient access to care. Although many states have already begun to allow pharmacists to initiate medications through prescriptive authority models, much opportunity exists for implementation in states that lack legislation granting pharmacists prescriptive authority, as do additional opportunities related to expanded implementation in states that have such legislation in place.

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Relevant APhA Policies

2014 Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.

4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014) (Reviewed 2015)

2005, 1971 *Cigarette Sales in Pharmacies*

1. APhA recommends that tobacco products not be sold in pharmacies.
2. APhA recommends that state and local pharmacist associations develop similar policy statements for their membership and increase their involvement in public educational programs regarding the health hazards of smoking.
3. APhA recommends that individual pharmacists give particular attention to educating young people on the health hazards of smoking.
4. APhA recommends that APhA-ASP develop projects aimed at educating young people on the health hazards of smoking, such as visiting schools and conducting health education programs.

(JAPhA NS11:270 May 1971) (JAPhA NS45(5):555 September/October 2005) (Reviewed 2009)
(Reviewed 2014)

2013 *Revisions to the Medication Classification System*

1. APhA supports the Food and Drug Administration's (FDA's) efforts to revise the drug classification paradigms for prescription and nonprescription medications to allow greater access to certain medications under conditions of safe use while maintaining patients' relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists' implementation and provision of services related to a revised drug classification system.
3. APhA supports a patient care delivery model built on coordination and communication between pharmacists and other health care team members in the evaluation and management of care delivery.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications under FDA's approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists' input in the development and adoption of technology and standardized processes for services related to medications under FDA's defined conditions of safe use.

6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications under FDA's approved conditions of safe use.
7. APhA encourages the inclusion of medications and services provided under FDA's defined conditions of safe use within health benefit coverage.
8. APhA supports compensation of pharmacists and other health care professionals for the provision of services related to FDA's defined conditions of safe use programs.

(JAPhA 53(4): 365 July/August 2013)

2006 *Drug Classification System*

1. APhA supports restructuring the current drug classification system and drug approval process. Evidence should drive the restructuring beyond the current prescription and nonprescription classes to ensure appropriate access to medications and pharmacist services and improve medication use and outcomes.
2. APhA encourages pharmacists to exercise their professional judgment to manage access to nonprescription medications and dietary supplements to facilitate patient/caregiver interaction with their pharmacist.

(JAPhA NS46(5):561 September/October 2006) (Reviewed 2011) (Reviewed 2013)

2003, 2000 *Emergency Contraception*

APhA supports the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraceptive programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications.

(JAPhA NS40(5):Suppl. 1:S8 September/October 2000) (JAPhA NS43(5):Suppl. 1:S58 September/October 2003) (Reviewed 2006) (Reviewed 2008) (Reviewed 2009) (Reviewed 2014)

2013, 2009 *Independent Practice of Pharmacists*

1. APhA recommends that health plans and payers contract with and appropriately compensate individual pharmacist providers for the level of care rendered without requiring the pharmacist to be associated with a pharmacy.
2. APhA supports adoption of state laws and rules pertaining to the independent practice of pharmacists when those laws and rules are consistent with APhA policy.
3. APhA, recognizing the positive impact that pharmacists can have in meeting unmet needs and managing medical conditions, supports the adoption of laws and regulations and the creation of payment mechanisms for appropriately trained pharmacists to autonomously provide patient care services, including prescribing, as part of the health care team.

(JAPhANS 49(4):492 July/August 2009) (Reviewed 2012) (JAPhA 53(4):366 July/August 2013)

2013, 1980 Medication Selection by Pharmacists

APhA supports the concept of a team approach to health care in which health care professionals perform those functions for which they are educated. APhA recognizes that the pharmacist is the expert on drugs and drug therapy on the health care team and supports a medication selection role for the pharmacist, based on the specific diagnosis of a qualified health care practitioner.

(Am Pharm NS20(7):62 July 1980) (Reviewed 2003) (Reviewed 2007) (Reviewed 2008) (Reviewed 2009) (Reviewed 2011) (Reviewed 2012) (JAPhA 53(4):366 July/August 2013)

2016–2017 APhA Policy Committee Report

Pharmacists' Role within Value-Based Payment Models

The committee recommends that the association adopt the following statements:

1. APhA supports value-based payment models that include pharmacists as vital health care team members and that promote coordinated care, improve health outcomes, and lower total costs of health care.
[Refer to Summary of Discussion Items 3, 4.]
2. APhA advocates for the development and implementation of meaningful quality measures within value-based payment models that achieve optimal health and medication outcomes that pharmacists can impact.
[Refer to Summary of Discussion Items 5, 6.]
3. APhA advocates for mechanisms to recognize and compensate pharmacists for their contributions toward meeting quality measures and reducing total costs of care in value-based payment models.
[Refer to Summary of Discussion Items 5, 6, 7, 8, 9, 10.]
4. APhA advocates that pharmacists must have the ability to access and exchange electronic health record data within value-based payment models in order to achieve optimal health and medication outcomes.
[Refer to Summary of Discussion Item 11.]
5. APhA supports education, training, and resources that help pharmacists transform and integrate their practices with value-based payment models and programs.
[Refer to Summary of Discussion Items 12, 13.]

Summary of Discussion

1. The committee considered the terminology *value-based care models* but used instead the terminology *value-based payment models* because it more accurately reflects current and familiar terminology without limiting the scope of policy statements to existing models.
2. The committee reviewed current definitions and explanations for value-based payment models from the Centers for Medicare and Medicaid Services (CMS) and specifically reviewed the concepts described in CMS's Quality Payment Program. The committee also reviewed a white paper developed by Optum, titled "Can Value-Based Reimbursement Models Transform Health Care?"¹ and released in August 2013, to gain additional guidance when discussing value-based payment models.
3. The committee discussed the importance of concepts behind value-based payment models (coordinated care, improved health outcomes, and lower costs) and wanted to support the direction in which value-based payment models are leading patient care. The committee also wanted to ensure that pharmacists are recognized as a part of the health care team in value-based payment models.
4. The committee reviewed existing APhA policy on the topic of team-based care and believed a policy statement should support a pharmacist's role on the health care team within existing and future value-based payment models, regardless of setting.
5. The committee does not intend for this statement to require the creation of additional pharmacist-only measures, but rather to assist in identifying measures where a pharmacist can assist other providers within a value-based payment model.
6. The committee discussed specifically including only *patient care quality measures*, but it did not want to limit the statement to only patient care measures because pharmacists may have a broader effect on organizational quality or other measures.

7. The committee recognized the need for a pharmacist to be recognized as a provider and reviewed the APhA **2013 Pharmacists Providing Primary Care Services** and **2013 Ensuring Access to Pharmacy Services** policy statements. The committee discussed how recognition as a provider supports the economic standing of a value-based payment model.
8. The committee recognized that value-based payment models are measured through multiple metrics and that identification of the specific measures in which pharmacists have an effect on patient care is important.
9. The committee recognized that as outcomes become broader, attributing a pharmacist's role in meeting a measure will be increasingly difficult. The committee believed, regardless of the type of measure, that determining how pharmacists assist in meeting measures is imperative.
10. The committee discussed including the terminology *team-based care* within statement 4, but determined it was not necessary because a pharmacist will be practicing as part of the team within a value-based payment model.
11. The committee recognized the importance of health information technology (HIT) and reviewed the APhA **2009 Health Information Technology** and **2015 Interoperability of Communications Among Health Care Providers to Improve Quality of Patient Care** policy statements. Because patient data are essential to the success of a value-based payment model, the committee developed an additional policy statement regarding HIT to reiterate the importance of HIT not being a barrier.
12. The committee discussed the importance of continuing education providers and colleges and schools of pharmacy providing education related to value-based payment models.
13. The committee discussed that education, training, and resources should cover all aspects of specific payment models used within value-based payment models. Specifically, the committee recognized that risk-based contracting is an important strategy within value-based payment models that pharmacists need to understand.

14. The committee discussed the existing role of fee-for-service payments as part of existing models in the health care landscape. However, the committee did not address fee-for-service models because it wanted policy statements under this topic to focus on future value-based payment models.
15. The committee recognized the incentive measurements used in the Merit-based Incentive Payment System (MIPS) developed by CMS, Advancing Care Information, which outlines objectives and measures related to HIT services within value-based payment models. The committee discussed the importance of pharmacists' inclusion in the implementation of the following objectives: access to protected health information, electronic prescribing, patient electronic access, coordination of care through patient engagement, health information exchange, and public health and clinical data registry reporting. These objectives and measures are outlined in a Notice of Proposed Rule Making titled "Merit-based Incentive Payment System: Advancing Care Information," a document published by CMS.²
16. The committee discussed the concept of pharmacy group practices as a strategy for participation in value-based payment models, but it did not believe this strategy needed a specific policy statement because this concept is still in the early stages of development.

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Pharmacists' Role within Value-Based Payment Models
Background Paper Prepared for the 2016–2017 APhA Policy Committee

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2016–2017 Policy Committee to recommend policy to the APhA House of Delegates related to pharmacists' role in value-based care models.

Summary of Key Concepts

- An objective recent revision to the U.S. health care system provided health care access to all patients, while also addressing the cost and quality of health care. This approach has provided more opportunities for all health care professionals to better use their knowledge in serving patient health care needs. These changes have led to an increasing need for health care providers of all types to be more involved in the care of patients and assume greater roles and responsibilities.
- The current fee-for-service (FFS) model of health care delivery differs from value-based health care delivery in its overall approach and philosophy, but elements of the FFS model continue to be used in the model transition.
- The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) supports the development and testing of innovative health care payment and service delivery models, including value-based care models.
- Certain structural components must be put in place in order to maintain a successful value-based care model. A patient-centered, multidisciplinary approach to care is an important component of value-based health care delivery.
- Pharmacists already serve roles that fit into a value-based health care model. However, acknowledgment of a pharmacist as part of a multidisciplinary team is important in achieving a comprehensive team approach.
- Pharmacists' roles and scope of activities are typically regulated by their respective state board of pharmacy. Optimizing pharmacists' scope of practice in accordance with their training and knowledge is pertinent in adding value to the health care system.
- The Doctor of Pharmacy degree provides the majority of tools necessary to develop roles within value-based care models, and in some instances, additional training may be necessary.
- Patients see pharmacists as trustworthy members of the health care team who can add value to patients' overall health. Gaining the trust and recognition of patients and colleagues rests on pharmacists' demonstration of their value through their actions.
- Pharmacists affect patients' health care outcomes throughout the health care continuum, including the community and inpatient settings. Metrics will always be needed to help define these outcomes regardless of the health care delivery model.

- Currently, value-based care model examples exist where pharmacists are integrated and are serving the needs of their health care system.
- The pharmacy profession is working persistently to develop a comprehensive, structured plan to obtain compensation for the services it provides.

Introduction

The means by which patients access and use health care in the United States is ever expanding. The most significant legislative and regulatory overhauls of the U.S. health care system were the enactment of Medicare and Medicaid in 1965; the Medicare Prescription Drug, Improvement, and Modernization Act on December 8, 2003; the Patient Protection and Affordable Care Act on March 23, 2010; the Health Care and Education Reconciliation Act on March 30, 2010; and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) on April 16, 2015. Overall, expectations for health care systems have shifted to convert from supply-driven systems to patient-centered systems. Within these changes, a major objective has been to provide increased health care access to patients.¹ Pharmacists have always provided specific services to patients. However, the current attempts to increase access to health care have generated opportunities for pharmacists to step up and provide expanded patient care services in a variety of ways. In order for pharmacists to provide additional services, sustainable mechanisms for reimbursement and compensation must be established. Value-based care models have evolved rapidly. However, an outline defining a role for pharmacists and the care they can provide does not exist. This paper will discuss pharmacists' role within value-based care models.

Definitions

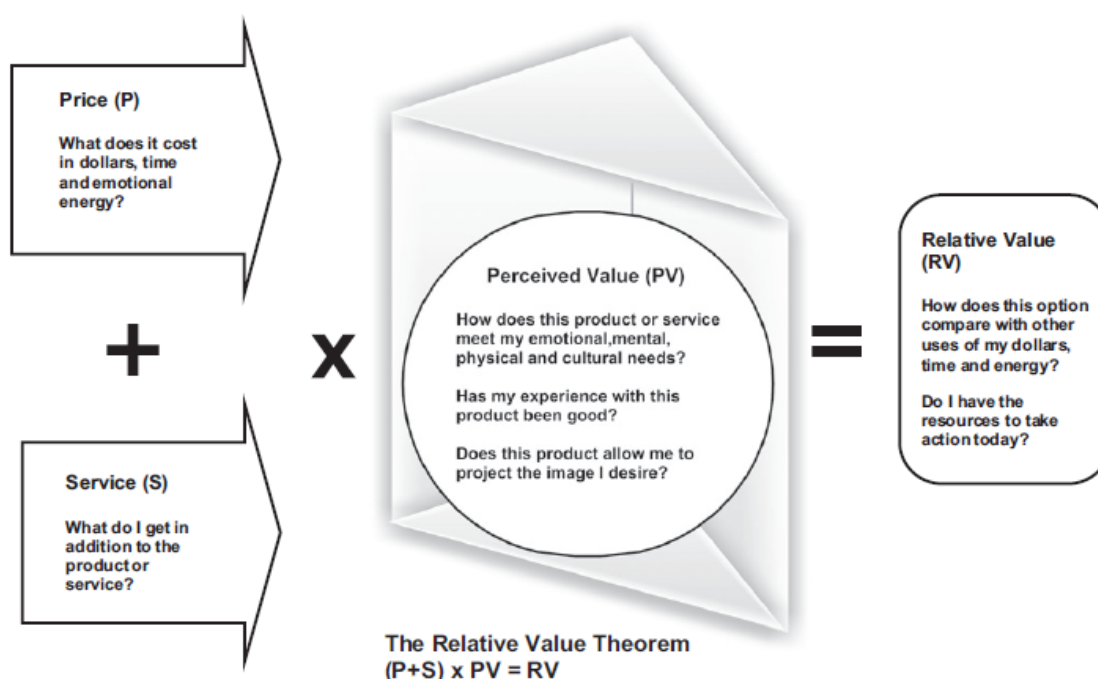
Defining the current health care model, fee-for-service (FFS) and the value-based care model will help define pharmacists' roles in a health care setting. CMS is transitioning away from FFS, the current central payment model in the United States, for physicians and other eligible professionals. Under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), reporting for two separate payment tracks—the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models—will go into effect in 2017. In the FFS model, services are unbundled and paid for separately. Essentially, FFS is a process in which physicians and other health care providers receive payment for each service performed (e.g., tests, laboratory tests, and office visits).²

Value-based care can present itself in a variety of models. To define value-based care, one must first consider the definition of *value* in relation to health care as well as the value equation ($\text{Value} = \text{Outcome}/\text{Cost}$). According to Professor Michael Porter of the Harvard Business School, value is “neither an abstract ideal nor a code word for cost reduction”; however, it “should define the framework for performance improvement in health care.” Value is defined as patient health outcomes achieved relative to the costs of care. It is measured by outputs. Value depends on the actual patient health outcomes, not the volume of services provided.³

The concepts of value and perceived value have been defined by Zeithaml. She proposed that value is a utility of the consumer's desire to obtain high-quality goods and services that meet the consumer's needs and wants, as well as the sacrifices made by the consumer to obtain those goods and services. These sacrifices are typically a resource such as money (cost). The perceived value is the patient's “overall assessment of the utility of a product based on perceptions of what is received and what is given.”⁴ Alston

and Blizzard define value as it relates to relative value (RV). RV can be expressed by a mathematical equation: $[RV = (P+S) \times PV]$, where P is price, S is service, and PV is perceived value. Figure 1, the Relative Value Theorem, as described by Alston, illustrates a more extensive definition of this concept.⁵

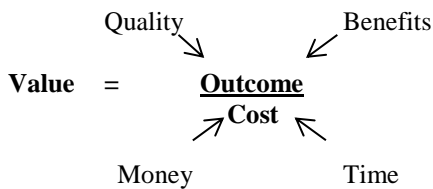
Figure 1. Relative Value Theorem



Source: Reference 5.

In a thriving health care system, value should always be centered on patients. The value equation can be viewed several ways, but the result is the same. Simply, value equals outcome over cost (Figure 2).³ Outcome, the numerator, takes into consideration a bundle of services that achieve quality and benefits. The outcome is what a patient receives from a health care provider as a result of care. Outcomes are condition specific and multidimensional. Cost, the denominator, refers to the total costs for the full cycle of care for a patient. Cost includes aspects of care such as time, which then relates to efficiency.¹ To increase value, one must increase the outcome (quality and/or benefits), lower the cost (money and/or time), or both. Value-based health care delivery is a model that is centered on patients and their condition and that considers value, not volume. Value should be universally measured and reported. Finally, the reimbursement component should be aligned with value and reward innovation.⁶

Figure 2. Value Equation



Source: Reference 6.

How Do Value-Based Care Models Differ from Fee-for-Service Models?

In the current FFS model of reimbursing providers for health care services, providers and organizations have incentives to do more. The more patients seen, tests ordered, and procedures performed, the more money the provider or organization generates. Sometimes, this model can prove effective. However, a volume-driven model often comes with abundant variation in the number of procedures and tests performed and patients seen. In health care, the FFS model incentivizes physicians to provide more treatments because payment depends on the quantity of care, rather than the quality of care. When patients are shielded from cost sharing by health insurance coverage, they are incentivized to seek any medical service that may do some good. Unfortunately, this course of action can raise costs of health care and discourage the delivery of efficient, effective, coordinated evidence-based care.⁷ In this model, as health plans try to control costs, often the compensation for services decreases, causing providers to try to see more patients, thereby spending less time per visit with patients. The result is that quality and continuity of care can suffer, leading to fragmented, inefficient care. Regarding the value equation, this model has the potential to decrease value.

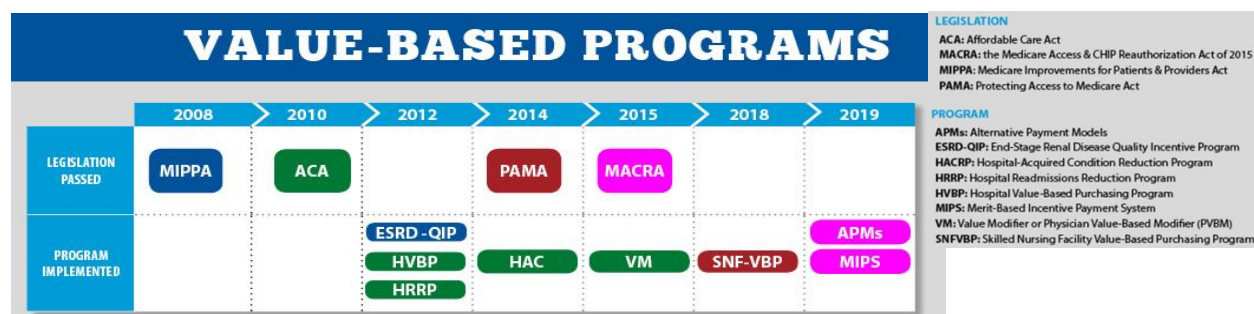
If value-based care models are successful, they can become very attractive to health care providers and organizations because they provide proof of enhanced quality and reduced cost of care. Ideally, quality is one of the most pertinent principles in health care. Patients' ultimate goals are to be treated appropriately (quality) and to become healthy (outcomes). If a health care model is aligned in a way that satisfies patients and providers alike, then health care is moving in the proper direction. For patients, this means safe, appropriate, and effective care with lasting results, at a justifiable cost. For providers, it means using evidence-based medicine with proven treatments and processes while taking into account patients' desires.⁸ The value-based care model uses a collaborative approach to treat patients whereby every team member works together for the same goal—making patients better and decreasing the possibility of their becoming sick again.

CMS Guidance for Value-Based Care Models

CMS has initiated programs that are part of the quality strategy to reform how health care is delivered. These programs align the goals of providing better care for individuals, better health for populations, and lower costs.^{9–11} The intent is to move provider compensation from FFS to provider compensation based on quality, rather than quantity. CMS initiated four original value-based programs: the Hospital Readmissions Reduction Program (HRRP), the Hospital Value-Based Purchasing Program (HVBP), the Value Modifier (VM), and the Hospital Acquired Condition Reduction Program (HACRP). CMS has also initiated other value-based programs, including the End-Stage Renal Disease Quality Initiative Program (ESRD-QIP), the

Skilled Nursing Facility Value-Based Purchasing Program (SNFVBP), and the Home Health Value-Based Program (HHVBP). See Figure 3 for the timeline for these programs.¹²

Figure 3. Timeline for CMS Value-Based Programs



Source: Reference 12.

Pharmacists' roles within each of these programs will evolve into more direct involvement in patient care and population health. To improve outcomes in the HRRP, pharmacists will need to be involved in patients' transitions of care. This approach will include focusing on management of medications during care transitions, improved coordination of care through communication with all providers involved, enhanced discharge education and follow-up, and the ability to view and document information using a shared electronic medical record to provide continuity of care. To improve outcomes in the HVBP, pharmacists could be involved in the formulary management and in committees outlining specific structures for each organization. The VM program lists physicians, practitioners, and therapists as eligible professionals. The pharmacist can fit into this model by helping providers meet the required quality metrics within the program. Pharmacists could aid in the safety, quality, care coordination, and medication costs of patients seen by each of these health care providers because this program is incorporated under the MIPS. The MIPS is a new program that merges the Physician Quality Reporting System (PQRS), the VM, and the Medicare Electronic Health Record (EHR) incentive program into a single program that measures Eligible Professionals (EPs) on quality, resource use, clinical practice improvement, and meaningful use of certified EHR technology.¹³ For 2017, the HACRP has a scoring system for a Total HAC (hospital acquired condition) Score, which is based on data for the six quality measures of Patient Safety Indicator (PSI) 90 Composite, Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Surgical Site Infection (SSI)—colon and hysterectomy, Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI).¹⁴ Pharmacists' roles in this model could include antibiotic susceptibility monitoring, antibiotic stewardship, and outpatient follow-up. Under each of these models, pharmacists are dependent on another provider allowing them to participate and share compensation for the services they provide.

Structuring the Components of a Successful Value-Based Health Care Model

Restructuring the mechanism by which health care is delivered requires defining aspects of care to build structure and accountability within a system. According to the work of Professor Michael Porter of the Harvard Business School, there are several key components to the success of a value-based health care delivery model:¹⁵

1. Organization of care around patient medical conditions and distinct segments by a multidisciplinary team
2. Measurement and tracking of the health outcomes and the actual cost of care for each patient
3. Reimbursement for the entire care cycle (bundled payments) for medical conditions
4. Integration of care across a network of facilities
5. Geographical expansion of excellent and innovative providers within their areas of expertise and integration of their care across community providers
6. Creation of a reliable information technology platform to support each of these processes

Pharmacists' integration into multidisciplinary teams should add value for patients, providers, and the system. Measuring health outcomes and tracking the cost of care for each patient are relevant to defining roles for a health care provider. Measurement and tracking will help determine exactly where the intervention is needed and also reduce the overlapping of roles and responsibilities of each member of the multidisciplinary team. Bundled payments, or payments for episodes of care, could serve in stimulating each provider to optimize health care outcomes because the provider is responsible for the patient across the continuum of care. In some aspects, bundled payments may also decrease patients' unwillingness or inability to seek care for a health care episode. Integrating a system of communication through shared access of a patient's care enables optimization of care and should decrease medical and medication errors. This integration also should eliminate duplicate work, thereby improving efficiency. Additionally, acknowledging and expanding the use of each provider's expertise should further facilitate a multidisciplinary approach to health care.

Furthermore, a recent study indicated that individual physicians might benefit from understanding the actual costs of care and the specific outcomes achieved by certain patients with certain conditions. Researchers from the University of Utah measured quality and outcomes from 2012 to 2016. In particular, they outlined a strategy based on three essential concepts. First, their business model became value improvement instead of FFS. Second, their work was organized around specific patient conditions. Third, their value improvement effort was driven by the creation of multidisciplinary teams.

In a one-year span from July 1, 2014, to June 30, 2015, researchers measured 1.7 million patient visits and 34,000 inpatient discharges. In their study, they determined that professional costs accounted for 24.3% of total costs for inpatient episodes and 41.9% of total costs for outpatient visits. They also broke down these costs into total direct costs for each specific disease state or health care event (e.g., sepsis, organ transplant, total joint replacement, hospital laboratory testing). Their results are important to consider. For example, for total joint replacement, clinical outcomes were improved while costs declined by 11%. Another example of improvement in quality and efficiency was modification of physical therapists' schedules so that most patients were out of bed or mobile on the day of surgery. This change was associated with a 9.5% decrease in average length of stay. These observations resulted in changes that can help improve the success of a value-based care model. Notably, these outcomes occur when health care teams place emphasis on specific conditions in which patients have similar needs and align a multidisciplinary team to serve the specific

patient or condition.¹⁶ In an editorial, Porter and Lee stated that these “findings offer proof of concept that improving value by patient condition can lead to lower costs and better quality—at the same time.”¹⁷ If prescribers and health care systems alike can better understand and align the costs and outcomes involved, they may aid in the integration of a pharmacist on a multidisciplinary team to improve outcomes.

Acknowledgment of a Pharmacist as Part of the Health Care Team

Pharmacists are already providing services within their current roles that should fit the model of a value-based health care delivery model. A key component to creating value and improving outcomes is acknowledgment of a pharmacist as part of the multidisciplinary health care team. Pharmacists serve an essential role in the medication-use process. In this role, they are part of each patient’s care in his or her journey throughout a health care event, no matter how small or large. Therefore, a pharmacist has an essential role in a successful value-based care model. As described by The Joint Commission, the medication-use process includes prescribing, dispensing, administering, monitoring, and systems and management control. See Table 1 for details on pharmacists’ roles in the medication-use process.¹⁸

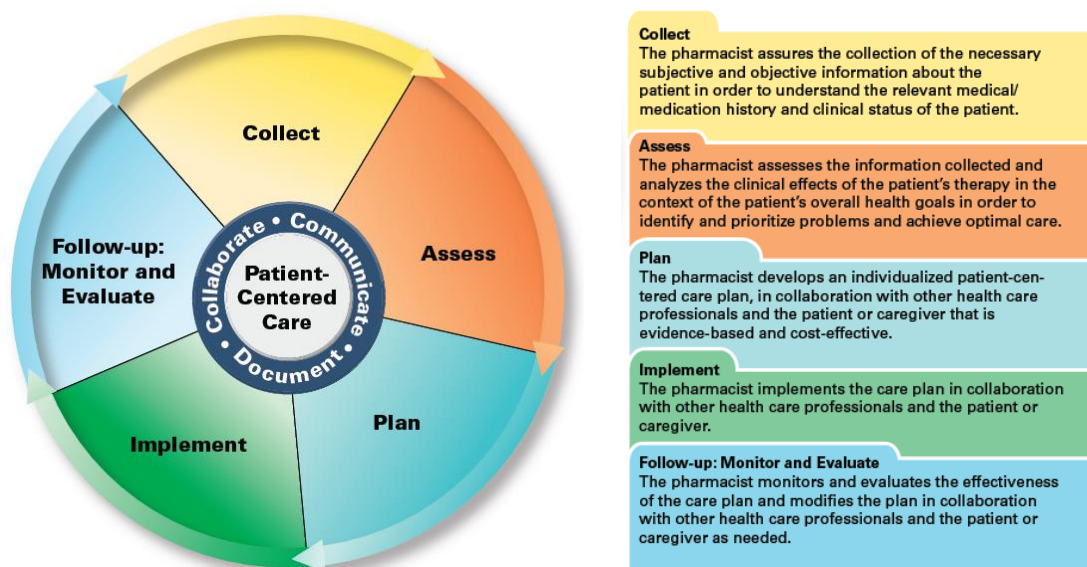
Table 1. Description of the Medication-Use Process

Role	Action
Prescribing	Assessing the need for and selecting the correct drug Individualizing the therapeutic regimen Designing the desired therapeutic response
Dispensing	Reviewing the order for correct dose and indication for use Processing the order Compounding or preparing the drug Dispensing the drug in a timely manner
Administering	Administering the correct medication to the correct patient Administering the medication when indicated Informing the patient about the medication Including the patient in administration
Monitoring	Monitoring and documenting the patient’s response Identifying and reporting adverse drug reactions Reevaluating the drug selection, drug regimen, frequency, and duration
Systems and management control	Collaborating and communicating among caregivers Reviewing and managing the patient’s complete therapeutic drug regimen

Source: Reference 7.

Additionally, pharmacists are trained to use a patient-centered approach in collaboration with other health care providers to optimize patient health and medication outcomes. See Figure 4 for the Pharmacists’ Patient Care Process that provides a framework for delivering patient care in any practice setting.¹⁹

Figure 4. Pharmacists' Patient Care Process



Source: Reference 19.

In addition to medication-related services through the medication-use process, pharmacists can serve roles in prevention and wellness and chronic condition management. If one considers pharmacists' abilities, training, and expertise, acknowledging a pharmacist as part of a team should serve to add value, decrease cost, and increase efficiency. Overall, outcomes based on metrics will typically be necessary, and pharmacists are already providing services within their current scope of practice that should fit within a value-based health care delivery model.

Pharmacists' Scope of Practice and Educational Training

A pharmacist's scope of practice refers to the boundaries in which one may practice. It is established by state legislatures and typically regulated by the State Boards of Pharmacy. In general, the goals of the Doctor of Pharmacy (PharmD) curriculum are to produce pharmacists who have the abilities and skills necessary to achieve certain outcomes related to health care and to improve patient safety. To afford student pharmacists the opportunity to develop a strong foundation to build on these skills, the curriculum emphasizes several areas of instruction. The American Association of Colleges of Pharmacy (AACP) publishes the Center for the Advancement of Pharmacy Education (CAPE) outcomes, which help define curricular priorities. These educational outcomes include the following:²⁰

1. Foundational Knowledge
 - a. Life-long learning (Learner)
2. Essentials for Practice and Care
 - a. Patient-centered care (Caregiver)
 - b. Medication use systems management (Manager)
 - c. Health and wellness (Promoter)
 - d. Population-based care (Provider)

3. Approach to Practice and Care
 - a. Problem solving (Problem Solver)
 - b. Educator (Educator)
 - c. Patient and health care advocacy (Advocate)
 - d. Interprofessional collaboration (Collaborator)
 - e. Cultural sensitivity (Includer)
 - f. Communication (Communicator)
4. Personal and Professional Development
 - a. Self-awareness (Self-aware)
 - b. Leadership (Leader)
 - c. Innovation and Entrepreneurship (Innovator)
 - d. Professionalism (Professional)

Student pharmacists are expected to achieve these outcomes by the end of their professional program.

In order for pharmacists to define and expand their roles in a value-based care model, legal and regulatory aspects also need to be considered. First and foremost, governing agencies and boards (pharmacy and medical) will need to support pharmacists in actively serving a role in a multidisciplinary health care team through scopes of practice that fully reflect their training. Furthermore, a pharmacist's scope of practice can be expanded through collaborative practice authority. Currently, 48 states and the District of Columbia authorize pharmacists to enter into collaborative practice agreements (CPAs) with a prescriber. CPAs expand the services a pharmacist may provide through prescriber delegation of certain functions in accordance with the terms of the agreement.²¹

Pharmacists are already the most accessible health care professionals. They are widespread throughout the nation in both urban and rural settings.²² Pharmacists' centralized placement in the community and their clinical expertise place them in the ideal position to both educate patients and advocate for the overall systems' health needs.

Pharmacists' Effect on the Value of Services Provided

A pharmacist serves a key role between a prescriber and patients. Typically, to receive medication or medication education, it is necessary for a patient to interact with a pharmacist. Pharmacists can have a significant effect on patient care through medication therapy management, medication reconciliation, monitoring of contraindications and medication overuse, monitoring of patient safety, development of personalized medication care plans, chronic disease state management, establishment of self-management goals, and communication and counseling on the care plan with a patient and others. Typical roles of a pharmacist include screening and early detection for disorders and disease states (e.g., dyslipidemia, hypertension, diabetes), health promotion and disease prevention (e.g., immunization, smoking cessation), medication history and assessment, review and application of evidence-based medication, pharmacotherapeutic interventions (e.g., drug-related problems, initiation, modification, discontinuation, monitoring), documentation, and communication and follow-up. There is clear evidence of value-added pharmacist services in various practice settings dating back several years. This evidence includes increased physician availability, decreased hospitalization rates,²³ medication cost savings,²⁴ improved quality of care through a more thorough work-up of patients, management of adherence issues,²⁵ improved treatment outcomes,²⁶⁻²⁸ and fewer adverse drug reactions.²⁹ More recently, a report released by Avalere Health

highlights numerous value-added services by pharmacists, including chronic disease state management, medication reconciliation, preventive care services, educational and behavioral counseling, and collaborative care team-based models.³⁰ As evidenced by a systematic review of 298 studies in the United States, direct patient care provided by pharmacists demonstrated favorable effects across various patient outcomes, health care settings, and disease states.³¹ To advance in a value-based care model, all pharmacists need to promote their services in order to spread awareness to other health care providers and patients.

Pharmacists' Role in the Outpatient and Inpatient Health Care Settings

Pharmaceutical care can be described as the “direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient’s quality of life.”³² Pharmaceutical care is taught in pharmacy schools and used throughout pharmacists’ careers in a variety of ways. Pharmaceutical care should include high-quality, coordinated, and continuous medication management.

The American Society of Health-System Pharmacists has set forth minimum standards for pharmaceutical care services in ambulatory care. These minimum standards include the following:³³

- Leadership and practice management
- Management of the medication-use process
- Drug product procurement and inventory management
- Patient care
- Preparation, packaging, and labeling of medications
- Medication delivery
- Evaluation of the effectiveness of the medication-use system
- Research

Value-based health care models affect the outpatient setting as well as the inpatient setting. Research suggests that the demand for primary care physicians will increase by 14% from 2010 to 2020. At the same time, the supply of primary care physicians will increase only marginally by 8%.³⁴ This research clearly acknowledges that a greater demand exists for multidisciplinary, team-based approaches to deliver primary care services.³⁵ Primary care has been described as the health care setting accountable for addressing the majority of a patient’s health care needs. Primary care is often the beginning and the end of the health care cycle. Pharmacists are capable of delivering expanded services through pharmaceutical care in collaboration with other health care providers. In these roles, pharmacists can provide benefits to patients including, but not limited to, valuable access to medication information, prevention and resolution of medication-related problems, improved outcomes, and increased patient satisfaction. Pharmacists’ primary responsibility should be to optimize patients’ medication regimen in order to improve patient safety and health care outcomes. In doing so, pharmacists should serve a role in each component of the medication-use process. The statement of the American Society of Health-System Pharmacists on a pharmacist’s role in primary care demonstrates that in collaboration with a prescriber, pharmacists’ roles could include the following:³⁶

- Performing patient assessment for medication-related factors
- Ordering laboratory tests necessary for monitoring outcomes of medication therapy
- Interpreting data related to medication safety and effectiveness
- Initiating or modifying medication therapy care plans on the basis of patient responses

- Providing information, education, and counseling to patients about medication-related care
- Documenting the care provided in patients' records
- Identifying any barriers to patient compliance
- Participating in multidisciplinary reviews of patients' progress
- Communicating with payers to resolve issues that may impede access to medication therapies
- Communicating relevant issues to physicians and other team members
- Providing individualized health promotion and disease prevention, including administration of immunizations where authorized
- Performing limited physical assessment and supervising medication therapy with appropriate authority for collaborative drug therapy management

In each role listed above, a pharmacist can provide a wide range of services, from consulting to direct patient involvement. To be a part of value-based care, the service must be proven to be cost-effective with improved outcomes. In the primary care setting, history has demonstrated well-documented cases of value-added services for chronic disease state management services (e.g., asthma, hypertension, dyslipidemia, anticoagulation, dermatology, diabetes, and psychotherapeutics).³⁷⁻⁴⁴

Additionally, 91% of Americans live within 5 miles of a community pharmacy.⁴⁵ Community pharmacists are the most accessible health care practitioners. Their roles in value-based care models include not only traditional medication dispensing but also direct patient care services. Some of these roles are outlined as follows:⁴⁶

- Medication dispensing
- Immunizations
- Wellness and prevention screening
- Medication management
- Chronic condition management
- Patient education and counseling

An overarching role for pharmacists could include helping define a high-risk patient as well as aiding in the management of the high-risk patient population. The role of inpatient–hospital pharmacists in value-based care models includes expanding their roles into a multidisciplinary approach and transitions of care. Inpatient–hospital pharmacists are in an ideal position to help manage a high-risk patient population because this population typically comprises patients with multiple chronic disease states taking multiple medications. The inpatient–hospital pharmacist could play a role in coordination of care by providing thorough education; notifying a patient's primary care clinical pharmacist, community pharmacist, or provider of his or her discharge; and performing thorough medication reconciliation at admission and discharge. Additionally, according to the Centers for Disease Control and Prevention, direct pharmacist involvement is one of the seven core elements of hospital antibiotic stewardship programs. The Centers for Disease Control and Prevention reports the necessity of appointing at minimum a single pharmacist leader as a drug expert responsible for working to improve antibiotic use.⁴⁷ Pharmacists' direct involvement in antibiotic stewardship in inpatient and outpatient settings can help decrease costs and improve patient outcomes, thereby increasing value.⁴⁸

Finally, medication reconciliation is extremely important in value-based care models. Pharmacists play an essential role in medication reconciliation in the inpatient and outpatient setting. As stated previously,

value-based care models include a comprehensive team-based approach to care. Medication errors can be better circumvented with pharmacist involvement. Around 60% of medication errors in patient charts occur at transitions of care.⁴⁹ Additionally, between 54% and 74% of patients admitted to a hospital may have at least one discrepancy in their admission medication history.^{50–54} Pharmacists' roles in medication reconciliation should include, but are not limited to, the following:⁵⁵

- Providing leadership in designing and managing medication reconciliation systems
- Educating patients and health care professionals about the benefits and limitations of the medication reconciliation process
- Providing medication reconciliation and medication management during care transitions
- Serving as patient advocates throughout transitions of care

Value-Based Payment Models: Accountable Care Organizations, Patient-Centered Medical Homes, and Bundled Models

The National Commission on Physician Payment Reform requested a restructuring of physician payment, including eventually rejecting the current FFS payment model in favor of a payment model that rewards value rather than volume. Several care and payment models have evolved from this ideal including, but not limited to, pay-for-performance (PFP), care coordination payments, bundled payments, patient-centered medical homes (PCMHs), and accountable care organizations (ACOs).⁵⁶

Pay-for-Performance

PFP is one of the most rudimentary models of payment reform. Essentially, it is a health care payment model that rewards providers for meeting benchmarks of quality service. This model generates a system that incentivizes health care providers to improve the quality of their services. PFP differs from FFS for all health care providers. For pharmacists specifically, a FFS model rewards production of more units of service such as the number of prescriptions filled. In contrast, the PFP model rewards the quality of those units, such as patient adherence to prescriptions dispensed. In relation to the value equation, cost needs to be considered as well. According to a systematic review on health policy, the “evidence is not convincing” from a cost-effectiveness perspective of PFP.⁵⁷ Unfortunately, additional costs are associated with managing and funding rewards. Cost-effectiveness also depends on a variety of factors, including the actual measures used to assess performance, the extent of the performance payments, and the recipients of the rewards.⁵⁸

Care Coordination Payments

CMS and certain private insurers use care coordination payments with some primary care practices. This model combines the FFS payment model with the addition of a small capitation payment. This additional payment is thought to enable resources and incentives for enhanced management of patients with chronic conditions. For example, a primary care office caring for 100 patients with diabetes may render a bill of \$40 per patient with diabetes per month. The theory is that the primary care office will use those additional funds to hire a health coach, nurse case manager, or ancillary staff member to aid in coordinating patients' control of their diabetes.⁵⁶ In this model, pharmacists placed in primary care practices can use their knowledge and skills in chronic disease state management to increase the value of care for the patient by assisting with care coordination and helping manage patients' diabetes, including their medications. Although pharmacists may not be able to render a bill for their services, this model could enhance the role of a pharmacist by increasing his or her visibility to the health care team and patient, improve the value of

services, and improve the number of services allotted to each patient. It also could create efficiencies in the primary care practice, and incentive payments for meeting quality metrics could contribute to supporting a pharmacist in the practice.

Bundled Payments

The bundled payment model differs considerably from the FFS model. Payments for a health care episode essentially are bundled together into a single payment. As described by CMS's Bundled Payments for Care Improvement Initiative, health care organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For Medicare, these models have the potential to lead to higher quality and more coordinated care at a lower cost.⁵⁹ One example would be a bundled payment for a heart failure episode. Substantial evidence shows that patients who experience heart failure are prone to increased hospitalizations as a result of inpatient and outpatient complications and lack of understanding of how to manage the disorder through medications, diet, and lifestyle.⁶⁰ Heart failure is one of the most expensive conditions billed to Medicare.⁶¹ All coordinated care of a patient from the time of the event, including admission, to discharge to post-discharge care is bundled together. In this model, all health care stakeholders are equally involved in the care of a patient. A bundled payment model is an opportunity for pharmacists to be involved in and to improve care. Here, pharmacists' roles could be focused on medication reconciliation, medication management, education, and transitions of care.

Patient-Centered Medical Homes

PCMHs are a team-based approach to comprehensive primary care coordinated by a personal physician or other primary care provider. The term *PCMH* encompasses five functions and attributes, including comprehensive care, patient-centered care, coordinated care, accessible services, and quality and safety.⁶² Comprehensive care requires a team of health care providers that could include, but is not limited to, prescribers, nurses, pharmacists, nutritionists, social workers, educators, and care coordinators. In the PCMH, pharmacists generally serve a pertinent role in chronic condition management and medication management. Pharmacists also can be instrumental in helping implement evidence-based prescribing guidelines, providing Annual Wellness Visits (AWV) and other preventive services, and helping meet required quality metrics for the practice. Being patient centered means that care is focused on the whole patient and providers work to equip patients with the necessary tools to self-manage and self-organize their care while considering patients' culture and values. Patient-centered care increases relative value by enhancing perceived value. Coordinated, patient-centered care is pertinent to decrease costs, errors, and confusion. Throughout a health care event, patients can experience many transitions of care. Aligning patients with providers helps build a network of communication and trust between the patient and the health care stakeholders. Providing patients with accessible services can decrease wait times and improve patient satisfaction and access to health care. Therefore, improving access should, in theory, improve value. Finally, quality and safety are of utmost importance. Using evidence-based medicine and clinical decision-support tools within a system helps improve performance, health outcomes, and safety and aids in the guidance of shared decision making. Therefore, improving quality and safety should, in theory, improve value.⁶³ Pharmacists can help improve access to health care and quality and safety by providing their expertise in these areas.

Accountable Care Organizations

As stated previously, comprehensive care aids in value. Regardless of the role of the health care provider, the goal of each care model should be outlined so that the method improves quality and reduces spending, enables the provision of comprehensive care, and maximizes the efficiency of the system within a bundle of care. ACOs are groups of physicians, hospitals, and other health care providers who voluntarily come together to provide coordinated, high-quality care to patients, demonstrating a value-based health care model. ACOs provide the pharmacy profession with the opportunity to optimize the use of medications and to help medication management services evolve into current and future health care models. ACOs focus significantly on population health by addressing gaps in care, developing and managing best practices and quality metrics, and using data analytics to identify high-risk patients in need of care. Pharmacists delivering direct patient care within ACOs focus on transition-of-care services and readmission reduction programs, medication adherence services, and medication management and chronic disease state management services.⁶⁴ Pharmacists' roles in ACOs could include quantifying and preventing medication discrepancies and errors, notifying health care providers when prescriptions are filled, minimizing polypharmacy by implementing protocols to eliminate duplicate medications, and participating in direct patient care. Additionally, a pharmacist could aid in formulary management by exploring coverage of providers' services and optimizing the use of the highest-value medications, medication reconciliation, and therapy optimization.

Others

The Part D Enhanced Medication Therapy Management (MTM) model launching through the Center for Medicare and Medicaid Innovation (CMMI) in January 2017 may offer enhanced opportunities for pharmacists as well. Rolling out the model in five regions over a five-year period, CMS will relax current regulatory requirements for Part D MTM, allowing participating plans in those regions to deliver innovative MTM services. The objectives of this program are for stand-alone Part D Prescription Drug Plan sponsors to identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen system linkages. These strategies should permit individualized health care interventions through a multidisciplinary approach, and pharmacists' roles can align with each incentive.⁶⁵

Medicare also has outlined a value-based insurance design model that is ready to begin operation in January 2017. This model is focused on chronic conditions and should reduce costs for medications and health care services that are considered most effective for chronic conditions. In each of these models, pharmacists' roles could include development and use of clinical pathways based on the most effective treatment through evidence-based medicine. Promotion of ongoing research to monitor outcomes that can involve pharmacists will be needed.⁶⁶

Current Examples of Pharmacists Involved in Value-Based Care Models

At Kannapolis Internal Medicine in Kannapolis, North Carolina, pharmacists have integrated into a PCMH model. Essentially, the pharmacists are involved in a multidisciplinary approach to care in a variety of chronic disease state management models. Their model has been shown to improve value, and some pharmacists are clinical pharmacist practitioners as well. In this model, pharmacists' roles include a collaborative practice approach to care whereby the pharmacists optimize a patient's medication regimen based on the patient's medical conditions. A manuscript by Sheehan et al. illustrates some of the pharmacists' services performed as the main care provider for each chronic disease state, and resulting

effects, with regard to medications for anticoagulation, diabetes, dyslipidemia, metabolic syndrome, hypertension, and chronic obstructive pulmonary disease (COPD). Over a one-year review in 2012, Sheehan et al. noted the following under the pharmacists' services:⁶⁷

- Anticoagulation:
 - Share of INRs (international normalized ratios) in range on warfarin was 74.62% (higher than national average).
 - Time in therapeutic range was 82.95% (higher than national average).
- Diabetes:
 - Share of patients with A1Cs > 9% was 5.25% (lowest percentage in the local physician network).
- Dyslipidemia:
 - Of the 1,391 patients with dyslipidemia and diabetes, 54.43% achieved a low-density lipoprotein (LDL) < 100 mg/dL in 2012.
 - Of the patients with dyslipidemia with coronary artery disease (CAD), 82% achieved an LDL < 100 mg/dL and 43% achieved an LDL < 70 mg/dL in 2012.
- COPD:
 - Of the patients evaluated by the pharmacist, 82% said they experienced overall improvement in their COPD symptoms.
- Metabolic syndrome:
 - Only 6% of patients developed type 2 diabetes.
 - Only 11% of patients were diagnosed with CAD.
 - All patients improved in at least one of the following components: blood pressure, cholesterol, and fasting blood glucose.

Use of this model continues to spread across a variety of chronic disease states. It helps prove that pharmacists serve an integral role in the PCMH model. Also, the team-based approach helps achieve high-quality outcomes.

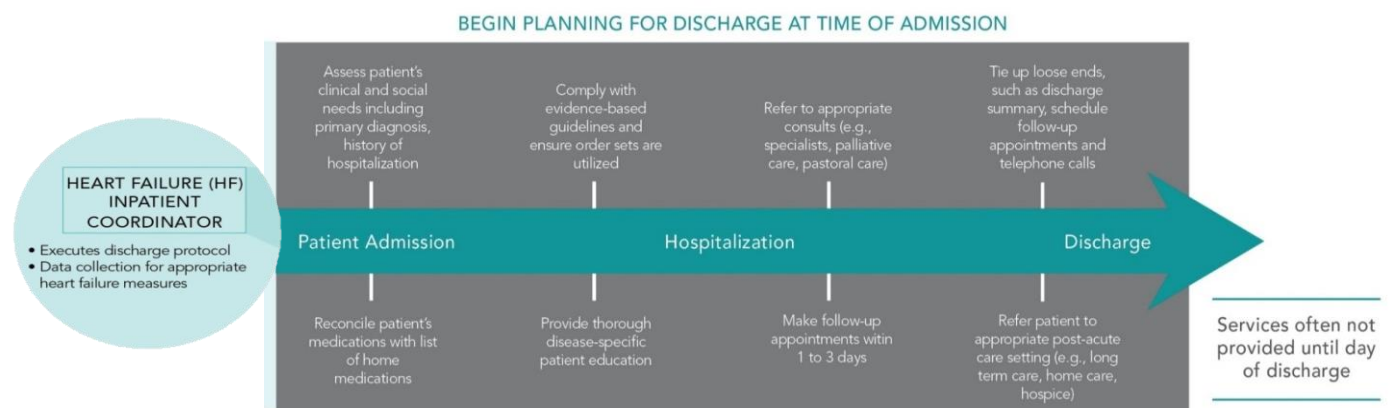
Another type of multidisciplinary approach to care has been demonstrated by the Advanced Heart Failure and Cardiac Transplant Service of the Sanger Heart and Vascular Institute in Charlotte, North Carolina, part of the Carolinas HealthCare System. This team manages several different cardiovascular disorders through a variety of clinic models. These clinic or disease state models all emphasize the same essential aspect of care—a multidisciplinary approach centered on a patient. The staff that assesses the patient includes a physician or advanced clinical practitioner (ACP) (i.e., PA-C or NP), clinical pharmacist, nurse, social worker, dietician, health advocate, and medical office assistant. One clinic is the Heart Success Transition Clinic (HSTC). This is a multidisciplinary team approach model and represents patient care from the beginning of a patient's hospital stay until a minimum of four weeks or visits after their discharge. The nurse navigator identifies patients and enrolls them in the HSTC, follows their progress throughout the clinic, and ensures that the patients have proper follow-up for their condition. The multidisciplinary team assesses a patient at each visit. A pharmacist's roles in this model include, but are not limited to, the following:

- Preparation and work-up of the patient:
 - Pharmacist aids the nurse navigator in his or her roles of inpatient and outpatient evaluation.

- Before the office visit:
 - Pharmacist meets with the ACP to discuss the patient, provide recommendations, and discuss a potential plan.
- During the office visit with the ACP, pharmacist, and nurse, and patient:
 - Pharmacist examines medications and aids in medication reconciliation.
 - ACP and pharmacist collaboratively evaluate a plan based on examination, medication reconciliation findings, and the patient's abilities and wishes.
- After ACP and nurse leave the office visit:
 - Pharmacist discusses and educates the patient on each medication (indication, dosing, monitoring, potential side effects, etc.).
 - Pharmacist aids in insurance and cost-containment management.
 - Pharmacist educates the patient on the medication plan and potential future plan with regard to medications.
 - Pharmacist provides tools necessary for adherence and education (e.g., pill planner, medication bag, pill splitter) and fills a pill planner if necessary.
 - Pharmacist discusses medications to avoid.
- Pharmacist aids in laboratory recommendations before and after each visit, follow-ups, refills, prior authorizations, and in providing any additional information dealing with medications.

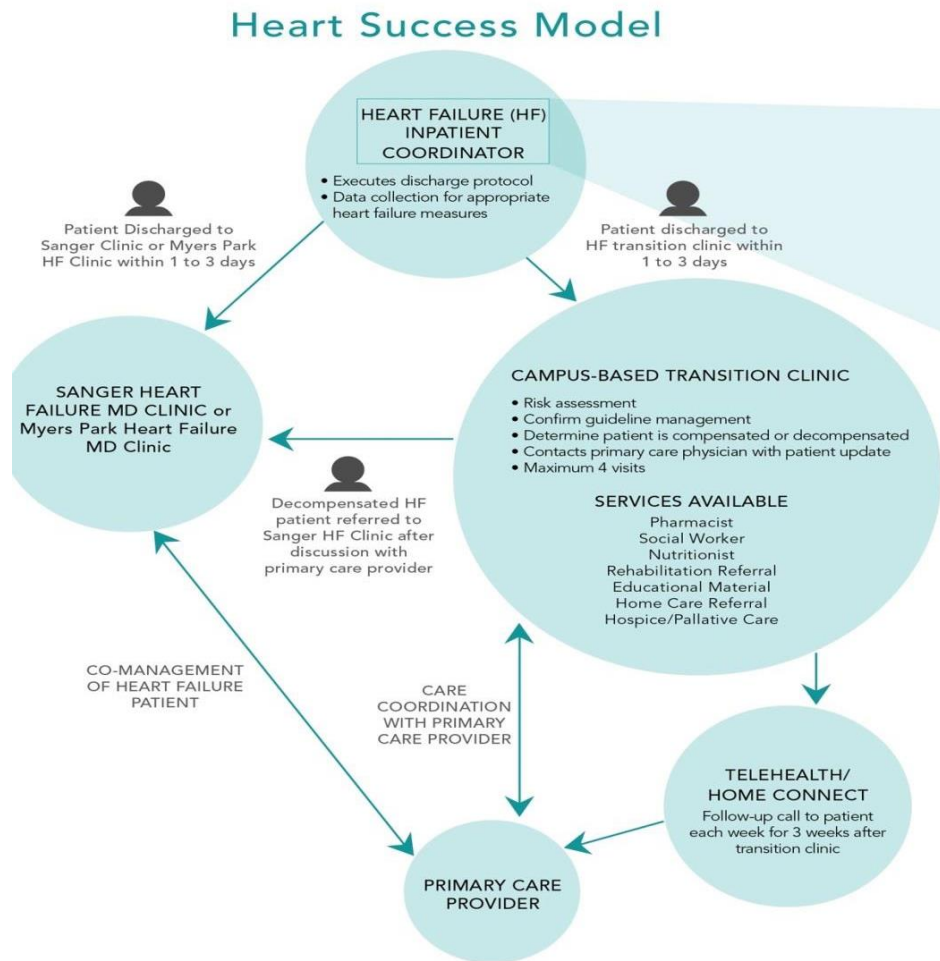
See Figures 5 and 6 for a pictorial description and timeline of the HSTC model by the Sanger Heart and Vascular Institute.⁶⁸

Figure 5. Planning Timeline of Heart Success Transition Clinic



Source: Reference 68.

Figure 6. Description of Heart Success Transition Clinic Model



Source: Reference 68.

The multidisciplinary team of the HSTC model continues to improve patient outcomes as compared to the national average. According to CMS (reporting period of July 2011 through June 2014), the median national average for heart failure readmissions was 21.9%.⁶⁹ Table 2 lists the readmission outcome measures for this team's multidisciplinary approach, including its HSTC, Longitudinal Heart Failure and Cardiac Transplant Clinic (HFC/Txplnt), Myers Park Heart Failure Clinic (MPHFC), and noncaptured patients.

Table 2. Readmission Statistics for the Advanced Heart Failure and Cardiac Transplant Services

Statistic	HSTC	HFC/Txplnt	MPHFC	Noncaptured patients	Total
Index admissions	258	271	81	254	864
Readmissions	17	40	13	48	118
Readmission rate (%)	6.6	14.7	16.0	18.9	13.6
Share of index Admissions (%)	29.9	31.3	9.4	29.4	100.0

Source: Reference 69

Furthermore, this clinic also uses a virtual heart success clinic that models the multidisciplinary team clinic approach with the addition of video software, virtual stethoscope hardware and software, and a home health or clinic nurse on the phone line helping assess the patient. The multidisciplinary team virtual clinic has proven value, including the following:

- Time, efficiency, and convenience: savings of > 34,500 miles (travel distance avoided) and > 950 hours for patients and families
- Noncapture rate: < 5% versus 30% at Carolinas Medical Center
- No-show rate: < 2% (Sanger Heart and Vascular Institute–Lincolnton) versus 8–9% at Carolinas Medical Center and Carolinas HealthCare System–Northeast
- All patient satisfaction surveys: top-notch rating
- Clinical facetime: improved to 100% in home
- Ratio of observed-to-expected readmissions: 0.78 (mortality rate 22% lower than expected)

In this multidisciplinary team approach, value-based care is used. In the clinic and virtual settings, pharmacists are not billing specifically for their services. However, readmissions are significantly reduced, and patient outcomes have improved. The clinic uses provider-based billing based on the level of service provided by the physician or the ACP. Although patients are not charged for use of the multidisciplinary team, the contribution margin is increased for the system. Specifically, patients are being monitored more appropriately, the number of diagnostic tests is decreasing and tests are ordered more appropriately, and overall patient outcomes are improved. In general, final revenue can be related to patient outcomes. Clearly, a pharmacist serves many roles from medication reconciliation to education and follow-up in this setting. The pharmacist is able to provide patient care through the scope of practice and cognitive services to help achieve optimal outcomes efficiently. This clinic distinctly shows that value is created with a multidisciplinary team that includes pharmacists' involvement by reducing readmissions and costs, improving patient satisfaction, and improving outcomes.

Moreover, another model that brings together inpatient and outpatient settings is the Carilion Clinic in Virginia. It developed a project (involving one urban and six rural hospitals and 20 primary care practices) that unites hospital pharmacists, community pharmacists, primary care clinical pharmacists, and physicians to improve medication therapy and chronic disease state management for at-risk patients. The care delivery model trains pharmacists in transitions of care and chronic disease state management protocols. The

pharmacists have shared access to electronic medical records and participate in care coordination. This approach enables pharmacists to participate in improving medication adherence and management, ultimately resulting in better health, reduced hospitalizations and emergency room visits, and fewer adverse drug events for patients with multiple chronic diseases. This project is ongoing and helps prove that acute care pharmacists, ambulatory care pharmacists, and community pharmacists can serve major roles within value-based care models.⁷⁰

Challenges and Aspects That May Have Contributed to Lack of Pharmacist Involvement

Pharmacists face several challenges as their roles progress throughout health care evolution. Some of these challenges include building team dynamics, gaining nonintegrated access to medical records, changing the public's perception of the pharmacist, marketing pharmacists' services, delivering patient education, and being reimbursed for services. Building team dynamics is especially important and challenging because an overlapping scope of practice within a multidisciplinary team is likely to occur. However, clarifying roles and responsibilities of each team member will be necessary to enhance the dynamics and improve patient outcomes. Currently, a lack of communication exists between community providers.

Most pharmacists do not have access to patients' medical records or do not share similar electronic medical records. Creating a system of shared access should improve communication and decrease errors. This approach also would aid in developing pharmacists' role in better serving patients.

Additionally, changing the public's perception of pharmacists is particularly important. Pharmacists are already a trusted profession, but likely they are not yet viewed as members of a multidisciplinary team for the public. Marketing pharmacists' services always has been challenging. Pharmacists will need to educate patients and health care providers alike on the vast scope of practice that pharmacists can provide. Pharmacists' extensive expertise providing medication management will improve the prescriber's confidence in pharmacists' providing medication management services outside of the prescriber's office. Patient education is difficult for all providers. For pharmacists, effectiveness of patient education will need to be emphasized, and they will need training throughout school and via professional development. Pharmacists will need to explore different education methods for subjects such as group disease state, medication education visits, and interactive versus didactic education while also considering the varying levels of education and multicultural aspects among patients. Creating a demand for the cognitive services that pharmacists can provide will bring together team dynamics, marketing of pharmacists' services, and patient education alike. The development of demand and the creation of awareness will generate an improved recognition for reimbursement of pharmacists' services.

Future

As the U.S. health care delivery model moves toward value-based care delivery models, pharmacists will need to examine how to enhance their roles. Future directions for pharmacists in value-based care models include identifying representative metrics to measure the quality of care, measuring and documenting pharmacists' effect on longer-term health outcomes, and becoming collaborative providers or prescribers. Gaining trust from other health care colleagues and patients is extremely important for enhancing pharmacists' roles in an ever-expanding health care system. Furthermore, one would expect that expanding the regulatory boundaries of a pharmacist to permit prescriptive authority in collaboration with a physician would add value to a health care system. Finally, as stated by Desselle and Zgarrick, "One of the goals of

value-added services is to receive compensation for services. This means that the patient, insurance company, or some other entity has paid for the direct cost of the service plus the perceived value of that service.”⁷¹ Pharmacists and their regulatory counterparts are needed to aid in the development of reimbursement mechanisms for pharmacists’ patient care services. Even in a value-based care model, pharmacists’ services can be measured and reimbursed through outcomes from the team rather than the individual.

Conclusion

Health care delivery is changing in a way that one hopes will provide pharmacists increased opportunity to add value to the system. Currently, the pharmacy profession is not fully integrated into a health care team so that it could better service the roles outlined in a value-based health care delivery model. A value-based health care delivery model is patient centered, includes a multidisciplinary team, and pays for the value versus volume of care. Typically, metrics will be necessary to measure outcomes, which will include integrating some degree of incentives similar to other health care delivery models. Pharmacists are accessible and trustworthy health care professionals. They have the training, knowledge, and tools to become a direct player in a value-based health care delivery model. Pharmacists are already serving roles that fit into a value-based health care model, and these include more direct patient care opportunities:

- Medication reconciliation
- Medication-use process
- Transitions of care
- Pharmacotherapeutic interventions
- Medication therapy management
- Chronic disease state medication management
- Immunizations
- General health and wellness prevention and screenings
- Patient education and counseling

Acknowledgment of a pharmacist as part of the multidisciplinary team is pertinent to achieving these roles. Support from legal and regulatory bodies is necessary. Pharmacists in each health care setting can serve in roles in a value-based health care model. Michael Porter, professor at Harvard Business School, described a solid foundation of structural components for a successful value-based health care delivery model, and a pharmacist should fit the mold in each of these components. Pharmacists’ are responsible for integrating themselves into a value-based health care delivery model and further defining their roles to fit this model. Challenges will need to be overcome, and metrics will need to be measured to improve outcomes. However, pharmacists are already adding value in the roles they serve. Pharmacists are in the ideal place to be directly involved in a value-based health care delivery model.

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Relevant APhA Policies

2011 Pharmacist's Role in Health Care Reform

1. APhA affirms that pharmacists are the medication experts whose accessibility uniquely positions them to increase access to and improve quality of health care while decreasing overall costs.
2. APhA asserts that pharmacists must be recognized as the essential and accountable patient care provider on the health care team responsible for optimizing outcomes through medication therapy management (MTM).
3. APhA asserts the following: (a) Medication Therapy Management Services: Definition and Program Criteria is the standard definition of MTM that must be recognized by all stakeholders. (b) Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model, as adopted by the profession of pharmacy, shall serve as the foundational MTM service model.
4. APhA asserts that pharmacists must be included as essential patient care provider and compensated as such in every health care model, including but not limited to, the medical home and accountable care organizations.
5. APhA actively promotes the outcomes-based studies, pilot programs, demonstration projects, and other activities that document and reconfirm pharmacists' impact on patient health and well-being, process of care delivery, and overall health care costs.

(JAPhA NS51(4) 482; July/August 2011)

2013 Ensuring Access to Pharmacists' Services

1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists' services.
3. APhA supports pharmacists' ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists' credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
6. APhA advocates for pharmacists' access and contribution to clinical and claims data to support treatment, payment, and health care operations.
7. APhA actively supports the integration of pharmacists' service level and outcome data with other health care provider and claims data.

(JAPhA 53(4): 365 July/August 2013)

2013, 2009 *Independent Practice of Pharmacists*

1. APhA recommends that health plans and payers contract with and appropriately compensate individual pharmacist providers for the level of care rendered without requiring the pharmacist to be associated with a pharmacy.
2. APhA supports adoption of state laws and rules pertaining to the independent practice of pharmacists when those laws and rules are consistent with APhA policy.
3. APhA, recognizing the positive impact that pharmacists can have in meeting unmet needs and managing medical conditions, supports the adoption of laws and regulations and the creation of payment mechanisms for appropriately trained pharmacists to autonomously provide patient care services, including prescribing, as part of the health care team.

(JAPhANS 49(4):492 July/August 2009)(Reviewed 2012)(JAPhA 53(4):366 July/August 2013)

2013, 2001, 1994 *Pharmacist-Patient-Prescriber-Payer Responsibilities in Appropriate Drug Use*

1. APhA advocates the following guidelines for pharmacist-patient-prescriber-payer responsibilities in appropriate drug use:

(a) Pharmacists' Responsibilities

- Serve as a drug information resource;
- Provide primary care;
- Collaborate with the prescriber and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
- Identify formulary or generic products as a means to reduce costs;
- Intervene on behalf of the patient to identify alternate therapies;
- Educate the patient about the treatment regimen and expectations, and verify the patient's understanding;
- Identify, prevent, resolve, and report drug-related problems;
- Document and communicate pharmaceutical care activities;
- Monitor drug therapy in collaboration with the patient and prescriber to ensure compliance and assess therapeutic outcomes;
- Maintain an accurate and efficient drug distribution system; and
- Maintain proficiency through continuing education.

(b) Patients' Responsibilities

- Assume a responsibility for wellness;
- Understand the coverage policies of their benefit plan;
- Share complete information with providers, including demographics and payment mechanism(s);
- Share complete information regarding medical history, lifestyle, diet, use of prescription and over-the-counter medications, and other substances;
- Participate in the design of the treatment regimen;
- Understand the treatment regimen and expected outcomes;
- Adhere to the treatment regimen; and
- Alert prescribers and pharmacists to possible drug-related problems or changes in health status.

(c) Prescribers' Responsibilities

- Assess and diagnose the patient;

- Share pertinent information in collaboration with the pharmacist and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
- Clearly communicate the treatment plan and its intended outcomes to the patient directly or in collaboration with the pharmacist;
- Remain alert to the possible occurrence of drug-related problems and initiate needed changes in therapy;
- Collaborate with the patient and the pharmacist in drug therapy monitoring; and
- Maintain proficiency through continuing medical education.

(d) Payers' Responsibilities

- Determine the objectives and desired benefits of pharmacy service;
- Design the coverage with patient and provider input using products and services to produce beneficial outcomes;
- Contract with providers on the basis of outcomes and efficient use of resources;
- Adopt efficient, clear, and uniform administrative processes;
- Communicate requirements of compensation for levels of care;
- Educate patients and providers about current eligibility and benefit information;
- Expeditiously process payments; and
- Be responsive to advances in contemporary practice.

(Am Pharm NS34(6):57 June 1994)(JAPhA NS41(5):Suppl.1:S9 September/October 2001)(Reviewed 2008)(Reviewed 2010)(Reviewed 2011)(Reviewed 2012)(JAPhA 53(4):367 July/August 2013)

2005, 1993 *Payment System Reform*

1. APhA must advocate reform of pharmacy payment systems to enhance the delivery of comprehensive medication-use management services.
2. APhA must assume a leadership role, in cooperation with other pharmacy organizations, patients, other providers of health services, and third-party payers, in developing a payment system reform plan. 3. APhA should encourage universal acceptance of all components of pharmaceutical care and their integration into pharmacy practice to support payment for services.

(Am Pharm NS33(7):53 July 1993) (Reviewed 2005) (Reviewed 2009)(Reviewed 2011)

1994 *Product and Payment Systems*

1. APhA shall work with public and private sectors in developing timely educational processes which assist pharmacists to implement patient care, understand new payment systems, and apply emerging therapeutic advances to achieve desired patient outcomes.
2. APhA supports payment systems that distinguish between compensation for the provision of pharmaceutical care and reimbursement for product distribution.
3. APhA shall participate in the identification, development, and implementation of models for procurement and handling of therapeutic and diagnostic pharmaceutical products and devices which assure the continuous provision of pharmaceutical care by pharmacists.

(Am Pharm NS34(6):56 June 1994) (Reviewed 2005) (Reviewed 2009) (Reviewed 2010)

2016–2017 APhA Policy Committee Report

Pharmacy Performance Networks

The committee recommends that the association adopt the following statements:

1. APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.
[Refer to Summary of Discussion Items 2, 3, 4, 5, 6.]
2. APhA urges public and private payers to develop transparent and fair reimbursement strategies for medication products separate and apart from performance measurements associated with the provision of pharmacists' patient care services.
[Refer to Summary of Discussion Items 7, 8, 9, 10, 11, 12.]
3. APhA advocates for prospective notification of evidence-based quality measures that will be used by a performance network to assess provider and practice performance. Further, updates on provider and practice performance against these measures should be provided in a timely and regular manner.
[Refer to Summary of Discussion Items 12, 13, 14.]
4. APhA supports pharmacists' professional autonomy to appropriately identify and select the interventions that improve evidence-based quality measures within performance networks.
[Refer to Summary of Discussion Items 15, 16, 17.]

Summary of Discussion

1. The committee first acknowledged APhA's antitrust policies before discussing this topic and developing associated policy statements. The committee inherently did not want to oppose parts of contract negotiations.
2. The committee reviewed the APhA **2011 Pharmacy Practice Accreditation** policy statement on pharmacy practice accreditation and acknowledged that accreditation can be a mechanism for the credentialing process for pharmacy performance networks.
3. The committee discussed that the pharmacy performance network topic should focus on the value of pharmacists and pharmacies in affecting performance in a given network. The committee was not tied to a single definition for *performance network* and determined that coordination of the provider working with the payer to improve outcome measures that affect the Triple Aim (improve outcomes, increase access, decrease cost) was the best focus for these statements.
4. The committee discussed how networks are driven and defined primarily by health plans and/or pharmacy benefit managers, but noted that nothing precludes pharmacies or pharmacists from creating their own performance networks. Pharmacy performance networks could be created by payers, individual practices, or anyone who has a common goal in meeting certain standards.
5. The committee discussed the potential existence of a performance network as part of a larger offering of additional networks for pharmacies as a means to avoid reducing access to patients.
6. The committee discussed that the goal for performance networks related to pharmacy services is to provide adequate patient access to high-quality pharmacists or pharmacies. The committee recognized that performance networks should not be used by a health plan or pharmacy benefit manager to recoup fees imposed on it by another source.

7. The committee discussed the importance of each practice setting developing and implementing strategies related to performance measures. A pharmacist is the individual who determines what is best for the patient at the setting where services and medications are delivered.
8. The committee discussed the use of compensation versus reimbursement and determined that reimbursement was the most correct choice for this topic.
9. The committee discussed how the quality and performance of a pharmacist or pharmacy is not always related to a medication, and therefore a fee should not be imposed on product reimbursement because of variance in quality and performance. The committee acknowledged that a separate service reimbursement and product reimbursement should exist and that associated fees would be imposed on the respective reimbursement.
10. The committee discussed the current issue surrounding direct and indirect remuneration fees and other fees being imposed on pharmacies. The committee intended to keep the statement broad in order to avoid limiting it to a single type of fee or deduction to a pharmacy when future fees may arise.
11. The committee reviewed the APhA **2004, 1968 Manufacturers Pricing Policies** policy statement as it pertains to the issue of transparency related to pricing.
12. The committee acknowledged that transparency means prospective and retrospective disclosure of information as it applies to the inclusion of specific measures and to the calculation of payment related to performance.
13. The committee discussed that all measures included in performance networks should be evidence based and show improvement in patient outcomes. Although all measures may not always be tied specifically to medication, they should show a pharmacist's effect on total quality and costs of health care.

14. The committee discussed how a standard list of measures should be available for all pharmacy settings and that there would be flexibility in which of these standard measures pharmacies would then be measured and graded upon. The committee reviewed the existing quality measures, including CMS's Accountable Care Organization quality program measures, Pharmacy Quality Alliance–developed measures, measures used within the Comprehensive Primary Care Initiative, and measures to be included in the Medicare Access and CHIP Reauthorization Act of 2015.
15. The committee discussed the inclusion of both services and tools and determined that both are important to call out in the policy statement. Some aspects of patient care are more administrative by nature and are included in the term *tool*, whereas *services* includes activities related to cognitive services provided by a pharmacist.
16. The committee acknowledged that *processes* and *clinical interventions* include the Pharmacists' Patient Care Process by the Joint Commission of Pharmacy Practitioners, clinical interventions, documentation tools, and other tools and resources used by pharmacists.
17. The committee specifically used the term *appropriate* to ensure a measure would be used in the same manner that it was developed. The committee discussed the process of measure development and identified that use of a measure outside of the scope in which it was scientifically developed is inappropriate. The committee also acknowledged that measures should come with some form of guidance in order to ensure adherence to their scope of effective measurement.
18. The committee discussed the need for the use of quality measures to incentivize continuous quality improvement in the practice setting. The committee reviewed the nature of risk-based payment models and determined that if pharmacists participate in one of these models, then pharmacists need to be willing to risk losing dollars owing to a lack of performance.

19. The committee reviewed the need for pharmacist education, development, and training regarding performance networks, but believed that the important part of this policy topic is transparency. Therefore, a transparent process would result in pharmacists understanding how they are being measured and how any reimbursement would be affected by quality.

Pharmacy Performance Networks

Background Paper Prepared for the 2016–2017 APhA Policy Committee

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2016–2017 APhA Federal Fellow

Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2016–2017 Policy Committee to recommend policy issues to the APhA House of Delegates. As described herein, the policy is related to pharmacists' involvement in performance-based networks. The Board's guidance on this topic included, but was not limited to, issues related to (1) direct and indirect remuneration (DIR) fees and the negative implications for the profession and the delivery of care to patients; (2) performance measurement as it relates to pharmacies and pharmacists; (3) contract transparency between pharmacies and other organizations; and (4) potential harm to patients who are unable to choose which pharmacy to use to obtain their medications and patient care services.

Summary of Key Concepts

- The health care payment model is moving from a fee-for-service model to a quality-based payment model providing opportunities for pharmacists to affect quality measures.
- Numerous rating systems, such as the Part D Star Ratings program, have been developed to measure and assess the quality of health care provided to patients.
- Significant gaps still exist in the standardization and implementation of performance metrics in health care.
- A need exists for pharmacist education on current performance measurement, the way to access performance data, and the way such data ultimately affect payment.
- The definition and implementation of DIR fees have changed over time and affect the profitability and viability of community pharmacy operations.
- New legislation and payment models have created opportunities for pharmacists to partner with providers and access alternate funding streams.
- Concern exists about the lack of transparency in pharmaceutical benefit manager (PBM) contracts related to performance and other quality measures and compensation policy.

Background

The Centers for Medicare and Medicaid Services (CMS) defines quality measures as “tools that help measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care.”¹ These measures may be referred to as performance measures, star measures, quality metrics, or any other number of names. Regardless of the name used, the goal is the same—to recognize, reward, and improve the quality of the care delivered to patients. Payers across the United States currently use quality measures in performance-based networks to identify and reward high performers and best practices.

The ability to document appropriately the patient care delivered, as it relates to the quality measure, is an essential task in implementing and being compensated for the care provided. Additionally, a clear understanding of what is being measured by the person(s) delivering care and the way it is being evaluated by those paying for the care is needed. Given the multitude of different health care plans that a pharmacy may service, the disparity in the quality metrics being evaluated, and the lack of transparency in some plans as to how the metrics are calculated, tremendous potential exists for a negative effect on pharmacy operations and patient care, which is opposite of the intended purpose articulated by CMS for quality measures.

Pharmacy Profession's Role in Quality Measures

For well over half a century, agencies such as The Joint Commission have been involved in assessing the quality of health care organizations. This assessment affected prestige and accreditation but was not tied directly to funding. Change began in 2003 when The Joint Commission and CMS aligned their quality measures and published a document titled *Specifications Manual for National Hospital Inpatient Quality Measures*.² The goal of this process was to minimize data collection efforts for common measures so that these common data could be used to improve the health care delivery processes and provide a mechanism for benchmarking practices. Shortly before this period of time, the National Quality Forum (NQF) had been established and began creation of the quality measurement framework we see today.

NQF was created in 1999 after a presidential commission concluded that an organization was needed to promote and ensure health care quality and patient protection by assessing and measuring health care quality and reporting its findings publicly. NQF is the only consensus-based organization recognized by the Office of Management and Budget. Thus, its endorsed measures are used by federal, state, and private sector organizations to evaluate performance and share information.³

The pharmacy profession was not a primary stakeholder in the early discussions on quality. Because of the importance of and need for the pharmacy profession to have a voice in this discussion, the Pharmacy Quality Alliance (PQA) was established in 2006. Its initial focus was “improving health care quality and patient safety through a collaborative, consensus-based process aimed at defining performance measures that focused on appropriate use of medications and pharmacy services.”⁴ PQA’s focus broadened in 2009 as it moved to collaborate more with key stakeholders to improve all processes related to medications. PQA continues to evolve in its staffing, processes, and initiatives. It has a number of notable accomplishments over the past several years: receipt of NQF endorsement of several quality measures; use by CMS of a number of measures for evaluation of Medicare Part D plans; and inclusion as a member organization of the National Priorities Partnership convened by NQF.

The role of PQA continues to grow in effect and importance as quality becomes more and more linked to reimbursement and compensation. The traditional fee-for-service (FFS) payment structure is nearing its end as quality and value move to the forefront. This shift is reflected in PQA’s current mission statement: “improve the quality of medication management and use across healthcare settings *with the goal of improving patients’ health* through a collaborative process to develop and implement performance measures and recognize examples of exceptional pharmacy quality [emphasis in original].”⁵ On a broader

scale, this change is evidenced by the aggressive push of the Department of Health and Human Services (HHS) to move to value-based health care that measures both the quality and the cost of care delivered. HHS outlined its plan in early 2015:

HHS has set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. HHS also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs. This is the first time in the history of the Medicare program that HHS has set explicit goals for alternative payment models and value-based payments.⁶

Star Ratings

With the paradigm shift from using FFS to paying for quality, payers like CMS had to determine how to measure and assess this quality. This assessment is based on a set of predefined performance measures, and, in the case of CMS, measures form the foundation for many different programs, including the Part D Star Ratings Program. Part D prescription drug plans are rated between one and five stars depending on how a plan meets a variety of quality metrics, with five stars being the best.⁷ Plans with higher ratings might receive incentives such as better marketing or bonus payments, while poorly performing plans risk being dropped from the CMS contract. One should note that star ratings apply to health plans, not pharmacies, but pharmacies can affect the overall star rating through their services provided to improve patient health and outcomes. Pharmacies that positively affect quality metrics can see benefits such as preferred pharmacy network status, which would allow them to charge lower copays and have access to more patients.⁸ Although each plan determines its own metrics for quality, noting that PQA measures account for almost 50% of Part D summary ratings for stand-alone prescription drug programs is important.⁷

Though the star ratings system applies to Medicare only, HHS is soliciting participation from state and commercial plans as well. It hopes to align efforts across government and private sector plans to meet its goals for shifting the payment structure from FFS to performance based. As such, the Health Care Payment Learning and Action Network was established. It is a collaboration between CMS, private payers, employers, consumers, and state programs to support and expand alternative pay models for their programs:⁹

The Health Care Payment Learning and Action Network will:

- Serve as a convening body to facilitate joint implementation of new models of payment and care delivery,
- Identify areas of agreement around movement toward alternative payment models and how best to analyze data and report on these new payment models,
- Collaborate to generate evidence, share approaches, and remove barriers,

- Develop common approaches to core issues such as beneficiary attribution, financial models, benchmarking, quality and performance measurement, risk adjustment, and other topics raised for discussion, and
- Create implementation guides for payers, purchasers, providers, and consumers.⁹

Because this network will be building practice models, shaping collaboration efforts, and developing payment structures, pharmacists and pharmacy organizations absolutely must play a role.

Standardization of Metrics

As stated by PQA's executive director, Laura Cranston, last year, "It is critically important for pharmacists to understand not only what is being measured but also which payers are using the measures. Then, pharmacists can determine what role they can play in delivering point-of-care interventions and services that will help drive safer and more appropriate medication use in a measurable way."⁷

A significant number of quality metrics, with noteworthy variability between them, exist. These differences can be overwhelming to providers and pharmacies alike. This lack of consistency speaks to the need for standardized metrics, and efforts are being made to improve the current environment. An initial step occurred in February 2016, when an agreement was announced between CMS and America's Health Insurance Plans. This agreement outlines seven sets of standardized quality measures across both public and private payers.¹⁰ The focus areas surrounded specialty practice areas of cardiology, gastroenterology, HIV (human immunodeficiency virus) and hepatitis C, medical oncology, obstetrics and gynecology, and orthopedics. However, one of the sets has a much broader scope; it covers accountable care organizations, patient-centered medical homes, and primary care.¹¹ The overall goal of the agreement is to avoid the costs and confusion inherent in separate systems developed between public and private plans. This collaboration also should help provide more clarity to patients who will now have more information available for comparison shopping in the health care marketplace.

From a pharmacy standpoint, having standard core measures for different services would be helpful. Finding meaningful medication-related measures that matter is the ultimate goal. PQA is performing measure development work in this area and participating in national efforts to create core measure sets. By having a set of standardized metrics, pharmacies and pharmacists can gain insight to identify areas that they might affect, benchmark their performance against high-performing organizations, and seek to improve revenue streams on the basis of actions taken on the data.

Access to Data

Accompanying the movement to more standardized quality metrics is a need to identify the way to gather the data regarding how a particular provider, plan, or pharmacy is meeting the metric. Even just a few years ago, this endeavor was very difficult. Metrics were designed for health plans, not for pharmacies. Additionally, most pharmacists lacked the ability to access data on the metrics being measured by the health plans. This circumstance affected the average community pharmacist's ability to identify areas in which to affect practice and to improve the quality of care provided to patients.

In an effort to address this deficiency, PQA partnered with CECity in 2013 and created Pharmacy Quality Solutions (PQS). Their goal was to create a measurement tool for health plans and pharmacies that is timely, reliable, actionable, and simply understood.¹² PQS's most widely used resource, EQuIPP (Electronic Quality Improvement Platform for Plans and Pharmacies), is a national platform for quality measurement and benchmarking. By serving as a neutral intermediary and aggregating data from multiple health plans and pharmacies, PQS hopes to foster collaboration among health plans, PBMs, and pharmacies. As of October 2015, EQuIPP encompassed prescription claims data for more than 55% of Medicare beneficiaries nationwide and was used in almost 90% of community pharmacies.¹³

One of PQA's early demonstration projects showing the value of such a tool was dubbed "The Pennsylvania Project." The study involved more than 29,000 patients across more than 200 community pharmacies. The pharmacists involved initially received training on quality and the way to interpret quality report cards. The second phase of the project included pharmacists taking action on adherence data reflected in quality reports received in the pharmacies. Pharmacists involved also received training on how to assess adherence using established survey tools as well as access to monthly benchmarking reports from PQS. Adherence was assessed using proportion of days covered (PDC). A PDC of 80% (PDC80), meaning a patient had medication on hand for at least 80% of the expected period, is considered to be the minimal amount of medication needed to achieve the desired clinical outcome.¹⁴ At the end of the one-year pilot, PDC80 increased in the study group, as compared to the control group, ranging from a 3.1% increase in PDC80 for beta-blockers and a 4.8% increase for diabetes medications. As adherence increased, costs decreased. The study results showed an annual decrease of \$341 per patient in health care costs for patients on diabetes medication and \$241 per patient for those on a statin medication.¹⁴ This pilot study emphasizes the value of the community pharmacist in decreasing overall health care costs, as well as the value of using and tracking quality metrics to improve the overall care of the patient.

Reimbursement Structure

Complicating the pay-for-quality discussion is the current landscape of compensation for pharmacy services in general. Navigating the reimbursement landscape for community pharmacies can be difficult. Medicare, Medicaid, and private plans all use different processes to calculate the reimbursement paid on prescription medications. Average manufacturer price (AMP) is the principle component for drug pricing under Medicaid. CMS then uses this number, along with several weighted factors, to calculate the federal upper limit (FUL), which is the actual number used for Medicaid payment.¹⁵ With the advent of the Affordable Care Act, FUL reimbursement rates for brand name drugs and generic drugs available from multiple manufacturers were reduced. This calculation of lower FUL reimbursement became known as the maximum allowable cost (MAC). An additional variable is the ingredient cost calculation, which is determined by each state's Medicaid program and differs from state to state.¹⁶

These processes cover (or may not fully cover) only the ingredient cost of the medication being dispensed. A community pharmacy still must address rent, utilities, insurance, payroll, equipment, and patient care services related to the medication product. A dispensing fee comes into play at this point. The dispensing fee should be high enough to cover these expenses while allowing a little room for profit. However, in recent years, this area has seen drastic cuts from state Medicaid programs in their effort to

save dollars. Additionally, the Medicaid dispensing fee varies from state to state and consists of a sizable range of values, further emphasizing the need for consistency in pricing calculations and methodology.¹⁶

In an effort to increase pricing transparency, CMS issued its final rule for Part D prescription drug benefit programs in May 2015. This rule contained two main provisions that help create transparency. First, Part D drug plans and PBMs are now required to make available to contracted pharmacies their reimbursement rates under MAC pricing standards. Second, these reimbursement rates must be updated every 7 days.¹⁷ These changes went into effect for the 2016 plan year.

At the same time, CMS had planned to publish the final Medicaid AMP-based FULs in July 2015. However, because of concerns from the field regarding the rapid implementation timeline, this publication was delayed. The final AMP-based FULs became effective April 1, 2016, with a 30-day window for states to implement the FULs. CMS provided states 1 year to move to cost-based product reimbursement and make any necessary adjustments to dispensing fees.¹⁸ This approach would provide better updated pricing at the time of dispensing, thereby protecting pharmacists when the AMP-based FUL is actually less than the acquisition cost of the medication.

DIR Fee Issues

CMS established DIR fees to track rebates and other price adjustments affecting the cost paid by the consumer for a given prescription drug. The savings were then passed back to CMS.¹⁹ Apparently, the original intent of this measure was to develop a means to pass PBM savings back to Medicare. However, the definition and application of DIR fees have changed over time. DIR fees now encompass a wide range of definitions and costs that include the pay-to-play cost for a pharmacy to participate in a PBM's network, the adjustment of the MAC and the rate a pharmacy can expect to be reimbursed for a medication, and any adjustments to pharmacy fees (positive or negative) based on quality metrics.¹⁹

Problems arise with this system because pharmacies have no way to determine what profit, if any, is made at the point of sale. As a general rule, the PBM industry does not publish MAC rates, and it retains the right to change these rates for any reason and at any time.²⁰ Moreover, most DIR fees are assessed as part of the reconciliation and claims adjudication process, so the additional charges do not appear until several months later. Because of this delay, a pharmacy has extreme difficulty assessing its actual reimbursement rate at the start of a contract, at the dispensing of the prescription, and at the end of the contract term.²¹

On September 29, 2014, CMS published *Proposed Guidance on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions* (the Proposed Guidance), revising the definition of the “negotiated price.” This negotiated price would be the net of all price concessions and would eliminate possible sponsor manipulation of pharmacy network pricing when DIR fees are added to a year-end report rather than being applied as part of the negotiated price with the pharmacy.²² These proposed changes were slated to go into effect January 1, 2016. The National Association of Chain Drug Stores and National Community Pharmacists Association have lobbied CMS to require that the calculation of pharmacy reimbursement be reflected in the drug cost reported to CMS. They asserted that this requirement would increase pricing transparency, decrease the complexity of tracking prices, and ensure that pharmacy reimbursement structures were not the cause of increased Medicare costs.²³ Additionally, APhA urged CMS to consider working with health care plans to set reasonable thresholds for DIR fees.²² Unregulated

fee structures can limit pharmacy participation in Part D programs as pharmacies withdraw from networks with the result being limited patient access to pharmacy services.

The proposed guidance did not go into effect January 1, 2016, and has started gaining the attention of Congress. In June 2016, 30 members of the House of Representatives and 16 members of the Senate signed respective letters to HHS CMS Acting Administrator Andy Slavitt stating their support of the proposed guidance and requesting finalization and implementation of the proposed changes.^{24,25} Congress also introduced legislation in early September (H.R. 5951,²⁶ S. 3308²⁷) that would prohibit health care plans from retroactively being able to assess DIR fees on clean claims submitted by pharmacies. If passed, this legislation would allow community pharmacies to know the total cost of the claim at the time of processing.

Alternate Funding Streams

Just as pharmacists are trying to navigate star rating systems and DIR fees, physicians deal with similar challenges in navigating measures by the Physician Quality Reporting System and the Merit-based Incentive Payment System (MIPS). MIPS presents an emerging opportunity for pharmacists to collaborate with providers, increase future revenue streams, and improve overall patient outcomes.

On October 14, 2016, HHS issued its final rule to implement key provisions of the Medicare Access and CHIP Reauthorization Act of 2015. The overarching goal of the act was to align value-based health care delivery with payment models.²⁸ The final rule outlines a framework for a Quality Payment Program that includes two paths: MIPS and the Advanced Alternative Payment Models (APMs).²⁸ APMs provide opportunities for pharmacists working with physicians in accountable care organizations and patient-centered medical homes. For the 85% of providers forgoing the APM pathway, opportunities exist for pharmacist collaboration through the MIPS pathway.

MIPS is a pay-for-performance system in which base payments to physicians for services provided to Medicare beneficiaries will be increased or decreased by 4% to 9% annually on the basis of the physician's performance compared with other physicians.²⁹ Four performance categories will be used to make up the composite performance score to determine payment adjustments: (1) quality of care (replacing the physician quality reporting system); (2) resource use (replacing the cost component of the value-based modifier); (3) clinical practice improvement activities; and (4) advancing care information (meaningful use of certified electronic health record technology).²⁹ Pharmacists have the ability to affect both quality of care and clinical practice improvement activities, which encompass 65% of the MIPS weighting scale. This effect can be achieved through diabetic education, comprehensive medication reviews, reduction of hospital readmission, tobacco cessation counseling, and much more.³⁰ Additionally, opportunities exist to partner with physicians to provide chronic care management and transitional care management services. Many of the services pharmacists provide while assisting with MIPS can also meet the chronic care management standard. These activities justify additional discussions with providers on collaboration.

Contract Transparency and Patient Accessibility

If pharmacies or pharmacists are proactive, understand the metrics being measured, implement a means for data review and action, and establish provider collaborations, they still may find themselves at the mercy of an ambiguous or unclear contract. PBMs have a history of providing limited transparency in how much revenue they generate and whether this revenue is being shared according to terms of the contract.³¹ PBMs contend that providing these data will increase administrative costs and prevent PBMs from negotiating the largest rebate possible. However, data from an analysis provided to CMS show just the opposite. From 2006 to 2016, rebates grew from 8.6% to 16.8% despite more stringent transparency requirements for Part D plans.³²

PBMs continue to leverage their pull and force community pharmacies into some very rapid, difficult decisions. One recent example came at the end of May 2016. Humana sent a letter to pharmacies with a proposed amendment to its 2017 pharmacy provider agreement for the 2017 Part D plan year. In this letter, Humana outlined its plan to withhold a certain sum from every eligible claim that could be “earned back” on the basis of quality performance. From receipt of the letter, pharmacies would have 30 days to opt out or Humana would assume they agreed with the proposal. If a pharmacy decided to opt out, it would no longer be listed as an in-network pharmacy.³³

On the surface, the offer looked reasonable. A pharmacy that performed well would receive its withheld money. Pharmacies had the opportunity to make an additional amount by hitting the 80th percentile in adherence measures for three classes of drugs. The National Community Pharmacists Association dug deeper and identified concerns with the transparency of the document. First, the money would be taken from every eligible claim, not just those for the classes of drugs affecting the quality measures. Second, Humana lists classes of excluded claims but fails to define or provide examples of any of them. Finally, the letter suggests that any pharmacy hitting the 80th percentile of PDC would receive the withheld money plus the additional money as payback. However, because Humana would assess all pharmacies against each other, pharmacies would need to be in the 80th percentile of all participating pharmacies.³⁴ This approach would lead to a scenario where all pharmacies in the network would be performing at the 80th percentile for PDC, yet only 20% of them would receive the full reimbursement and the rest potentially would lose money per claim.

These types of contracts place community pharmacies in very difficult positions. Pharmacies must determine whether to accept the terms of a less favorable contract or risk losing a portion of their potential patient base. For patients, these types of contracts cause further contraction of the network and limit their choices of where they can obtain their care.

Model Networks

Although some PBMs and health plans are manipulating performance-based networks in a negative way, others have used this platform to recognize and reward quality pharmacy performance. For instance, Sunflower Health Plan is a state Medicaid program in Kansas. Sunflower Health Plan recognizes that community pharmacies accredited by the Center for Pharmacy Practice Accreditation improve health outcomes and lower health care costs for their patients. Thus, beginning April 1, 2016, Sunflower Health Plan has been paying an enhanced professional fee on every claim paid to a center-accredited pharmacy

within its network.³⁵ A second example is the Inland Empire Health Plan Pharmacy Pay-for-Performance Plan. Under this plan, Inland Empire Health Plan has partnered with PQS to develop a way to validate the roles of community pharmacies in promoting health care quality and develop a pharmacy payment model for outcome-based medication therapy management services.³⁶ Under the provisions of this plan, participating pharmacies are assigned a star rating based upon their performance in several quality metrics. All pharmacies that receive a 3-star rating (average) or better receive full reimbursement on their claims. For all pharmacies that excel and meet certain thresholds, an additional bonus payment is made every 6 months on the basis of store volume.³⁶ This approach shows a process the industry could adopt regarding pay for performance: establish clear metrics up front, provide them to the participating pharmacies, and assess no penalty on pharmacies that meet the metric and reward those that exceed the metric. Ultimately, the higher the quality of care the pharmacies provide, the lower the overall health care costs for the plan.

Conclusion

The advent of value-based care is upon the health care industry. Demonstrating quality is more important now than ever before. With this paradigm shift comes a plethora of opportunities for pharmacists and pharmacies to demonstrate their value at improving patient outcomes and reducing overall health care costs. As a profession, pharmacists must continue to push for transparency in determining both how quality metrics are developed and how pharmacists are compensated for their effect on those metrics.

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Relevant APhA Policies

2011 Pharmacist's Role in Health Care Reform

1. APhA affirms that pharmacists are the medication experts whose accessibility uniquely positions them to increase access to and improve quality of health care while decreasing overall costs.
2. APhA asserts that pharmacists must be recognized as the essential and accountable patient care provider on the health care team responsible for optimizing outcomes through medication therapy management (MTM).
3. APhA asserts the following: (a) Medication Therapy Management Services: Definition and Program Criteria is the standard definition of MTM that must be recognized by all stakeholders. (b) Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model, as adopted by the profession of pharmacy, shall serve as the foundational MTM service model.
4. APhA asserts that pharmacists must be included as essential patient care provider and compensated as such in every health care model, including but not limited to, the medical home and accountable care organizations.
5. APhA actively promotes the outcomes-based studies, pilot programs, demonstration projects, and other activities that document and reconfirm pharmacists' impact on patient health and well-being, process of care delivery, and overall health care costs.

(JAPhA NS51(4) 482; July/August 2011)

2004, 1968 Manufacturers' Pricing Policies

APhA supports pharmaceutical industry adoption of a "transparent pricing" system which would eliminate hidden discounts, free goods, and other subtle economic devices.

(JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

2013 Ensuring Access to Pharmacists' Services

1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists' services.
3. APhA supports pharmacists' ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists' credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.

6. APhA advocates for pharmacists' access and contribution to clinical and claims data to support treatment, payment, and health care operations.
 7. APhA actively supports the integration of pharmacists' service level and outcome data with other health care provider and claims data.
- (JAPhA 53(4): 365 July/August 2013)*

2012, 2005, 1969 Medicare and Patient Care Service

1. APhA believes that Health care, including the essential component of patient care services, should be made available to as many people as possible in our society through the most economical system compatible with an acceptable standard of quality.
2. APhA should support the Part B mechanism which is the voluntary supplementary medical insurance program financed equally by beneficiaries and the government.
3. APhA should oppose legislation which would restrict the Medicare drug benefit to specific, chronic diseases.
4. APhA should support the inclusion of patient care services under Medicare or any other federal financing mechanism, providing the program is designed to help persons who need it most and is administratively efficient and economical.

(JAPhA NS9:363 July 1969) (JAPhA NS45(5):558 September/October 2005) (Reviewed 2009) (JAPhA NS52(4) 460 July/August 2012)

2004, 1990 Freedom to Choose

1. APhA supports the patient's freedom to choose a provider of health care services and a provider's right to be offered participation in governmental or other third-party programs under equal terms and conditions.
2. APhA opposes government or other third-party programs that impose financial disincentives or penalties that inhibit the patient's freedom to choose a provider or health care services
3. APhA supports that patients who must rely upon governmentally-financed or administered programs are entitled to the same high quality of pharmaceutical services as are provided to the population as a whole.

(Am Pharm NS30(6):45 June 1990) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (Reviewed 2015)