Education Standards for Pharmacists Providing Comprehensive Medication Management in Outpatient Nephrology Settings



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Chronic kidney disease is a public health problem that has generated renewed interest due to poor patient outcomes and high cost. The Advancing American Kidney Health initiative aimed to transform kidney care with goals of decreasing the incidence of kidney failure and increasing the number of patients receiving home dialysis or a kidney transplant. New value-based models of kidney care that specify inclusion of pharmacists as part of the kidney care team were developed to help achieve these goals. To support this Advancing American Kidney Health-catalyzed opportunity for pharmacist engagement, the pharmacy workforce must have a fundamental knowledge of the core principles needed to provide comprehensive medication management to address chronic kidney disease and the common comorbid conditions and secondary complications. The Advancing Kidney Health through Optimal Medication Management initiative was created by nephrology pharmacists with the vision that every person with kidney disease receives optimal medication management through team-based care that includes a pharmacist to ensure medications are safe, effective, and convenient. Here, we propose education standards for pharmacists providing care for individuals with kidney disease in the outpatient setting to complement proposed practice standards.

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INTRODUCTION

It is well established that kidney disease is a significant public health problem and major contributor to increasing Medicare expenditures that has prompted innovations in patient care models to prevent and manage kidney disease. Medication regimens in patients with chronic kidney disease (CKD) become increasingly complex as the disease progresses and contribute to the high costs of care and CKD-related morbidity. Medication reconciliation and management by pharmacists reduces medication therapy problems and 30-day readmissions in patients with CKD. Medication of pharmacists into the multidisciplinary kidney transplant team has also led to improved medication safety. Medication safety.

Pharmacists can offer more advanced care through comprehensive medication management (CMM), a patient-centered process of optimizing medications that is delivered by a pharmacist collaborating on an interprofessional team to improve health outcomes. CMM is of particular importance given the new value-based kidney care models that are being developed in response to the Advancing American Kidney Health executive order enacted in 2019. These care models incentivize clinicians to provide high-value services focused on quality, outcomes, and cost containment. Pharmacists have the opportunity to integrate into the new kidney care models and play a key role, especially in the performance-based components (eg, patient activation, depression management, reduced hospitalizations, and reduced cost of care).

This concept is supported in several guidelines and commentaries such as the Kidney Disease: Improving Global Outcomes clinical practice guidelines for diabetes in CKD, which advocate involvement of a clinical pharmacist in the care team to optimize medications that improve patient outcomes (eg, sodium/glucose cotransporter 2 inhibitors). Integration into the kidney care team requires that pharmacists have core knowledge of common comorbid conditions and secondary complications and the skills needed to provide CMM. Here, we describe the work of the Advancing Kidney Health through Optimal Medication Management (AKHOMM) initiative and propose educational standards for pharmacists providing direct patient care and CMM to individuals with kidney disease.

CURRENT NEPHROLOGY EDUCATION FOR PHARMACISTS

The provision of CMM to patients with kidney disease requires knowledge beyond that attained by most Doctor of Pharmacy (PharmD) graduates in the United States. Although PharmD graduates have fundamental knowledge of kidney disease, the extent to which the unique complications and comorbid conditions of CKD are covered varies greatly across educational programs. The Accreditation Council for Pharmacy Education evaluates the quality of pharmacy professional programs to ensure they meet established qualifications and education standards but does not dictate specific topics to be covered in

the PharmD curricula. The nephrology-specific topics included (eg, glomerular disorders, secondary CKD complications such as mineral and bone disorder) vary among programs and may be based on faculty expertise. Opportunities for elective and advanced practice experiential training in nephrology also depend on the availability of faculty in clinical practice sites offering nephrologyspecific training. Indeed, this variability in nephrology content and experiential training opportunities was validated by a 2021 survey of pharmacy faculty to assess nephrology pharmacy curricula in the United States (K. Cho, personal communication, April 5, 2022). Historically, pharmacists have not been integrated into nephrology practices, which limits the availability of practice sites in nephrology clinics and outpatient dialysis units. Inclusion of pharmacists into the care team within outpatient dialysis units, although encouraged to help reduce medication therapy problems, was not mandated under the End-Stage Renal Disease Conditions for Coverage. 21

The American College of Clinical Pharmacy does provide some guidance on inclusion of nephrology-related topics through its Pharmacotherapy Didactic Curriculum Toolkit that provides a list of topics to guide curricular design, with a breakdown of topics by tier levels 1-3.20 This toolkit is neither prescriptive nor uniformly used among colleges/schools of pharmacy. Rather, it is a resource available to those planning curricula in PharmD programs and designed to train the entry level generalist pharmacist. Tier 1 topics are those considered likely to be encountered in most practice settings and should be included in the PharmD curriculum to prepare the graduate to provide collaborative, patient-centered care upon graduation and licensure (eg, CKD progression, electrolyte disorders). Tier 2 topics are suggested to be part of the curriculum, but additional knowledge and skills may be required after graduation such as through residency training or equivalent experience (eg, CKD mineral and bone disorder). Tier 3 topics are those encountered less commonly by most pharmacists and may be included as part of the curriculum, but it is expected the trainee will obtain required knowledge and skills on their own if required in their practice (eg, polycystic kidney disease). Only 31% of nephrology-specific topics in the toolkit are tier 1 topics, which highlights the need for postgraduate training for pharmacists integrated into most nephrology clinical settings.²⁰

Currently there are no postgraduate year 2 nephrology residency programs accredited by the American Society of Health-System Pharmacists Commission on Credentialing. The available postgraduate year 1 training programs may or may not have advanced training opportunities in nephrology. There are postgraduate year 2 residencies in solid organ transplant; however, these are specialized for the clinician focused in the transplant setting and not focused on CKD and its complications. In addition, opportunities for pharmacists to obtain specialized training

relevant to nephrology settings, such as through nephrology fellowships, are limited. There is a critical need to augment training for pharmacists integrated into nephrology settings.

AKHOMM INITIATIVE

In 2020, a group of nephrology pharmacists convened to discuss potential roles of pharmacists in the new practice models and published an opinion paper on this topic.²² From this activity, the AKHOMM initiative was developed with the vision that every person with kidney disease receives optimal medication management through teambased care including a pharmacist to ensure medications are safe, effective, and convenient for them to use.²³ AKHOMM is positioned to help nephrology practices, health systems, and wrap-around kidney care companies implement CMM within their practices by incorporating pharmacists into their care teams to help achieve the quadruple aim of health care; that is, reducing costs of care, improving population health, enhancing the patient experience, and improving provider satisfaction.²⁴ The AKHOMM leadership recognized the need to address the gap in nephrology training for pharmacists. To achieve this goal, 2 workgroups were formed: one to create practice standards and another to develop education standards for nephrology pharmacists providing CMM to patients with kidney disease. Each workgroup had 2 leaders who recruited additional members based on the expertise needed. The practice and the education standards workgroup leaders met monthly to strategically align the 2 sets of standards (Fig 1). This paper describes the process and deliverables from the education standards workgroup. The reader is also directed to the proposed nephrology pharmacy practice standards.25

PROCESS OF DEVELOPING EDUCATION STANDARDS

The AKHOMM education standards workgroup consisted of pharmacists with expertise primarily in adult nephrology and transplantation, with some representation from pediatric nephrology. The workgroup included full-time clinicians, full-time academicians, those with roles in both the clinical setting and academia, and individuals involved in postgraduate/residency training programs. In total, 11 individuals collaborated on the education standards.

The workgroup convened regularly over a 12-month period to draft the education standards. At the beginning of this process it was assumed that pharmacists at all levels (whether new graduates or pharmacists with practices of varying vintages) could perform medication reconciliation, evaluate a medication profile for medication therapy problems, and provide education to patients, other providers, and pharmacy trainees; therefore, the creation of education standards focused on these areas was not

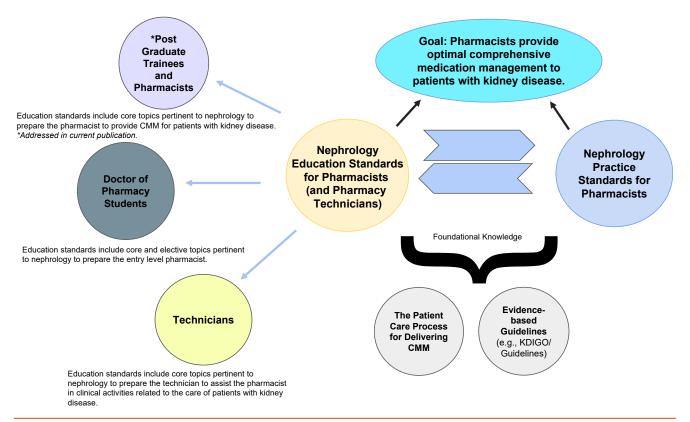


Figure 1. Interplay between education and practice standards. Abbreviations: CMM, comprehensive medication management; KDIGO, Kidney Disease Improving Global Outcomes.

necessary. The workgroup was tasked to specifically consider more specialized topics relevant to CKD (eg, new therapies for delaying progression of CKD, mineral and bone disorder, drug dosing in kidney disease) and unique management considerations of comorbid conditions in patients with CKD (eg, hypertension, diabetes). Other areas important in the clinical practice setting were also considered, including the fundamentals of CMM, processes of patient care delivery, patient advocacy, and health disparities.

The workgroup members used the American College of Clinical Pharmacy Pharmacotherapy Didactic Curriculum Toolkit as a starting point to rank topics deemed important for pharmacists.²⁰ The emphasis was on pharmacists involved in outpatient settings (eg, CKD clinics) as this is the focused practice setting for implementation of new kidney care models. The proposed education standards focused on transplantation were intended primarily for pharmacists without specialized training in this area (eg, without a postgraduate year 2 Solid Organ Transplant residency). The standards related to transplantation were designed to introduce topics needed to facilitate the transition of patients with advanced kidney disease to kidney transplant and support patients with graft failure. Similarly, it was anticipated that individuals in pediatric settings would have specialized training in pediatrics but may require additional knowledge of the unique aspects of

kidney disease (eg, considerations for drug dosing in pediatric patients, nutrition in pediatric patients).

Education standards were drafted and reviewed by all members. The practice standards workgroup and the AKHOMM leadership reviewed the draft education standards and provided additional input. The final step included external review by pharmacists in a variety of clinical settings. A final list of 28 education standards was created and grouped in the following categories: (I) CKD (Progression, Comorbid Conditions, and Complications), (II) Drug Regimen Design and Medication Safety, (III) Public and Population Health, (IV) CMM and Processes of Care Delivery, (V) Advocacy and Health Disparities, and (VI) Special Populations (Transplantation and Pediatrics) (Table 1).

EDUCATION STANDARDS FOR PHARMACISTS

The sections that follow discuss key aspects of the standards within the defined categories. It should be emphasized that for most of the topic areas covered it is expected that the pharmacist will work with other health professionals (eg, nephrologists, advanced practice providers, nurses, dietitians, primary care physicians, social workers) to facilitate delivery of CMM and patient education. These standards should be considered in conjunction with the practice standards for pharmacists.²⁵



Table 1. Education Standards for Pharmacists in Outpatient Nephrology Practice Settings

 Design prevention, treatment, and patient education strategies for CKD that incorporate evidence-based pharmacologic and nonpharmacologic treatment and that address disparities in care. Design prevention, treatment, and patient education strategies for the common comorbid conditions in patients with CKD that incorporate evidence-based pharmacologic and
nonpharmacologic treatment options and that address disparities in care.
3. Develop prevention, treatment, and patient education strategies for the common complications of CKD that incorporate evidence-based pharmacologic and nonpharmacologic treatment options and that address disparities in care.
 Describe common glomerular diseases of the kidneys and the evidence-based pharmacologic and nonpharmacologic treatment options based on cause.
5. Design prevention, treatment, and education strategies for acute kidney injury.
6. Discuss the importance of individualized nutritional regimens for patients with kidney disease and the need for the expertise of a dietitian.
7. Adopt patient-centered medication management strategies to address kidney diseases and the associated comorbid conditions and complications in collaboration with other providers using the pharmacist patient care process (collect, assess, plan, implement, monitor and evaluate, and document activities).
1. Assess kidney function using contemporary methods for estimating glomerular filtration rate with consideration of the utility and limitations of each method.
2. Design a medication regimen that accounts for pharmacokinetic changes observed in kidney disease and potential removal by kidney replacement therapies.
3. Describe kidney replacement therapies (in-center hemodialysis, home hemodialysis, and peritoneal dialysis) in terms of the process, indications, and major complications to facilitate drug regimen design in patients requiring these modalities.
4. Recommend strategies for the prevention and treatment of drug-induced nephrotoxicity based on the potential causative agent.
5. Initiate appropriate deprescribing measures to reduce medication burden and/or harm in patients with kidney disease.
6. Describe the cognitive, functional, and psychosocial components of the comprehensive geriatric assessment that may affect medication safety and the importance of the comprehensive medication review and assessment in older individuals with kidney disease.
7. Promote safe and effective medication processes through effective communication with other health care providers and with patients during and after transitions of care.
Facilitate creation of care plans to safely transition patients with CKD to dialysis or transplantation and those with failed kidney allografts to other kidney replacement therapies.
1. Design and conduct a medication use evaluation when needed to ensure clinical and quality metrics are met.
2. Determine the appropriate immunizations and timing for administration in patients with kidney disease and transplant patients.
1. Describe CMM and its components and how this process may be applied to individuals with kidney disease.
Identify and prioritize opportunities for pharmacists to optimize health care and provide CMM for patients in value-based payment systems.
3. Apply available telehealth technologies to deliver care to patients with kidney disease.
4. Implement the components of practice management necessary to provide medication management for patients with CKD, kidney failure, and transplant including the collaborative practice agreement, quality measures/metrics, key billing and reimbursement processes for various payers, and ongoing review processes of quality and financial measures.
 Describe health disparity factors that present barriers to health care access for patients with kidney disease and provide solutions.
Explain strategies to engage patients and care partners in advocacy activities related to CKD, dialysis, and kidney transplantation.
3. Develop and tailor pharmacotherapeutic plans to the economic capabilities of the patient and discuss resources available to assist with access to medications.
4. Individualize and communicate plans of care while considering the importance of cultural sensitivity and person-centered care.
Understand barriers to medication adherence and facilitate strategies to improve medication adherence in patients with CKD, kidney failure, and transplant.
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(Continued)

Table 1 (Cont'd). Education Standards for Pharmacists in Outpatient Nephrology Practice Settings

Category	Education Standards
VI. Special populations (transplantation and pediatrics)	1. Discuss characteristics of a suitable kidney transplant candidate and develop medication regimens used in organ transplantation to ensure optimal graft performance while minimizing adverse effects and medication-related problems, improving medication adherence, and utilizing patient-specific characteristics to alter regimens.
	 2. For pharmacists providing care for pediatric patients with kidney disease, advanced training to address the following topics is recommended: a. Nutrition delivery in infants and children with available nutritional supplements. b. Drug dosing and delivery solutions in pediatric patients. d. Effects of CKD on growth and development of children d. Common glomerular diseases in children (eg, minimal change disease). e. Optimal timing of and psychosocial barriers to successful kidney transplant.

Abbreviations: CKD, chronic kidney disease; CMM, comprehensive medication management.

Education Standards by Category (I) CKD Progression, Comorbid Conditions, and Complications

The education standards that address CKD focus on the prevention, treatment, and patient education necessary to prevent CKD progression (education standard I-1) and address the common comorbid conditions (I-2) and secondary complications (I-3). With regard to CKD progression, particular emphasis is placed on pharmacologic treatments affecting the renin-angiotensin-aldosterone system (ie, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers), sodium/glucose cotransporter 2 inhibitors, glucagon-like peptide-1 receptor agonists (GLP-1RAs), and the nonsteroidal mineralocorticoid receptor antagonist (finerenone). Comorbid conditions include potential causes of CKD (eg, diabetes, hypertension), but also disorders associated with significant morbidity and mortality where inclusion of a pharmacist to provide CMM is beneficial (eg, infection and antimicrobial stewardship, pain management, psychiatric disorders). Depression remission is a specific metric that will be evaluated in the new kidney models.²⁶ Pharmacists working in conjunction with other providers can help to address this metric given the extent of pharmacologic management often required to manage depression.

The complications of CKD require multiple pharmacologic interventions leading to a large medication burden and potential for medication therapy problems. Understanding the secondary complications of CKD facilitates identification and management of medication therapy problems. Although glomerular disorders are more specialized, some pharmacists are involved in clinical settings where patients with glomerular diseases are evaluated; therefore, an educational standard to address glomerular disorders was included (I-4). Acute kidney injury is a focus of one education standard in this category (I-5), primarily with the goal of providing education on prevention of acute kidney injury in individuals with CKD through risk mitigation of medication-induced acute kidney injury. This is also important for patients with a recent hospitalization for acute kidney injury transitioning back

to the outpatient setting. Pharmacists are also expected to understand general aspects of nutrition management and work in conjunction with kidney dietitians to promote appropriate nutritional interventions geared for individuals with CKD (I-6). The importance of the patient care process for delivering CMM is also emphasized (I-7). The patient care process for delivering CMM provides essential functions along with associated operational definitions that cover the entire scope of providing CMM to any patient and are also included in the practice standards. 15

(II) Drug Regimen Design and Medication Safety

The education standards in this section focus on the knowledge and skills necessary to design appropriate drug regimens and promote medication safety in patients with kidney disease. It is important for pharmacists to understand the utility and limitations of available methods to assess kidney function and to recognize situations when a confirmatory test (eg, cystatin C-based equations, measured glomerular filtration rate or measured creatinine clearance) to determine glomerular filtration rate is necessary. This information is applicable to drug regimen design, assessment of CKD stage, and evaluation of interventions to delay CKD progression (II-1). Pharmacists must have knowledge of the potential pharmacokinetic changes that occur in individuals with kidney disease (II-2) and understand the effect of modalities of kidney replacement therapy on drug disposition (II-3). Knowledge of kidney replacement therapy modalities is also important for pharmacists to promote home modalities for patients with kidney failure and address potential complications of kidney replacement therapy in conjunction with other health care providers.

Specific standards related to medication safety are included in this section. Pharmacists in nephrology settings require specialized education on high-risk medications, deleterious medication combinations, and indicators of nephrotoxicity (II-4). This is critical for patients with CKD at high risk of medication-induced kidney injury. Deprescribing is addressed as a separate education standard (II-5) since processes to facilitate deprescribing have been

developed in the CKD population to reduce medication burden and/or prevent harm.²⁷⁻³¹ Deprescribing is the planned and supervised process of discontinuing medications that may cause harm or are no longer of benefit and may help to minimize use of potential nephrotoxic agents as well as those that may cause harm. The increased susceptibility of older individuals with advanced kidney disease to medication therapy problems prompted a separate education standard to focus on unique consideration to prevent such medication therapy problems in the geriatric population with kidney disease (II-6).

Transitions of care between health care settings (eg, from inpatient setting to outpatient dialysis or CKD clinics, CKD clinic to primary care clinic, etc) increase the risk of medication errors. Frequent medication changes may not be communicated effectively to patients or other providers and may not be appropriate based on kidney function. Facilitating appropriate medication use during and after transitions of care through effective communication and follow up is an essential function that pharmacists can lead. Understanding key processes to promote effective transitions of care is important and justified the education standard in this area (II-7).8,32 An education standard focused on creating care plans to safely transition CKD patients to dialysis (peritoneal or hemodialysis) or transplantation and those with failed kidney allografts to dialysis is included in this section, given the complex changes in medication regimens that occur during these transitions (II-8).

(III) Public and Population Health

Education standards to address broader aspects of public and population health were developed to align with practice standards. Practice standards on population health focus on program evaluation to ensure appropriate medication use and safety and to optimize immunizations in the clinical setting. Education standards in this section address the design and conduct of a medication use evaluation to ensure clinical and quality metrics are met in the CKD clinical setting (III-1) and the required immunizations for those with advanced kidney disease and transplant (III-2).

(IV) CMM and Processes of Care Delivery

CMM is defined by the American College of Clinical Pharmacy as "the standard of care that ensures each patient's medications (i.e., prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbid conditions and other medications being taken, and able to be taken by the patient as intended." ^{15,33} CMM is a patient-centered approach to optimize medication use and improve patient health outcomes that is delivered by a clinical pharmacist working in collaboration with the patient and other health care providers. It addresses the quadruple aim of value-based care, which includes improving patient care, reducing health care costs, enhancing the patient

experience, and improving provider satisfaction. 34 Education standards focused on CMM and its potential application under the Advancing American Kidney Health initiative (IV-1, IV-2) as well as processes of delivering CMM through telehealth (IV-3) were developed. Other components for care delivery and sustainability that are important for pharmacists to understand include those in education standard IV-4. Depending on their background and prior experiences, pharmacists may need additional education on these components for care delivery. Although many aspects of care delivery are unique to a given clinical environment, the basics of collaborative practice agreements, quality measures/metrics, billing and reimbursement processes, and the process of ongoing review can be included in training programs to address the business and financial aspects important in nephrology clinical practice settings.

(V) Advocacy and Health Disparities

Health disparities are prevalent in patients with CKD and include racial, ethnic, and economic disparities that affect awareness, diagnosis, and treatment of CKD and access to kidney transplantation. There are national efforts to make health disparities a research priority in nephrology. 35,36 Social determinants of health affect access to care and the ability to adhere to medical care. As integrated members of the health care team, pharmacists should have a heightened awareness of equity issues and how they affect access to and adherence with care plans. Health disparities are of high priority, and pharmacists are in a position to address these disparities and advocate for patients. The education standards in this section (V: 1-5) also align with the practice standards addressing the patient care process for delivering CMM where the barriers to care and medication adherence are considered through all phases of the care plan. The rationale for the recent exclusion of race from methods to determine estimated glomerular filtration rate is an important consideration and supports the goal to minimize disparities in health care.³⁷

(VI) Special Populations (Transplantation and Pediatrics)

The AKHOMM education standards workgroup also included individuals specializing in solid organ transplantation and pediatric nephrology. The consensus was that pharmacists involved in these areas will likely have specialized training through postgraduate residencies and fellowships. The Board of Pharmacy Specialties provides certification for pediatric pharmacotherapy and recently added board certification in solid organ transplantation geared toward pharmacists providing evidence-based, patient-centered medication therapy management and care for transplant patients and patients with end-stage organ disease. Pharmacists in outpatient CKD clinics or dialysis facilities will not likely have these special certifications but will encounter patients as they transition to/from

transplantation and kidney replacement therapy, hence the rationale for an education standard that addresses basic knowledge to help with these transitions (II-8). A key goal of the Advancing American Kidney Health initiative is to increase the number of individuals who receive a transplant. Pharmacists can help facilitate this goal by working with other health care professionals to identify candidates, assist with medication regimen design, and improve access and adherence to medications. The education standard in this section (VI-1) focuses on the patient who is expected to receive a kidney transplant to better prepare them for transplantation and the medication regimens required.

For pharmacists involved in pediatric nephrology, the workgroup emphasized key areas for which pediatric pharmacists may need more advanced training, including nutritional requirements in CKD, considerations with assessment of kidney function and drug dosing, effects of CKD on growth and development, glomerular disorders, and aspects related to kidney transplantation (VI-2).

DISCUSSION

The education standards described were developed to provide enhanced training to facilitate the integration of pharmacists into practice settings for patients with CKD. Opportunities exist to enhance pharmacist involvement in health care teams that support patients with CKD through the new value-based care models and in wrap-around kidney care companies and health systems that have CKD patients within accountable care organization populations. The practice standards developed by the AKHOMM practice standards workgroup emphasize knowledge and skills needed to provide direct patient care (eg, education standards in sections I and II), but also cover population health (section III), important processes of care delivery (section IV), and health disparities (section V) that are important to complement the practice standards. The education standards are not inclusive of all potential topics that pharmacists may need to know in a CKD setting, but they include those identified as core or foundational topic areas. The intent is for these education standards to complement the practice standards for pharmacists in outpatient nephrology settings developed through the AKHOMM initiative. As more information develops regarding the role of pharmacogenomic testing and implementation in patients with kidney disease, the education and practice standards will be modified to incorporate this important element.38

Development of education and practice standards for pharmacists in outpatient nephrology settings is a starting point to standardize expectations for pharmacists. As nephrology practices begin to function within the framework of new practice models, the potential for significant contributions to the practice by nephrology-trained pharmacists may be realized, and more practices will integrate

pharmacists into their health care teams. Ideally, pharmacists working within the specific Comprehensive Kidney Care Contracting options can help to meet model metrics (eg, depression remission, patient activation, reduced hospitalizations and per-capita cost), provide patient and clinician education, promote and monitor therapies to reduce CKD progression, and increase awareness and selection of home dialysis modalities through collaboration with other health care providers. Through the efforts of the AKHOMM initiative, the goal is that pharmacists in these practice settings can use the education and practice standards to guide their training and activities. AKHOMM will also engage the nephrology community to promote the abilities of pharmacists to improve mediation management and the overall care of patients with CKD according to these standards.

The AKHOMM will next use these education standards as a framework to develop a curriculum for practicing pharmacists in need of kidney disease-focused advanced training programs (eg, clinical traineeship, certificate programs). A process of disseminating this information to professional pharmacy organizations (eg, American Colleges of Clinical Pharmacy, American Society of Health-System Pharmacists) and nephrology organizations (eg, American Society of Nephrology, National Kidney Foundation) to promote awareness of expectations of pharmacists and the availability of training programs is currently being developed. These efforts will help pharmacists to be successful members of interprofessional, multidisciplinary care teams, and optimize medication management in patients with kidney disease.

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