



Nephrology practice and research network opinion paper: Pharmacists' perspectives on the Advancing American Kidney Health initiative

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Abstract

Patients with chronic kidney disease (CKD) are at high risk for clinically significant medication therapy problems (MTPs) due primarily to the complex pharmacotherapy prescribed by numerous providers, and the significant changes in pharmacokinetic and pharmacodynamic properties of many medications due to their kidney disease. While MTPs are well recognized, pharmacists are not routinely involved in the health care teams that provide care for patients with CKD. The Advancing American Kidney Health initiative was announced in July 2019 and is poised to shift models of care in nephrology toward value-based payment. This represents an opportunity for pharmacists to integrate into teams to improve quality of care and outcomes for patients with CKD. Pharmacists should engage in medication reconciliation, transitions of care, and medication-focused kidney disease education programs within a comprehensive medication management (CMM) framework to optimize pharmacotherapy outcomes. To implement these services, pharmacists need to utilize certified pharmacy technicians, telehealth, interprofessional skills, and other tools in innovative ways. Current models of successful practice from Canada can serve as a template for United States-based nephrology pharmacy practice. In this opinion paper, we characterize the current state of nephrology practice and identify significant opportunities for advancement. We propose metrics to evaluate pharmacy services and a framework for key stakeholder engagement which will be critical to advance the profession of pharmacy within nephrology. The Advancing American Kidney Health initiative offers a distinct opportunity to demonstrate the value of CMM provided by pharmacists in the nephrology arena to optimize patient care.

KEYWORDS

nephrology, patient care, pharmaceutical services, pharmacists

1 | INTRODUCTION

This paper represents the opinion of the Nephrology Practice and Research Network of the American College of Clinical Pharmacy. It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

Approximately 37 million Americans suffer from chronic kidney disease (CKD), reflecting 15% of the country's population.¹ Patients with

end-stage kidney disease (ESKD) take an average of 9 to 12 prescription medications per day, totaling 19 pills per day.² The high medication burden, associated poor adherence, and declining kidney function that cause significant alterations in pharmacokinetics and pharmacodynamics all dramatically impact pharmacotherapy and associated clinical outcomes.³ Therefore, it is not surprising that patients with CKD experience a disproportionate number of medication therapy problems (MTPs), first defined by Hepler and Strand as “an event or situation involving drug therapy that actually and potentially interferes with an optimum outcome for a specific patient”.⁴ Pharmacists are highly accessible medication experts that have the potential to improve the quality of care for patients with CKD by addressing MTPs and providing comprehensive medication management (CMM). The current nephrology workforce largely includes physicians, mid-level practitioners (nurse practitioners and physician assistants), nurses, social workers, and dietitians without consistent pharmacist representation. Despite this, the Centers for Medicare and Medicaid Services (CMS) has stated that pharmacists are needed to address MTPs in patients with CKD through a Medication Therapy Management (MTM) program. Unfortunately, CMS does not mandate the inclusion of pharmacists on the interprofessional health care team in the “Conditions for Coverage” for ESKD patients receiving hemodialysis, though CMS did, “encourage dialysis facilities to use pharmacist expertise as appropriate”.⁵ Looking forward, rapidly evolving changes to the field of nephrology are creating opportunities for better patient care through pharmacist integration into teams caring for patients with kidney disease. A key factor prompting these changes is the Advancing American Kidney Health initiative, which is the focus of this opinion paper.

2 | OVERVIEW OF THE ADVANCING AMERICAN KIDNEY HEALTH INITIATIVE

Treatment of kidney disease is expensive; Medicare spends \$144 billion each year on ESKD and CKD care. Across insurance types, individuals with CKD compared with those without had \$17 472 higher incremental spending per year after adjustment for key variables.⁶ In recognition of the need to address escalating costs and disease management, the Advancing American Kidney Health initiative was announced on July 10, 2019, by the United States Department of Health and Human Services and put into motion through a presidential executive order.⁷ The three main goals are to: (a) Reduce the number of Americans developing ESKD 25% by 2030, (b) Increase the number of new ESKD patients in 2025 either receiving dialysis at home or receiving a transplant to 80%, and (c) Double the number of kidneys available for transplant by 2030.⁷ In order to move this initiative forward, the Center for Medicare and Medicaid Innovation announced new value-based payment models that will be implemented in 2020 and will include thousands of ESKD and CKD patients in demonstration projects to test whether payment changes can improve patient outcomes. These new payment models represent an opportunity for pharmacists to build collaborative teams and

integrate CMM into nephrology practice to improve patient outcomes and reduce health care costs.

It is imperative for pharmacists to understand where the opportunities lie within these new care payment models. An overview of models is found in Table 1. The Kidney Care Choices model options pertain to patients with CKD stages 4 and 5.⁸ These models shift Medicare dollars to reward: (a) Better CKD management and transitions to ESKD, (b) Reduced hospitalization as well as total cost of care, (c) Improved rates of kidney transplantation, and (d) Maintaining health of transplant.

These models will replace the current fee-for-service payment received for Medicare-covered CKD patients with quarterly capitated payments for CKD and dialysis patients, a kidney transplant bonus, and a performance-based adjustment. Pharmacists can participate in any of these models if nephrologists or nephrology practices choose to include pharmacists. Pharmacists can bring value to practices by helping them achieve higher scores on key quality and utilization measures and helping practices improve their relative performance compared with other nephrology practices.^{9,10} There are three quality measures that the Center for Medicare and Medicaid Innovation has outlined, all which could be impacted by pharmacists' care: (a) Gains in Patient Activation Measure (PAM) Scores (National Quality Forum

TABLE 1 Overview of new nephrology payment model options⁸

Payment options	Overview	Participants
Kidney care first option	Based on the primary care first model, nephrology practices receive payments for effective management of beneficiaries	Nephrology/nephrology practices only
CKCC graduated option	Lower reward, one-sided model allowing for incremental phase-in risk and reward	Nephrologists and/or nephrology practices and transplant providers (transplant centers, transplant surgeons, transplant nephrologists and/or OPOs) are required. Dialysis facilities and other kidney care providers are optional.
CKCC professional option	50% of shared savings or shared losses in total cost of care for medicare parts A and B	
CKCC global option	Risk for 100% of total cost of care for all parts A and B services	
ESKD treatment choices	Payments based on performance rates for home dialysis and transplantation	Mandatory for selected ESKD facilities in randomly selected geographic regions

Abbreviations: CKCC, comprehensive kidney care contracting model; ESKD, end-stage kidney disease; OPO, organ procurement organization.

[NQF #2483) measured by change in patient knowledge, skills, and confidence for self-management, (b) Depression Remission (NQF #1885), and (c) Controlling high blood pressure (NQF #0018).⁸ There are two utilization measures that can be impacted by pharmacists' care: (a) Hospitalization Costs based on the NQF Standardized Hospitalization Ratio (SHR) and (b) Total Per Capita Costs. Pharmacists can also impact the kidney transplant bonus (\$15 000 per patient aligned to who receives a transplant and remains alive with a functioning transplant) as well as the overall practice performance. Pharmacists could also enhance specific services that may improve patient care and outcomes. The new models expand the kidney disease education program. Currently, patients with CKD stage 4 are eligible for education that largely focuses on dialysis modalities and treatment choices in ESKD. In the new models, patients with CKD stage 5 or those within the first 6 months of dialysis initiation are now eligible for kidney disease education. It allows clinicians to cover other topics (eg, medication education) with additional payment on top of the quarterly capitated payment. The models also expand the use of telehealth from the use of real-time communication to asynchronous store and forward technologies. Finally, the models allow for nonphysician providers to make up to nine visits under the general supervision of a physician within 90 days following discharge from the hospital. All these enhancements pertain to qualified providers. Pharmacists are considered qualified providers as they perform professional services within their scope of practice and can independently report their professional services.

The last model is the ESKD Treatment Choices payment model (Table 1). This model was designed to encourage greater use of home dialysis, promote kidney transplants in Medicare beneficiaries with ESKD, and reduce expenditures. Pharmacist opportunities under this model include delivering kidney education (expanded types of providers are eligible), helping address MTPs that are barriers to home dialysis and transplantation, as well as optimizing medication management to reduce hospitalizations and mortality.

These new payment models do not include metrics evaluating patient or provider satisfaction. As innovative pharmacy services are integrated, patient and provider satisfaction and/or quality of life data should be collected. These results may demonstrate to providers and payers that pharmacists' care is integral to achieve the quadruple aim of CMM (better patient outcomes, improved patient experience, improved provider experience, and lower costs).

3 | OPPORTUNITIES FOR PHARMACISTS TO INTEGRATE INTO THE CARE OF PATIENTS WITH CKD IN THE U.S.

3.1 | Pharmacy workforce

The U.S. Bureau of Labor Statistics has indicated that there will be an imminent surplus of pharmacists given the increasing supply of graduates from pharmacy schools and declining demand of retail pharmacy positions which make up the majority of the labor force.¹¹ While the education of pharmacist trainees focuses primarily on clinical

pharmacy services and not the dispensing role, clinical roles have not expanded based on previous estimates.^{12,13} Pharmacists are not only highly trained medication experts, but often rank as the most accessible and most trusted health care professionals in the U.S. The pharmacy profession needs to leverage these attributes to carve out innovative clinical and hybrid dispensing clinical roles as the traditional dispensing roles continue to decline.¹¹ The field is at a tipping point that must be directed into more patient care-focused roles.¹⁴ We believe that the Advancing American Kidney Health initiative provides the opportunity for pharmacists to demonstrate their value in direct patient-care roles that provide added value for patients (improved outcomes) and health care providers (decreased workload,¹⁵ increased reimbursements). Limitations to pharmacists' involvement in nephrology are lack of consistency of nephrology education in Doctor of Pharmacy (Pharm.D.) programs, limited postgraduate training opportunities, and no standards of practice. Academic pharmacists will need to develop standard competencies in nephrology curricula that are systematically implemented in Pharm.D. programs. Postgraduate continuing education and certificate programs should be developed to train the current workforce in these competencies. Standards of practice from successful models in Canada are presented in this paper (see section on Standards of Nephrology Pharmacy Practice), but are under further development with the newly formed Advancing American Kidney Health through Optimal Medication Management agenda. This agenda, led by members of the Nephrology Practice and Research Network, will function as a task force to accelerate advancement in nephrology pharmacy and address gaps outlined in this paper.

Kidney team models in which pharmacists are key members in the care of patients with CKD are commonly found in Canada. One excellent example of this funding model is in the province of Manitoba.¹⁶ This Canadian provincial kidney program currently provides funding for pharmacists at a ratio of 1 pharmacist for every 100 hemodialysis patients, 1 pharmacist for every 200 peritoneal dialysis or home hemodialysis patients, and 1 pharmacist for every 300 kidney clinic patients.¹⁷ There are 468 086 hemodialysis, 52 718 peritoneal dialysis, and approximately 1 million CKD stage 4-5 nondialysis patients in the U.S.¹⁸ Extrapolating the ratios from the Manitoba model to the U.S. reveals the potential for thousands of pharmacist positions. This is likely an overestimate, but provides a benchmark against other successful models given the scope of CKD in the U.S. Additionally, the number of board-certified nephrologists is declining relative to other internal medicine subspecialties and the number of CKD and ESKD patients needing care is growing, creating a workforce shortage in nephrology.¹⁹ The surplus of pharmacists offers a win-win scenario to offload certain patient care responsibilities. Outlined below are pharmacy services that can be implemented for patients with CKD to develop new pharmacist jobs in the workforce.

3.2 | Transitions of care

Patients with CKD undergo many transitions of care that can introduce MTPs (Figure 1). Clinical pharmacy services are integral during

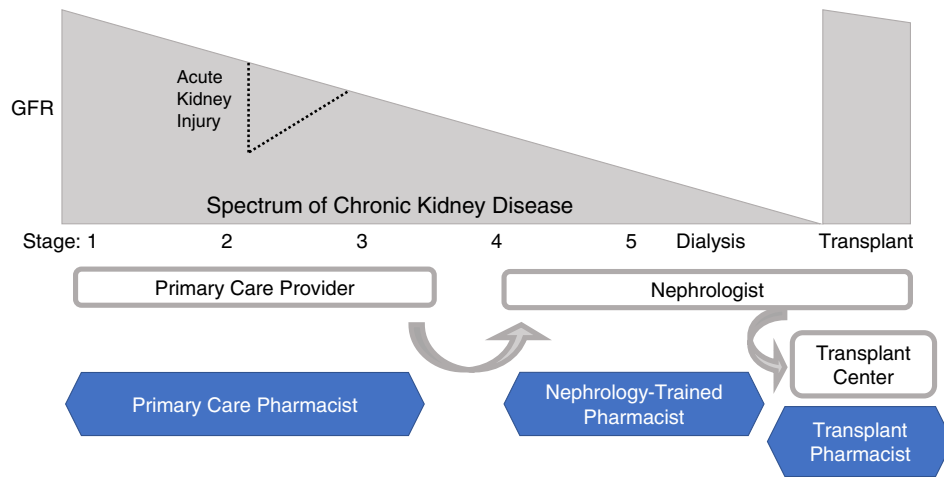


FIGURE 1 Transitions of care over the spectrum of kidney disease. Pharmacists can provide comprehensive medication management to patients throughout the spectrum of kidney disease. As GFR declines (y-axis), kidney care transitions to a nephrology-based practice. As patients transition to nephrology-specialty care, a nephrology-trained pharmacist can serve a vital role through that transition as well as transitioning to dialysis and between dialysis modalities. Acute kidney injury can occur at any point along this spectrum. Care transitions following acute kidney injury are critical to avoid further nephrotoxic injury, appropriately resume disease slowing therapy (eg, ACEis) and minimize the impact of the acute kidney injury on chronic kidney disease progression. ACEi, angiotensin converting enzyme inhibitor; GFR, glomerular filtration rate

care transitions with the role of the clinical pharmacist recently outlined.²⁰ Specific to kidney disease, a patient with CKD will transition from their primary care provider to a nephrologist as CKD progresses, with most nephrologist referrals occurring in CKD stages 4 and 5 (Figure 1). As dialysis becomes necessary, patients will choose a dialysis modality and will transition to a dialysis center. Some patients may need to change dialysis modalities, as in the case of a patient with recurrent peritonitis switching from peritoneal dialysis to hemodialysis. When a patient receives a kidney transplant, their care is transitioned to a transplant center where interprofessional teams specialized in solid organ transplant, many of which include a pharmacist, will provide care. Co-morbidities and complications increase as CKD progresses adding volume and complexity to the medication regimen. A clinical pharmacist with nephrology expertise can function as a coordinator of CMM during CKD. It is common for a patient with ESKD to see a primary care provider, nephrologist, vascular surgeon, endocrinologist, cardiologist, and other specialists. Each of these visits may include changes to the medication regimen.

Emergency department visits and hospitalizations also increase as CKD progresses, as do visits at medical rehabilitation centers and skilled nursing facilities. Patients with ESKD are admitted to the hospital nearly twice a year and have a median of 7 (range 3-15) annual health care visits.^{21,22} Each of these transitions between providers, hospitalizations, dialysis centers, etc., requires critical re-evaluation of the medication regimen. We believe that a readily accessible clinical pharmacist is the optimal provider to complete this as part of the CMM process. This “central clinical pharmacist” can serve as a coordinator of medication-related care between providers, hospitals, other health care organizations, and dispensing pharmacies.²⁰ Having nephrology-trained pharmacists available either physically or virtually in CKD and dialysis clinics, or patient homes, would be ideal in any transition of care.²³

Individuals treated with dialysis are medically complex and experience nearly two hospitalizations per year, with 35% resulting in readmission.²¹ A typical patient with ESKD has 2 to 9 different prescribers that treat their 5 to 11 comorbid conditions requiring 5 to 14 different medications and subsequent 17 to 25 doses per day.^{2,22,24,25} During care transitions, medication changes are common, may cause patient confusion regarding which medications to continue, discontinue, or modify, and may not account for key issues like dosing based on kidney function. Unresolved MTPs likely contribute significantly to the resources spent on CKD/ESKD care. The Kidney Care Choices model allows for pharmacists, as qualified providers, to perform home visits postdischarge to complete transitions of care services.

3.3 | Medication reconciliation

Accurate medication lists are vital clinical documents established during medication reconciliation. Medication discrepancies can be classified into four groups which places a patient at risk for MTPs (Table 2).²⁶ A number of studies have described medication discrepancy prevalence and type observed in dialysis patients.²⁶⁻³² Collectively, these reports illustrate that each time a dialysis patient has their medications reconciled, on average 2 to 3 (range 1.3-3.9) medication discrepancies can be identified. Extrapolating this to the entire U.S. hemodialysis (n = 468 086) and peritoneal dialysis (n = 52 718) population suggests that approximately 1 to 1.6 million medication discrepancies could be identified.²¹ An estimated 4% to 6% of medication discrepancies are clinically relevant.^{27,32} Therefore, the U.S. dialysis population has an estimated 41 664-93 744 clinically significant medication discrepancies that could cause patient harm.

TABLE 2 Medication therapy problems associated with medication record discrepancies in patients with kidney disease²⁶

Medication record discrepancy type	Medication therapy problem risk	Example from nephrology
Medication not in record (patient is taking a medication that the clinician was not aware of)	Failure to receive medication	Calcium carbonate used for phosphate binder not in record because it is over-the-counter
Medication has different directions (patient is taking correct dose but at different frequency than the clinician thought they were)	Medication overdose or under-dose	Gabapentin 300 mg taken three times daily instead of once daily at bedtime
	Adverse drug event	Somnolence, altered mentation, increased risk of falls from overdose of gabapentin
Medication has different dose (patient is taking different dose than what the clinician thought they were taking)	Medication overdose or under-dose	End-stage kidney disease patient taking sitagliptan 100 mg daily instead of 25 mg daily
	Adverse drug event	Hypoglycemia
Medication no longer taken (patient is no longer taking a medication that clinician thought they were)	Wrong drug	Sodium polystyrene sulfonate stopped by patient because they did not like the taste
	Adverse drug event	Hospitalization for emergent hyperkalemia

Medication discrepancies occur frequently in patients receiving chronic dialysis when admitted to the hospital.³³ Over a 12-week period, a pharmacist reviewed the medication history of 47 patients on chronic dialysis upon hospital admission to identify MTPs. There were 199 MTPs identified, of which 130 (65%) were attributed to an “information gap” (ie, medication discrepancy). Pharmacy teams could serve in this pivotal role to address medication discrepancies and communicate between providers, thereby identifying and resolving potential MTPs.

Dialysis organizations should include medication reconciliation as an integral component of their patient safety program. The current “Conditions for Coverage for End-Stage Renal Disease Facilities” requires a medication history be developed within 30 days of admittance to a dialysis facility, then annually for stable patients or monthly for unstable patients; however, there are no reportable quality measures linked to this process.⁵ Beginning in 2022, medication reconciliation will be included in the Medicare Quality Incentive Payment

Safety Domain (NQF# 2988).³⁴ The measure requires dialysis organizations to provide medication reconciliation on a monthly basis using qualified personnel (eg, physician, registered nurse, nurse practitioner, physician assistant, pharmacist, or pharmacy technician). Facilities will have to attest the accountable data elements were completed during the calculation month and that the patient’s most recent medication list in the dialysis medical record was reconciled to one or more external list(s) of medications. The accountable data elements align with the Kidney Care Quality Alliance definition of medication reconciliation as “the process of creating the most accurate list of all home medications that the patient is taking, including name, indication, dosage, frequency, and route, by comparing the most recent medication list in the dialysis medical record to one or more external list(s) of medications obtained from a patient or caregiver (including patient/caregiver provided brown bag information), pharmacotherapy information network (e.g., Surescripts), hospital, or other provider”.³⁵ The intermediate outcome desired is improved and expedited identification of real and potential MTPs. The anticipated health outcomes associated with medication reconciliation are improved medication adherence and reduction of adverse drug reactions, hospitalizations, readmission, mortality, and health care costs attributed to MTPs.

An updated accurate medication list also provides a resource that can be shared with other care providers. Surveyed family physicians and community pharmacists appreciated having current medication use information to update their records, and stated that this process improved continuity of care, communication, quality of care, patient safety, and allowed them more time for direct patient care.^{32,36} Surprisingly, simply sharing the dialysis patient medication list informed 10% of family physicians and 15% of community pharmacists that their patient was a dialysis patient.³⁶

3.4 | Comprehensive medication management

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 comorbidities and other medications being taken, and able to be taken by the patient as intended.”³⁷ Collaborative drug therapy management protocols are key to successful CMM. We believe that CMM provides the optimal framework for pharmacists to integrate into nephrology practice. As CMM becomes the standard of care, payers are increasingly recognizing it as an essential service and are exploring appropriate coverage and payment mechanisms. However, the new care models in the Advancing American Kidney Health initiative offer the prospect of CMM integration as a value-added service reimbursable through performance-based adjustments and/or shared savings mechanisms.

It is important to differentiate CMM from medication therapy management (MTM) because most of the data for pharmacist integration into nephrology practices focuses on MTM services. MTM is a

broad term that encompasses services provided by a health care professional, including pharmacists, but may not be comprehensive in nature or delivered through formal care team structures. MTM services range from those services focused on a particular population that can benefit from new or modified pharmacotherapy (eg, diabetic patient and statin therapy) to comprehensive medication reviews. MTM is a Medicare Part D benefit for which some ESKD patients may not be eligible.

Medication reconciliation is a critical service for patients with CKD, especially those receiving dialysis, and will be a new quality measure of care beginning in 2022. However, medication reconciliation is only effective in reducing MTPs if it occurs within the CMM framework.²³ In the general population, providing multidisciplinary comprehensive services involving pharmacists and nurses for discharge planning, medication reconciliation, and post discharge telephone follow-up reduces rehospitalization.^{38,39}

Studies that have assessed more comprehensive pharmacist-based care have demonstrated positive clinical and economic outcomes (Table 3). Lower hospitalization rates, and decreased drug utilization and costs support implementation of longitudinal CMM.⁴⁰ Focusing on transitions of care, multidisciplinary medication services decreased readmission rates when pharmacists identified and resolved MTPs.⁴¹ However, these services were MTM based and provided at one transition (hospital to home), not longitudinally. A study by Tuttle and colleagues included elements of MTM, but the single 1 to 2 hours pharmacist visit focused on identifying medication discrepancies, side effects, intolerances, and unfilled prescriptions and did not meet the definition of CMM.⁴² Identified MTPs were communicated to providers, but follow-up for resolution of MTPs and disease state management was not completed.⁴³ Pharmacist-based care in patients with CKD should be comprehensive and not limited to one particular service (eg, medication reconciliation) or one time point. Routine use of the cyclical pharmacist's patient care process is necessary to follow-up on patient care plans to ensure optimal longitudinal care.⁴⁰ This process is the cornerstone of CMM, which should be implemented and evaluated in nephrology team-based practices moving forward.

3.5 | Pharmacy services

Pharmacists provide a broad range of clinical services to patients with kidney disease. Assessment of medication adherence and interventions to improve adherence (eg, motivational interviewing, cost assistance programs, convenience packaging, etc.) should be considered in all patients with CKD given their comorbid and medication burdens. A systematic review of eight controlled trials involving 744 patients with CKD (403 hemodialysis, 294 CKD nondialysis, and 47 postrenal transplant) showed that clinical pharmacist interventions improved management of anemia, blood pressure, and lipids, as well as calcium and phosphate parameters.⁴⁴ In patients with kidney diseases, clinical pharmacists' interventions reduced hospital admissions, length of hospital stay, and incidence of ESKD or death.⁴⁴ A more recent systematic review demonstrated pharmacist services continue to

positively impact disease state management (anemia, blood pressure, and mineral bone disorder) with increasing focus on MTP identification, improvement in health-related quality of life, patient satisfaction, and cost savings.⁴⁵ Studies evaluating multidisciplinary teams with pharmacists vs nephrologist care alone in patients with CKD have demonstrated decreased hospitalizations and mortality.¹⁷ Importantly, these studies have supported the funding for pharmacists in CKD clinics across successful models in Canada.

Dose optimization based on kidney function, pharmacokinetic, and pharmacodynamic alterations, dialysis clearance, and therapeutic drug monitoring is a well-established critical pharmacy service. Pharmacists have been trailblazers in this area through pharmacokinetic research, promulgation of renal dosing guidelines, and clinical implementation.⁴⁶⁻⁴⁸ This work has laid the foundation for advancement of pharmacy services in nephrology as an integral component of the CMM process.

3.6 | Research

Drug dosing recommendations are specific to dialysis modality such that the pharmacokinetics of a drug differ greatly between intermittent hemodialysis, peritoneal dialysis, and home hemodialysis.^{46,49} Most drug dosing studies have been completed with intermittent hemodialysis, the most common current modality. The Advancing American Kidney Health Initiative will shift care toward home dialysis modalities which have sparse data for drug dosing. Pharmacists are well positioned to perform pharmacokinetic/pharmacodynamic studies of commonly used medications to determine optimal dosing in these home dialysis modalities. Additionally, an advantage to in-center hemodialysis is the ability to administer parenteral antibiotics (eg, vancomycin) for infectious diseases. This is not well-established in home dialysis and should be a focus of research moving forward. Home-based dialysis presents different MTPs than in-center dialysis,²⁴ offering opportunities for innovative care models (eg, telehealth and home visits) that include pharmacists. Health services research will be needed to connect MTP resolution to key health and financial outcomes. Pharmacy practice-based research can promulgate novel pharmacist roles and should link to improvements in quality of care, patient satisfaction, and cost. This opens opportunities for population health analytics and pharmacoeconomics to advance innovative care models.

3.7 | Opportunities to engage pharmacists in other settings

Community pharmacists are well positioned to screen patients for CKD and identify unrecognized disease.⁵⁰ The National Kidney Foundation has a new program titled, "Are you the 33%?"⁵¹ (<http://MinuteForYourKidneys.org>) aimed at identifying individuals who are at risk of CKD which can be utilized in the community pharmacy setting. This tool may leverage the community pharmacists' knowledge

TABLE 3 Summary of select studies of pharmacist-based care in patients with kidney disease^a

Citation	Design	Population	Intervention	Major findings
Manley HJ, et al. Am J Kidney Dis. 2020 ⁴¹	Retrospective cohort study	N = 1452 discharge encounters in dialysis patients	MTM: nurse medication reconciliation, pharmacist medication review, nephrology oversight No MTM (n = 586) Partial MTM (n = 704) Full MTM (n = 162)	30-day readmission rates were lower in patients that received full MTM (11%) compared with partial MTM (19%) and no MTM (29%; <i>p</i> < .001). In propensity score matched sensitivity analysis, full MTM was associated with lower 30-day readmission risk (HR 0.20; 95% CI 0.06-0.69)
Pai AB, et al. Pharmacotherapy. 2009 ⁴⁰	Prospective, randomized, single-center, controlled trial	N = 104 chronic hemodialysis patients followed for 2 years; 57 received intervention vs 47 received usual care	Longitudinal CMM (referred to using the older term pharmaceutical care): bimonthly medication reconciliation and review by clinical pharmacist compared with usual care (nurse conducted medication reviews)	Patients receiving pharmacy services had fewer hospitalizations (1.8 ± 2.4 vs 3.1 ± 3, <i>P</i> = .02), used 14% fewer drugs, and trended toward reduced lengths of stay (10 ± 15 vs 16 ± 16 days, <i>P</i> = .06). 530 MTPs were identified and resolved
Tuttle KR, et al. Clin J Am Soc Nephrol. 2018. ⁴²	Prospective, single-blind, randomized, single-center, clinical trial	N = 141 CKD patients, stages 3-5 nondialysis, enrolled during acute hospitalization	MTM: single pharmacist home visit within 7 days of discharge including personal medication list, comprehensive medication review, and medication action plan compared with usual care: nurse discharge education and updated medication list	Acute care utilization within 90 days after hospitalization was no different between MTM (44%) and usual care (41%, <i>P</i> = .72) groups

Abbreviations: CI, confidence interval; CKD, chronic kidney disease; CMM, comprehensive medication management; HR, hazard ratio; MTM, medication therapy management; MTP, medication therapy problem.

^aThis list is not inclusive of all studies of pharmacist-based care in patients with kidney disease, which is beyond the scope of this opinion paper. Refer to systematic reviews of this topic by Raiisi and colleagues and Salgado and colleagues.^{44,45}

of the patient's chronic medications/disease states and strong patient relationships to encourage the patient to engage in further testing and treatment for CKD when necessary. Barriers to clinical interventions by community pharmacists should be addressed, such as access to patient's medical records for updated monitoring and care plan information, as this will allow them to provide highly accessible care to the growing CKD population.

Pharmacists that practice in acute and critical care will encounter patients with acute kidney injury (AKI). Referral to nephrology team-based care following AKI can improve patient outcomes, yet it is done in less than 10% of hospital AKI cases.⁵² Acute and critical care pharmacists serve a vital role during care transitions to ensure optimal pharmacotherapy (dosing adjustment, avoidance of nephrotoxins, monitoring plan for kidney function) and appropriate follow-up with possible nephrology referral (Figure 1).

Pediatric pharmacists can improve care for the nearly 10 000 pediatric ESKD patients in the U.S. A randomized study of 50 hemodialysis pediatric patients showed that pharmacist-based care improved blood pressure, phosphorus, parathyroid hormone, and calcium-phosphate

product compared with usual care.⁵³ Importantly, pharmacist-based care also improved patient satisfaction. Another study demonstrated that a pharmacy-led vaccine program increased the proportion of pediatric patients with up-to-date vaccinations at the time of transplant compared with usual care (91% vs 80%, *P* < .001).⁵⁴ A multidisciplinary pediatric nephrology clinic that included a pharmacist improved hemoglobin, calcium, and albumin while slowing the decline in estimated glomerular filtration rate (eGFR) compared with usual care.⁵⁵

4 | TOOLS FOR IMPLEMENTATION OF PHARMACIST-BASED CARE IN KIDNEY DISEASE

4.1 | Interprofessional team

Numerous health care professionals care for patients with CKD: primary care physicians, nephrologists, physician specialists, nurse practitioners, physician assistants, nurses, social workers, and dietitians are

among those most commonly encountered in CKD and dialysis care. Pharmacists must actively engage these other professions at individual health-systems. Truly collaborative, interprofessional care dramatically improves the quality and outcomes of care for patients with CKD and should be the overarching goal of integrating pharmacists.^{10,17,55} As essential members of the interprofessional care team, pharmacists have the knowledge and skills to improve patient outcomes and satisfaction. Through provision of CMM services, pharmacists can unburden other providers allowing them to streamline their own activities, which may improve provider satisfaction. Thus, if implemented correctly, pharmacist inclusion on the interprofessional team can help achieve the quadruple aim.

4.2 | Role of pharmacy technician

The expanding role of the pharmacy technician includes important clinical tasks that support medication reconciliation, CMM, and documentation of pharmacy services.⁵⁶ The Pharmacy Technician Certification Board provides a valuable certification process for pharmacy technicians with annual continuing education requirements. The board also offers a Medication History Certificate for certified pharmacy technicians that provides specialized training in obtaining an accurate medication history to be used for reconciliation purposes. Pharmacy technicians have been shown to increase accuracy of medication histories obtained in the emergency department compared with non-pharmacy staff.^{57,58} Re-allocation of technician duties can expand pharmacists' clinical roles and create opportunities for implementation of new services.⁵⁹ Importantly, certified pharmacy technicians are considered qualified personnel in the upcoming medication reconciliation Quality Incentive Program in dialysis facilities.⁶⁰ Technicians and clinical pharmacists should identify innovative models to maximize efficiency and maintain quality. For example, technicians may rotate in person between proximal health care sites to create best possible home medication lists, while the clinical pharmacist works via telehealth to complete the medication reconciliation, and MTP identification and resolution processes. Multiple technicians working under a clinical pharmacist can allow for expansion of this service to free-standing dialysis units and patient homes to cover larger geographic regions. We encourage the use of certified pharmacy technicians as pharmacist extenders in nephrology practices. Models that include certified pharmacy technicians should be evaluated for quality and outcome measures as well as cost-effectiveness. Other pharmacist-extenders that may be utilized to implement clinical services include pharmacy students and residents.

4.3 | Telehealth

As more Americans transition to home dialysis modalities as directed by the Advancing American Kidney Health initiative, telehealth will play a major role in pharmacist-based care delivery. Pharmacists have been engaged with telehealth for a number of years, providing MTM

and medication adherence counseling via telephonic routes. However, these practices have not targeted patients with CKD or AKI, who are at high risk of MTPs and nonadherence. Access to telehealth resources will be essential to reach patients on home dialysis modalities to complete medication reconciliation and CMM services. Best practices for implementation of CMM via telehealth have been recently published and serve as an excellent resource for pharmacists starting these programs in nephrology practice.⁶¹ The Kidney Care Choices models provide additional payments for a kidney disease education benefit, which can be provided by pharmacists as a qualified provider. Telehealth may represent an ideal mechanism to perform this education as it allows for asynchronous storage of validated education materials that can be forwarded to patients for review with pharmacist follow-up. Pharmacists may need additional training on the technology, communication skills, privacy concerns, and documentation specific to telehealth activities.

5 | NEXT STEPS

5.1 | Standards of nephrology pharmacy practice

Standards of practice for pharmacists and pharmacy technicians that provide care for patients with CKD must be developed as the initial step to close the gap in medication management in CKD. Successful Canadian models of pharmacist-based care have published standards of clinical practice for pharmacists working in CKD and dialysis clinics. This practice guideline was developed by pharmacists, pharmacy managers, and nephrologist medical directors and they have now adopted these standards of clinical practice for their pharmacists.⁶² Main clinical activities include best possible medication histories, medication reconciliation, identifying MTPs, and developing a therapeutic care plan to prevent and resolve each problem. For hemodialysis patients, a medication history is performed by a clinical pharmacist at baseline and then every 3 to 6 months or more frequently if required. For each peritoneal dialysis patient, a medication history is performed at baseline and at every clinic visit (3 to 4 months). Medication histories are also completed at each kidney health clinic for those patients triaged by a pharmacist. Common therapeutic areas for pharmacist services include adjusting doses according to kidney function, management of hypertension, cardiovascular disease, diabetes, anemia management, bone and mineral metabolism, antimicrobial selection and dosing, pruritus, restless legs syndrome, and vaccinations.⁶² Clinical pharmacy services provided at a fixed patient ratio have allowed pharmacists to participate in numerous research projects, as well as provide education for pharmacy students, graduate students, and other health care professionals.⁶² Overall, the specialized kidney pharmacist has access to patient care records and has developed trusting relationships with nephrologists, other health care team members, and most importantly, the patient. An adaptation of the Canadian standards is presented in Table 4, which will serve as a baseline for additional development by the newly formed Advancing American Kidney Health through Optimal Medication Management agenda. Many of the activities can be

accomplished using telehealth technology to extend pharmacist-based care into private nephrology practices and free-standing dialysis units.⁶³

Development of standards of practice in the U.S. can be done rapidly through modification and integration of successful Canadian models,⁶² core competencies of clinical pharmacists from the American College of Clinical Pharmacy (ACCP),⁶⁴ and standards of practice examples from solid organ transplantation.⁶⁵ Qualifications of pharmacists should include eligibility to perform CMM (accredited

residency training or equivalent postlicensure clinical experience and board certification) and training in nephrology, including postgraduate and certificate programs. These standards should be adaptable to allow for tailoring of a program to each unique health system, academic or private practice, or freestanding dialysis clinic, but must address core pharmacy services and expected outcomes. The use of consistent terminology for MTPs and their resolution with thorough documentation will be necessary to evaluate the quality and impact of pharmacist-based care.⁶⁶ Embedded within the standards of practice

TABLE 4 Standards of clinical practice for pharmacists working with CKD and dialysis patients (adapted from Reference 61)

The pharmacist *must* perform these core clinical activities on fully staffed weekdays^a (in order of priority):

1. Participate in all nephrology office-based clinics or home-based nephrology visits (includes peritoneal dialysis, home hemodialysis, and CKD stages 1-5 patients):
 - Review laboratory test results and medications for all patients.
 - Document in health record any recommendations or further patient information required for patients that are not seen face-to-face or through a telehealth encounter by a pharmacist.
 - For patients seen by a pharmacist, generate best possible medication history and perform medication reconciliation and detailed medication review.
2. Attend multidisciplinary patient care rounds (for hemodialysis and peritoneal dialysis patients):
 - Contribute to interprofessional discussion about patients.
 - Identify admitted patients for discharge medication reconciliation.
 - Identify patients for medication review by a pharmacist.
3. Perform discharge (and transfer) medication reconciliation before discharge for admitted patients or at first subsequent home or center-based dialysis session (hemodialysis and peritoneal patients).
 - Reconcile inpatient medications with home and in-center medications.
 - Perform detailed medication review and document MTPs and recommendations for resolution and follow-up plan in the patient's medical record.
 - With collaborative practice agreement in place, write/send a prescription order for new medications started in hospital, at home or in-center. Contact prescribing nephrologist to make recommendations and confirm prescription.
 - Provide patient with reconciled medication list and counsel patient.
4. Review monthly laboratory test results for hemodialysis patients and prior to nephrology clinic or home visits.
5. Perform detailed medication review for new starts to hemodialysis or peritoneal dialysis within 2 weeks.
6. Perform detailed medication review for other patients on a regular basis.

The pharmacist will perform the following “must do” activities (prioritized according to pharmacist's professional judgment):

- Ensure follow-up laboratory tests are ordered, according to pharmacist's recommendations.
- Ensure patients have adequate prescriptions and refills.
- Liaise with community pharmacy as appropriate (eg, to facilitate prescription delivery, adherence aid, drug coverage, adherence packaging).
- Liaise with patient, caregivers, family members, and other health care professionals as appropriate to provide medication-related information to or for patients.
- Provide drug information for immediate patient care that day.
- Provide education to pharmacy students and residents.
- Provide monitoring and follow-up for recommendations.^b
- Provide communication with other pharmacists within the facility.^b

The pharmacist shall perform the following *desirable* activities as appropriate and as pharmacist is available:

- Participate in pharmacy program initiatives (eg, development of drug protocols, participation on committees, development of policy and procedures, responses to drug shortages).
- Provide education-related activities to health care professionals.
- Provide communication with other pharmacists at other facilities.
- Provide drug information not needed immediately.
- Perform drug-use management activities, including prospective audits.
- Participate in projects or research.
- Investigate medication incidents or errors.
- Review or triage new medication orders to identify drug therapy problems related to appropriateness, duration, and dosing of each medication, as well as drug interactions (as an activity separate from medication review, medication reconciliation, or clinic visit).
- Participate in nephrology organizations, including service on committees, presentation at national meetings, and publication in nephrology journals.

Note: The standards are adapted from successful Canadian models⁶¹ and serve as a baseline for additional development by the newly formed Advancing American Kidney Health through Optimal Medication Management agenda.

Abbreviations: CKD, chronic kidney disease; MTP, medication therapy problem.

^aEvening and weekend in-center hemodialysis patients are reviewed and seen by pharmacists who work later shifts periodically, in order that all patients are seen by a pharmacist.

^bWhen the pharmacy is short-staffed, these are considered “should do” (rather than “must do”) activities.

should be clearly defined metrics for benchmarking quality and outcomes. Metrics should include service-related (eg, medication reconciliation, MTP identification,⁶⁷ and resolution⁶⁶) and global (eg, hospitalization) end points, but also link to new value-based models of care (eg, performance-based adjustments, shared savings/shared losses of the Kidney Care Choices models) and importantly, patient-centered outcomes. Funding agencies such as the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Center for Medicare and Medicaid Innovation should work toward developing requests for application that support rigorous studies evaluating best practice metrics and outcomes. Table 5 displays metrics proposed by this working group and is meant to facilitate further development. It will also be critical to evaluate the cost-effectiveness of pharmacist-based care in the various new care models.

5.2 | Training opportunities for current workforce

Following a consensus standard of practice, training opportunities should be developed to equip pharmacists in the workforce to fully engage with the expectations of the standards. This would ideally include an accredited certificate program with a variety of knowledge, application, and practice-based continuing education offerings. Colleges and schools of pharmacy could offer the certificate program to interested students. This would serve a number of purposes: (a) Provide uniform education and training to pharmacists and students providing care for patients with CKD, (b) Engage students early in their education to stimulate interest in the field of nephrology pharmacy, and (c) Promote development of innovative advanced pharmacy practice experiences and postgraduate training programs in nephrology practice. Training should extend beyond therapeutic knowledge and include critical skills in CMM, telehealth, and medication reconciliation, each of which have currently available training programs from major pharmacy organizations. Focused training in dose optimization based on kidney function assessment, pharmacokinetic, and pharmacodynamic alterations in kidney diseases, dialysis modalities, and drug removal should be included given its complexity and importance to patient care. Training for certified pharmacy technicians should include a Medication History Certificate as well as additional training on kidney diseases and common medications used in management of patients with kidney diseases to prepare them for this specialized population.

For a number of years, postgraduate year 2 (PGY-2) residency training in nephrology was an excellent source of highly qualified clinical nephrology pharmacists. Graduates from these programs are current thought leaders in the field, driving forward innovative clinical pharmacy practice models in nephrology that will serve as a benchmark for the models moving forward. Unfortunately, nephrology PGY-2 residency programs are no longer available as accredited programs through the American Society of Health-System Pharmacists. Pharmacists in the ambulatory care setting are well positioned to provide the proposed CMM services in CKD and dialysis clinics. Nephrology is an optional specialty care experience for current ambulatory

TABLE 5 Proposed metrics to evaluate pharmacy services in patients with kidney disease

Task	Metrics
Medication reconciliation	Percent and types of medication discrepancies (omission, commission, or duplication) Number of patients with completed medication reconciliation: ^a <ul style="list-style-type: none"> • Upon hospital admission (all patients) • Upon hospital discharge (all patients) • Once per month (ESKD patients)
CMM	Number and type of MTPs identified using Pharmacy Quality Alliance categories framework ⁶⁶ Number, %, and type of MTPs resolved PROMs Patient satisfaction Provider satisfaction Rate of all-cause hospitalization Rate of medication-related hospitalization Total and medication-related hospitalization costs Total costs of care (per capita costs)
CMM focused in CKD	Depression screening and treatment effectiveness PAM scores Proportion of patients with diabetes and albuminuria receiving an ACEi or ARB Proportion of patients with diabetes receiving SGLT-2i or GLP-1a Change in albuminuria Proportion of patients achieving blood pressure target Rate of decline in eGFR Incidence of new onset ESKD Kidney disease medication-related education <ul style="list-style-type: none"> -Number of patients completing education -Patient knowledge -PAM scores
CMM focused in ESKD	Time to complete medication reconciliation after hospital discharge Time to complete CMM after hospital discharge Patient's health-related quality of life PROMs: for example, pruritis, pain, muscle cramping Through collaborative team-based care, pharmacists can help achieve a higher proportion of patients achieving guideline-directed targets for hemoglobin, transferrin saturation, and ferritin Kidney disease medication-related education <ul style="list-style-type: none"> -Number of patients completing education -Patient knowledge -PAM scores
Adherence counseling and aids	Proportion of days covered

Abbreviations: ACEi, angiotensin converting enzyme inhibitor; ARB, angiotensin-II receptor blocker; CKD, chronic kidney disease; CMM, comprehensive medication management; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; GLP-1a, GLP-1 receptor agonist; MTP, medication therapy problem; PAM, patient activation measurement; PROM, patient reported outcome measure; SGLT-2i, sodium glucose co-transporter-2 inhibitor.
^aMedication reconciliation as defined by the Agency for Healthcare Research and Quality (AHRQ) Medications at Transitions and Clinical Handoffs (MATCH) Toolkit; quality measures of medication reconciliation specific to the ESKD in-center dialysis population as defined by CMS National Quality Forum #2988 Safety Measure.³⁴

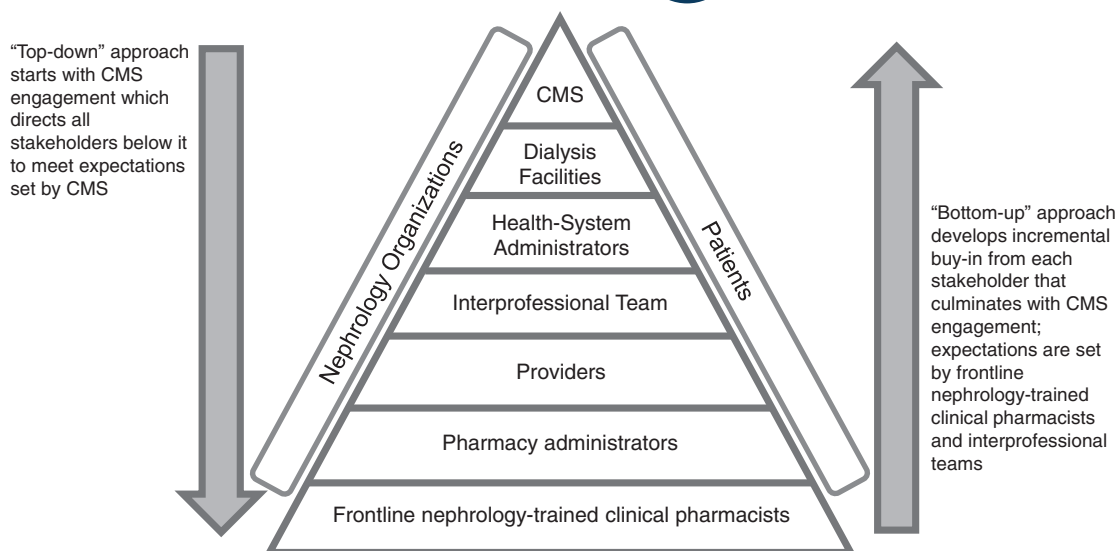


FIGURE 2 Approaches to engage key stakeholders. We propose a bottom-up approach to engaging stakeholders. This will build relationships and teams that can demonstrate value to health-systems, dialysis facilities, and CMS. Patients should be engaged throughout the process. Nephrology trained pharmacists should be active in nephrology organizations throughout stakeholder engagement. CMS, Centers for Medicare and Medicaid Services

care PGY-2 residency programs. In order to maintain a necessary pipeline of qualified pharmacists, we suggest: (a) Integrating a required nephrology care experience into ambulatory care PGY-2 residency programs with an option for a nephrology certificate program, (b) Reinstating nephrology as a recognized specialty PGY-2 program, and (c) Creating board certification in clinical nephrology pharmacy. The latter two recommendations represent long-term goals that may organically evolve as nephrology pharmacy becomes more mainstream.

5.3 | Engage key stakeholders

There are two basic approaches to engage stakeholders: “top-down” or “bottom-up” (Figure 2). The “top-down” approach was not successful in the last attempts to integrate pharmacists under “conditions for coverage” in the CMS final rule for dialysis facilities in 2009. Therefore, we propose a “bottom-up” approach to stakeholder engagement in the current climate. Frontline clinical pharmacists will need to engage health-system administrators to broaden their services for patients with CKD. Pharmacists should collaborate with key thought leaders in nephrology, nursing, and dietary fields to build high quality interprofessional teams. Academic settings are well suited to engage students to stimulate interest in nephrology-related training programs and careers. For example, the CKD initiative through the Student National Pharmaceutical Association, is an excellent pre-existing opportunity. Health-systems and dialysis facilities should be approached from these interprofessional teams, administrators, and frontline pharmacists to propose systematic pharmacists' care integration into CKD and dialysis

clinics. As highly successful, novel models of interprofessional practice are supported by the Advancing American Kidney Health initiative, these teams should engage CMS in dialog about the body of evidence showing improved patient outcomes. Patients should also be engaged throughout the process with a focus on their satisfaction with CMM services and quality of life.⁶⁸ The “bottom-up” approach allows for frontline pharmacists to provide much greater input to the development of successful interprofessional models and be viewed as a truly value-added component of the team. This approach will build a strong evidence base for pharmacist involvement that should touch on all components of the quadruple aim. In the new voluntary payment models, pharmacists can generate revenue for dialysis facilities through performance-based adjustments and shared savings mechanisms. Cost measures should be well documented and evaluate the incremental impact of pharmacists on cost savings/revenue generation in these new voluntary Kidney Care Choices models. We expect that positive results will motivate dialysis facilities and other health-systems to include pharmacists as members of their interprofessional teams and provide additional evidence-based justification for CMS to include pharmacists under “conditions for coverage.” The newly established Advancing American Kidney Health through Optimal Medication Management agenda will be developing and enacting a stakeholder engagement action plan in the near future.

6 | CONCLUSION

The Advancing American Kidney Health initiative and the new medication reconciliation Quality Incentive Program measure for ESKD

patients represent two significant opportunities for pharmacists to improve the care of patients with CKD. Building evidence shows that pharmacist-based care in patients with CKD leads to reduced hospital admissions, length of stay, readmissions, incidence of ESKD, and death. Despite these benefits, pharmacists are not routine members of nephrology care teams. The Advancing American Kidney Health initiative is shifting to value-based models of care where pharmacists will be critical to achieve optimal patient outcomes and reimbursement. As a profession, we must engage key stakeholders, including payers, nephrology practices, and patients to integrate pharmacists. Standards of practice for nephrology pharmacists, including core competencies and training programs to achieve these, should be rapidly developed. We must keep the patients with CKD at the center of this initiative as we firmly believe that pharmacists' care will improve their health outcomes and quality of life.

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CONFLICT OF INTEREST

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