Kidney Medicine

Pharmacy Practice Standards for Outpatient Nephrology Settings

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Patients with kidney disease represent a medically complex group of patients with high medication burdens that could benefit from clinical pharmacy services as part of the interdisciplinary care team to optimize medication use. The "Advancing American Kidney Health" executive order includes new value-based reimbursement models to be tested by the Center for Medicare and Medicaid Innovation beginning January 2021 and January 2022. Advancing American Kidney Health executive order poses opportunities for the inclusion of comprehensive medication management. Following an iterative process integrating input from a diverse expert panel, published standards, clinical practice guidelines, peer review, and stakeholder feedback, our group developed practice standards for pharmacists caring for patients with kidney disease in health care settings. The standards focus on activities that are part of direct patient care and also include activities related to public health and advocacy, population health, leadership and management, and teaching, education and dissemination of knowledge. These standards are intended to be used by a variety of professionals, from pharmacists starting new practices to practice managers looking to add a pharmacist to the clinical team, to create standardization in services provided.

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INTRODUCTION

Chronic kidney disease (CKD) is a burdensome health condition and significant public health concern.[1] At least 1 in 7 Americans has CKD, and the disease disproportionately affects people of racial or ethnic minorities and those with low socioeconomic status.[2] CKD is often the result of other chronic health conditions such as diabetes or hypertension and is progressive in nature. However, because of the lack of symptomatic disease until very late stages, it is often unrecognized or undertreated. Patients who progress to kidney failure require life-sustaining intervention with either dialysis or kidney transplant. Patients with kidney failure are medically complex and require an average of 11-12 home medications with even higher pill burdens to treat multiple chronic health conditions.[3,4] Once receiving dialysis, patients have an average hospitalization rate of 1.6 admissions per year.[5] Medication regimens are frequently changed during hospital stays, and likewise, medication therapy problems have the potential to cause or contribute to hospital admissions. Patients may have trouble managing their medication regimens that include not only a high number of medications but also complex instructions and frequent changes.[6-8]

The US government is a major stakeholder in the care of patients with CKD because most patients requiring dialysis and kidney transplant are Medicare beneficiaries regardless of age.[9] In 2018, there were 554,038 patients on dialysis and 229,887 patients with a functioning kidney transplant in the United States.[5] In 2018 dollars, this equated to an average annual per patient cost of $93,191 for hemodialysis, $78,741 for peritoneal dialysis, and $37,304 for kidney transplant.[5] The executive order "Advancing American Kidney Health" was signed in 2019 and included the following 3 aims: (1) to decrease by 25% the number of new patients with kidney failure; (2) to have 80% of new patients with kidney failure undergo either home dialysis or a preemptive transplant; and (3) to double the number of organs available for kidney transplant.[10] To accomplish these aims, new reimbursement models will be tested by the Center for Medicare and Medicaid Innovation beginning January 2021 for the End-Stage Renal Disease Treatment Choices model and January 2022 for the Kidney Care Choices model and will include patients with CKD who have not developed kidney failure.[11,12] All models are value-based and focus on cost sharing between Medicare and the participants as briefly described in Table 1.[13] The models are focused on preventive measures and outpatient interventions with opportunities for comprehensive medication management (CMM). In response to these new care models for patients with CKD, we herein present practice standards for pharmacists working with kidney patients to provide standardization in services provided.

PRACTICE STANDARDS DEVELOPMENT

Practice standards were developed using a multistep process with stakeholder feedback. A group of nephrology pharmacy experts was initially convened in April 2019 and established the Advancing Kidney Health through Optimal Medication Management (AKHOMM) initiative, whose vision is that every person with kidney disease receives optimal medication management through team-based care including a pharmacist to ensure medications are safe, effective, affordable, and convenient for them to use.[14] Based on their collective experience caring for patients

Table 1. Advancing American Kidney Health models[13]

Model	ESRD Treatment Choices	Kidney Care Choices (KCC) *Includes Kidney Care First and Comprehensive Kidney Care Contracting*
Participants	Nephrologists; dialysis facilities	Nephrologists; transplant centers; dialysis providers
Beneficiaries	Patients on dialysis	Patients with CKD 4 and 5 and on dialysis
Quality Measures	ESRD Quality Incentive Program	ESRD Quality Incentive Program; Depression Remission (NQF-1885); Increase in Patient Activation Measure (NQF-2483); Optimal ESRD starts; Decrease in total cost of care

Abbreviations: CKD, Chronic kidney disease; ESRD, end-stage renal disease.

with kidney disease, 2 subcommittee chairs were chosen for development of practice standards. They were assisted by the co-leader of the AKHOMM initiative, who served as a liaison between the practice standard group and the AKHOMM initiatives leadership group. The primary objective was to develop practice standards for addressing CMM issues in patients with kidney disease, including acute and chronic illnesses. Given the scope of the Advancing American Kidney Health executive order, the group focused its efforts on identifying practice standards for outpatient settings. Standards were developed using an iterative process that began with convening a broad group of experts, including pharmacists from across the United States and abroad (mainly Canada), working in inpatient, outpatient, public, private, family medicine, academia, and Veterans' Affairs settings. The group used published literature, existing standards (eg, American Society of Health-System Pharmacy Post-Graduate Year 2 (PGY2) Ambulatory Care residency competency areas, goals, and objectives[15]; the Patient Care Process for Delivering Comprehensive Medication Management[16]; previously published nephrology pharmacy practice standards for Canadian renal pharmacists[17]; and clinical practice guidelines [eg, Kidney Disease: Improving Global Outcomes (KDIGO) guidelines][18] as well as other disease-specific guidelines which include but are not limited to diabetes, cardiovascular disease, hypertension, and lipids), and practice experience to identify key interventions for optimizing medication use in outpatient settings where patients with kidney disease would be seen. Group leaders assembled an initial framework for the standards, modeling the Patient Care Process for Delivering Comprehensive Medication Management.[16] Published in 2018 and endorsed by the American College of Clinical Pharmacy, it provides essential functions along with associated operational definitions that cover the entire scope of providing CMM to any patient. Beyond direct patient care, these nephrology practice standards also discuss other services in the areas of public health and advocacy; population health; leadership and management; and teaching, education, and dissemination of knowledge. Panel members evaluated the framework for relevance and provided specific details pertinent to patients with kidney disease. Three rounds of review and comments from the panel were conducted. Stakeholder feedback (n = 12) was then collected from nephrology practitioners including physicians, advanced practitioners, pharmacists, nurses, and dietitians, then incorporated based on consensus among group leaders and reviewed by the remaining authors. The subcommittee chairs also met regularly with the leadership of AKHOMM's education standards subcommittee, focused on identifying key knowledge and skills for pharmacists, pharmacy technicians, pharmacy residents, and pharmacy students working with kidney patients, to ensure alignment such that the educational standards[19] would result in pharmacists prepared to follow these practice standards.

PHARMACY PRACTICE STANDARDS IN KIDNEY DISEASE

Under each core area below, practice standards are italicized and bulleted. Specific examples and details related to these standards can be found in Tables S1-S4.

Direct Patient Care

- *Pharmacists should regularly participate in direct patient care activities including comprehensive medication management.*

Boxes 1 and 2 provide an overview of the pharmacist's provision of CMM in outpatient settings where patients with kidney disease seek care. Detailed examples for each Essential Function are provided in Tables S1-S4. As part of all direct patient care activities, the pharmacist should individualize care whenever possible, considering individual patient preferences, gender preferences, social determinants of health, and health literacy, while exhibiting cultural humility. When working with an interprofessional team including a nephrologist, pharmacists often discover medication therapy problems outside the scope of kidney practice, requiring communication with the patient's primary care physician, other specialists, or other health care providers. Examples may include management of diabetes, pain, lipids, mental health, or antimicrobial therapies.

Frequency of pharmacist review should be individualized, based on the patient's acuity, risk stratification, level of kidney function, and around other medical visits. KDIGO recommends more frequent medical visits as CKD progresses (Fig 1).[21,22] We recommend using the frequencies listed in the figure as a reasonable starting point with adjustments as warranted. For patients on dialysis, the End-Stage Renal Disease Quality Incentive Program medication reconciliation measure dictates medication lists are updated at least monthly.[23] In all settings, it is recommended that medications be reviewed following hospitalization or other transitions of care.[24]

Box 1. Pharmacists' Provision of Comprehensive Medication Management in Outpatient Nephrology Settings

Essential Functions as defined by the Patient Care Process for Delivering Comprehensive Medication Management

Collect and Analyze Information

- Medication history including prescription, nonprescription, complementary/alternative agents, social drugs, and adherence
- Immunization status
- Kidney function evaluation
- Screen for social determinants of health
- Subjective and objective data regarding
  - ◇ Hypertension
  - ◇ Diabetes
  - ◇ Lipid panel
  - ◇ Chronic kidney disease
  - ◇ Acute kidney injury
  - ◇ Drug-induced kidney disorders
  - ◇ Anemia
  - ◇ Electrolytes/acid base
  - ◇ CKD mineral and bone disorder
- Glomerulonephritis

Assess the Information and Formulate a Medication Therapy Problem List

- A comprehensive medication review should be conducted and include these considerations:
  - ◇ Suitability of medications regarding documented need, adverse effects, polypharmacy, etc.
  - ◇ Medications to slow progression of CKD in patients without kidney failure
  - ◇ Dosage adjustment based on kidney function
  - ◇ Avoidance of nephrotoxins, when possible[20]
  - ◇ Adherence barriers such as cost, access, cognitive function, and need for education
  - ◇ Pretransplant
    - ▪ Assess for drug-drug interactions with immunosuppressants
    - ▪ Identify medications that should be stopped or avoided once transplant occurs
  - ◇ Determine need for adherence aids or community resources to support adherence
- Immunizations needed, including all Advisory Committee on Immunization Practices-recommended vaccines, with special attention to hepatitis B vaccination status for patients on dialysis
- Hypertension management
- Fluid balance and need for diuretics
- Diabetes management
- Lipid panel
- Nature of kidney disease (eg, chronic kidney disease, acute kidney injury, acute kidney disease, and drug-induced kidney disorders)
- Presence and status of anemia
- Status of electrolytes and acid-base
- Development of CKD mineral and bone disorder

Develop the Care Plan

- All components assessed (listed under Assess Information and Formulate a Medication Therapy Problem List)
- Shared decision-making with patient/care partner and consultation with interprofessional team
- Keep in mind overall goal of care: transplant vs kidney replacement therapy versus palliative care

Implement the Care Plan

- Communicate plan and seek input from the interprofessional team, which may include nonnephrology providers
- Discuss the plan with the patient, including providing individualized education, with consideration of health literacy, regarding the medication regimen, nonpharmacologic interventions, and resources to help overcome barriers to care
- Provide a patient-friendly copy of the updated medication list to the patient/caregiver
- Ensure patient has adequate prescriptions and refills and has timely access to their medications
- Document the encounter in the medical record

Follow-up and Monitor

- On a routine basis, collect follow-up information, update patient data, conduct assessments, and revise the care plan

Abbreviation: CKD, chronic kidney disease.

- *Pharmacists should assist in prescription drug plan selection, when warranted.*

Patients included in new value-based kidney care models are Medicare beneficiaries, and about 75% receive prescription drug coverage through Medicare Part D.[5] Pharmacists should be aware of the plan structure for Medicare Part D, including formulary tiers, open-enrollment periods, and medication therapy management

Box 2. Additional Details Regarding the Essential Functions for Each Unique Outpatient Setting

Collect and Analyze Information

Outpatient Kidney Clinic

- Medication lists include injectables administered at infusion clinics

Outpatient Dialysis Unit (IHD) or Home Dialysis (HHD, PD)

- Medication lists include injectables administered during dialysis
- Dialysis records
- Antimicrobial drug levels

Transplant Clinic

- Immunosuppression drug levels
- Infection-related screening
- Antimicrobial drug levels
- Complete blood cell count
- Pregnancy test

Assess the Information and Formulate a Medication Therapy Problem List

Outpatient Kidney Clinic

For patients with glomerulonephritis:

- Immunosuppressive pretreatment assessment
  - ◇ TB
  - ◇ HIV
  - ◇ Hepatitis B
  - ◇ Hepatitis C
  - ◇ CMV
- Immunosuppressive therapy

Outpatient Dialysis Unit (IHD) or Home Dialysis (HHD, PD)

- Timing of medications with regard to dialysis schedule
- Monitor IV antibiotic levels, dosage, and timing with regard to dialysis
- Dialysis adequacy
- Infection
- Intradialytic complications
- Restless leg syndrome
- Anticoagulant/antiplatelet dosing

Transplant Clinic

- Kidney transplant/graft function
- Infection prophylaxis

Abbreviations: CMV, cytomegalovirus; HHD, home hemodialysis; HIV, human immunodeficiency virus; IHD, intermittent hemodialysis; IV, intravenous; PD, peritoneal dialysis; TB, tuberculosis.

programs to guide patients in maximizing medication coverage.

These standards imply that the pharmacist will stay abreast of emerging treatment options, updates to kidney function evaluation, methods for improving health equity in patients with kidney disease, and updated treatment guidelines. The pharmacist is expected to be self-motivated to maintain the most up-to-date, evidence-based therapeutics through a variety of means including participation in national kidney and/or pharmacy organizations, continuing education programs, etc.

We recognize the importance of support staff in providing CMM services. We support the use of pharmacy technicians and pharmacy trainees (residents, interns, and students) in the delivery of care to patients in kidney settings with the proper oversight of licensed, trained pharmacists.[25]

Finally, although these standards are targeted toward adults with kidney disease, pediatric patients should also receive interprofessional team care that includes a pharmacist providing CMM.

Public Health and Advocacy

- *Pharmacists working with patients with kidney disease should be prepared to lead or participate in kidney educational initiatives, immunization campaigns, health screenings, and advocacy efforts.*

National health initiatives recognize the importance of kidney disease and focus on preventing, treating, and diagnosing CKD. As a member of an interprofessional care team, pharmacists play a key role in advocacy for and empowerment and education of patients with or at risk for kidney disease, especially in communities (African American, Latino/Hispanic, Native American, and Native Alaskan) disproportionately affected compared with White patients.[26] Specifically, pharmacists play a key role in awareness of kidney disease and preventive measures.

Population Health

As a member of an interprofessional care team, pharmacists can be involved in population-level health care where the entire population of patients with kidney disease for a given health care setting is managed or studied to assure equitable, inclusive care to meet quality metrics.[27-29] As such, pharmacists should engage in the following activities in this domain:

- *Pharmacists caring for patients with kidney disease should participate in the development, revision, and implementation of protocols related to the care of patients with or at risk for kidney disease or associated complications.*
- *Pharmacists should conduct medication use evaluations to ensure clinical and quality population metrics are met.*
- *Within the practice, pharmacists and the interprofessional team should promote equity to ensure all patients receive access to CMM without regard to socioeconomic status, race, gender, sex, religious beliefs/practices, sexual preferences, or health literacy.*

Leadership and Management

Pharmacists serve as leaders in health care settings and may oversee other pharmacy staff to support their work across the spectrum of clinical settings in which they practice.

- *The pharmacist should ensure proper supervision and professional development of pharmacy team members.*

Pharmacists may lead and supervise teams that include other pharmacists, pharmacy technicians, pharmacy residents, and interns or students.

- *Pharmacists should ensure that services are efficient, effective, and well-integrated into the interprofessional health care team.*[30,31]

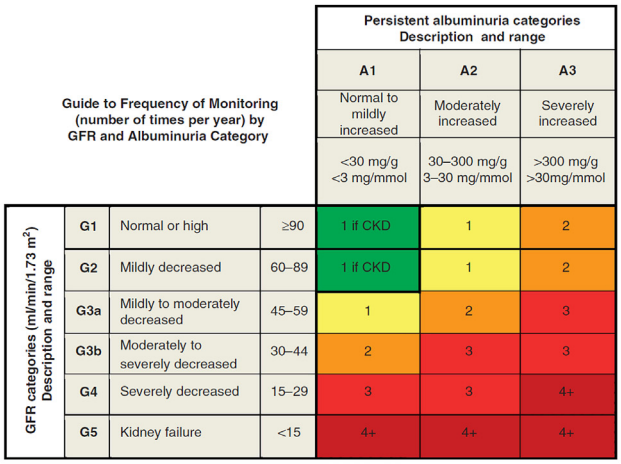

Figure 1. KDIGO Guide to Frequency of Monitoring by GFR and Albuminuria Category. Reprinted with permission of Elsevier.[21,22] Abbreviations: CKD, Chronic kidney disease; GFR, glomerular filtration rate. Abbreviations: CKD, chronic kidney disease; GFR, glomerular filtration rate.

Teaching, Education, and Dissemination of Knowledge

- *As part of the interdisciplinary team, pharmacists should play a key role in providing education on kidney disease and medication management to a variety of stakeholders, including administrators, payors, nephrologists, advanced practitioners, other pharmacists, nurses, dietitians, social workers, other health care providers, and patients.*

Although delivering individual patient care is of utmost importance, these larger audiences can result in improved care for the entire population of patients with kidney disease. Examples of various educational settings/groups include the following: group education to patients and care partners on kidney-related disease states and medications; administrator education on pharmacy services; interprofessional health care provider education on medication use in patients with kidney disease; pharmacy education, including pharmacy interns and postgraduate pharmacy residents through participation as a clinical training site; pharmacy technician and pharmacist education through continuing education programs focused on complications and medication management in kidney disease; training to all groups on the disproportionate effect of kidney disease on minorities (African American, Latino/Hispanic, Native American, and Native Alaskan); and social determinants of health and barriers to optimal medication use.

DISCUSSION

Pharmacists are well poised to address the breadth of medication therapy problems that affect care among patients with kidney disease. Although data exist demonstrating the benefits of pharmacist integration in patient care settings, and despite a well referenced report to the Surgeon General regarding pharmacist clinical services, there are currently few examples of sustainable pharmacist integration in outpatient nephrology settings.[32,33] Within kidney disease health care settings, there are limited opportunities for reimbursement for pharmacist services, and pharmacists are not currently required to be members of dialysis care teams according to the Centers for Medicare and Medicaid Services End-Stage Renal Disease Conditions for Coverage.[34] Clinical research within nephrology has demonstrated the need for pharmacist services[4,7,8] and the benefits of clinical pharmacist integration as part of the care team.[35,36] Briefly, these data demonstrate improved surrogate outcomes and in some cases, major clinical and cost outcomes. Examples include identifying and resolving medication therapy problems, deprescribing unnecessary or harmful medications,[37] improving blood pressure and albuminuria postacute kidney injury,[38] reducing risk categorization for patients with kidney transplant,[39] reducing hospital lengths of stay[35] and hospital readmissions among patients on dialysis,[36] and reducing medication errors, adverse events, and hospitalizations among transplant recipients[40] with associated cost savings.[41] Recent publications in primary care also demonstrated reduced physician burnout when pharmacists joined the care team as well as high levels of patient satisfaction.[42-44] Recently published clinical practice guidelines specifically highlight the important role of pharmacists in kidney care. Examples include the KDIGO 2009 Kidney Transplant Recipient Guideline,[45] the KDIGO 2020 Diabetes and CKD,[46] the American Diabetes Association Standards of Medical Care in Diabetes - 2022,[26] and the 2017 American College of Cardiology/American Heart Association Hypertension Guidelines.[47] These standards support not only pharmacist involvement in kidney clinics but also in primary care settings where patients with earlier

stages of CKD receive care and require optimization of key therapies (eg, renin-angiotensin-aldosterone system blockers, sodium/glucose cotransporter 2 inhibitors, glucagon-like peptide-1 receptor agonists, and mineralocorticoid receptor antagonists).

Inequities in the care of patients with kidney disease are well described in the literature and stem from a variety of factors termed social determinants of health. Social determinants of health impact access to care and the ability to adhere to medical care, which lead to increased morbidity and mortality for various groups of patients with kidney disease (eg, minorities, low socioeconomic background, etc) and reduced use of home dialysis modalities.[48-50] A recent report showed use of sodium-glucose cotransporter 2 inhibitors was lower in patients who were African American, female, or had low socioeconomic status compared with other groups, despite being an evidence-based intervention to slow CKD progression.[51] Pharmacists providing CMM to patients with kidney disease can help interdisciplinary teams to address each patient's unique social determinants of health with a goal of increasing access to key medications, adherence to prescribed medication therapy, and implementation of evidence-based guidelines.

The rapid expansion of new care models through Center for Medicare & Medicaid Innovation, including companies partnered with health plans to provide integrated care (wrap-around kidney care) and within health systems as well as mounting evidence on the benefits of medication management provided to patients by pharmacists, open up opportunities to integrate CMM into the routine care of patients with kidney disease. It is our hope that the practice standards presented here along with future curriculum and training programs developed through the AKHOMM initiative (www.kidneymedicationmanagement.org) will guide pharmacists and interprofessional care teams to implement CMM in kidney practice settings to address the quadruple health care aim. These standards are currently being disseminated to professional pharmacy organizations (eg, American Colleges of Clinical Pharmacy, American Society of Health-System Pharmacists, and American Pharmacists Association) and nephrology organizations (eg, American Society of Nephrology and National Kidney Foundation) to promote awareness of the role of pharmacists in the care of patients with kidney disease.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Table S1: Nephrology Pharmacy Practice Standards for Patient Care

Table S2: Nephrology Pharmacy Practice Standards for Population Health

Table S3: Nephrology Pharmacy Practice Standards for Leadership and Management

Table S4: Nephrology Pharmacy Practice Standards for Teaching, Education, and Dissemination of Knowledge

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