Medication Reconciliation and Therapy Management in Dialysis-Dependent Patients: Need for a Systematic Approach

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Summary
Patients with ESRD undergoing dialysis have highly complex medication regimens and disproportionately higher total cost of care compared with the general Medicare population. As shown by several studies, dialysis-dependent patients are at especially high risk for medication-related problems. Providing medication reconciliation and therapy management services is critically important to avoid costs associated with medication-related problems, such as adverse drug events and hospitalizations in the ESRD population. The Medicare Modernization Act of 2003 included an unfunded mandate stipulating that medication therapy management be offered to high-risk patients enrolled in Medicare Part D. Medication management services are distinct from the dispensing of medications and involve a complete medication review for all disease states. The dialysis facility is a logical coordination center for medication management services, like medication therapy management, and it is likely the first health care facility that a patient will present to after a care transition. A dedicated and adequately trained clinician, such as a pharmacist, is needed to provide consistent, high-quality medication management services. Medication reconciliation and medication management services that could consistently and systematically identify and resolve medication-related problems would be likely to improve ESRD patient outcomes and reduce total cost of care. Herein, this work provides a review of available evidence and recommendations for optimal delivery of medication management services to ESRD patients in a dialysis facility-centered model.


Introduction
Dialysis-dependent patients with ESRD have a high medication burden. Several surveys of dialysis patients in the United States indicate that they are prescribed an average of 11–12 medications per day and take, on average, 17–25 doses per day (1–4). This substantial medication burden comes at a considerable societal cost, because 61%–73% of Medicare-enrolled dialysis patients obtain prescription drug coverage through Medicare Part D; also, parenteral medications administered in a dialysis facility for these patients are paid through Medicare Part B. In 2010, the total per beneficiary per year costs for Medicare Parts D and B drugs and related supplies in hemodialysis patients were $15,311 and $7,728 for patients with and without the low-income subsidy, respectively (1).

The high medication burden also results in frequent medication-related problems (MRPs), defined as “undesirable events experienced by the patient that involves, or are suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy” (5). MRPs include adverse drug events and inappropriate under- and overuse of drug therapy (6). Dialysis-dependent patients have many of the risk factors consistently associated with a high likelihood of MRPs (2,7–9). Table 1 provides examples of potential MRPs in dialysis-dependent patients. Not surprisingly, several studies have shown a high prevalence rate of MRPs in patients undergoing maintenance dialysis (6,10–12) (Table 2).

Reducing MRPs has the potential to generate considerable cost savings to the health care system. Using data from the general population, it has been estimated that, for every $1 spent on detecting and addressing MRPs in the dialysis population, $4 may be saved by the health care system (13). More recently, Isetts et al. (14) analyzed medication therapy management (MTM) services in Minnesota and observed that the reduction in total annual health expenditures exceeded the cost of providing MTM services by more than 12 to 1 in the general population. These cost savings are expected to accrue from lower prescription drug costs from avoidance of unnecessary and/or inappropriate medications and fewer hospitalizations. Indeed, MRPs in the general population are implicated in approximately 16% of hospital admissions, and 50% of these hospitalizations are potentially avoidable (15). The actual costs attributable to MRPs in dialysis-dependent patients may be higher than the estimates derived from the general population. Medication costs continue to rise in ESRD patients, and responsibility for costlier medications in dialysis patients’ medication regimens (e.g., noncalcium phosphate binders and cinacalcet) will be...
assumed by the dialysis facility in 2016 (1). In one study of patients with stage 5 CKD, MRPs were implicated in nearly 50% of hospitalizations—they were the sole reason for 18% of hospitalizations, and they contributed to an additional 29% of hospitalizations (16). Additionally, over 50% of MRPs documented in hospitalized dialysis patients are preexisting and identified on admission (17).

### The Burden of MRPs in Dialysis Patients Is High

Most data regarding MRPs in patients with ESRD pertain to adults undergoing in-center hemodialysis (12). Over the past 20 years, 11 studies have evaluated MRPs in in-center hemodialysis patients. Collectively, pharmacists participating in these studies evaluated over 900 patients and found the average number of MRPs per patient to be 4.5 (range 2.8–7.2). Pharmacist drug therapy recommendations that address MRPs were implemented up to 96% of the time by the medical team (Table 2). Data for other populations of dialysis patients are relatively sparse. In a prospective, observational study of 42 patients undergoing peritoneal dialysis, the mean number of prescription medications was 9.2, and the mean number of nonprescription

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<tr>
<th>Medication-Related Problem (Abbreviation)</th>
<th>Description</th>
<th>Examples</th>
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<tr>
<td>Indication without drug therapy (IWD)</td>
<td>Patient is not receiving medication for a diagnosed medical condition</td>
<td>A patient with an elevated mean corpuscular volume not on a renal vitamin</td>
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<td>Drug use without indication (DWI)</td>
<td>Use of a medication without a valid indication</td>
<td>Failure to discontinue diuretic therapy in an anuric patient</td>
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<td>Improper drug selection (IDS)</td>
<td>Medication of choice is not being used</td>
<td>Initiating a calcium-based phosphate binder in a hypercalcemic patient</td>
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<td>Subtherapeutic dosage (UD)</td>
<td>Patient has a medical problem that is being treated with inadequate dose of the correct medication</td>
<td>A patient continues to receive the same dose of sevelamer carbonate despite serum phosphorus levels of &gt;6 mg/dl on the last two monthly measurements</td>
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<td>Overdose (OD)</td>
<td>Patient has a medical problem that is being treated with too high a dose of the correct medication</td>
<td>Not adjusting the dose of renally eliminated medications</td>
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<td>Adverse drug reaction (ADR)</td>
<td>Drug effects that are unwanted, unpleasant, or harmful</td>
<td>Nonproductive cough associated with angiotensin-converting enzyme inhibitor therapy</td>
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<td>Drug interaction (DI)</td>
<td>Negative effects of drug–drug, drug–disease, or drug–food interaction</td>
<td>Excessively dry mouth from clonidine leading to increased fluid intake and large interdialytic weight gain</td>
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<td>Failure to receive drug (FRD)</td>
<td>Patient is not receiving prescribed medication(s)</td>
<td>Nonadherence to medication regimen (e.g., patient does not bring phosphate binders when they eat out)</td>
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<td>Inappropriate laboratory monitoring (LAB)</td>
<td>Patient is not undergoing appropriate laboratory tests to adequately monitor medication therapy or determine if comorbid conditions are being treated properly</td>
<td>Medication is not accessible (e.g., cinacalcet is a nonformulary medication)</td>
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<table>
<thead>
<tr>
<th>Author, Publication Year</th>
<th>Patients</th>
<th>Study Design</th>
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<td>Tang <em>et al.</em>, 1993 (52)</td>
<td>55 HD patients</td>
<td>Prospective observational study of clinical interventions made by a clinical pharmacist at an outpatient HD facility over 6 mo</td>
<td>Assess the role of a clinical pharmacist as a member of a team and the nature and effectiveness of clinical pharmacy interventions</td>
<td>Of 205 interventions recommended by clinical pharmacist, 92% were accepted by the medical team; 91% resulted in positive patient outcomes; the most common reasons for interventions were abnormal laboratory test results, drug selection, and dose selection (36%, 32%, and 24%, respectively)</td>
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<td>Kaplan <em>et al.</em>, 1994 (53)</td>
<td>30 HD patients</td>
<td>Point prevalence study evaluating MRPs through a Focused Drug Therapy Review Program run by a clinical pharmacist</td>
<td>Describe medication use in HD patients and characterize the potential MRPs</td>
<td>An average of 10 prescription and 2 nonprescription medications were used per patient; incidence of potential adverse events/intolerances averaged 5.5 and 2.2 per patient, respectively</td>
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<td>Kaplan <em>et al.</em>, 1994 (54)</td>
<td>30 HD patients</td>
<td>Prospective evaluation of the impact of the Focused Drug Therapy Review Program model used in the care of HD patients over a 2-mo period</td>
<td>Test the value and measure the impact of a model of pharmacy practice (Focused Drug Therapy Review Program)</td>
<td>The pharmacist generated 114 therapeutic recommendations and 85 informative comments; prescribers accepted and implemented 76% and 70% of the pharmacist’s recommendations, respectively</td>
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<td>Grabe <em>et al.</em>, 1997 (55)</td>
<td>45 HD patients</td>
<td>Prospective, chart, and medication profile review by a clinical pharmacist over 1 m</td>
<td>Identify MRPs in an outpatient HD facility, make appropriate recommendations to resolve MRPs, and determine the clinical significance of any interventions</td>
<td>126 MRPs were identified, the most common (28%) being drug interactions. Interventions by clinical pharmacist were classified as significant, very significant, and extremely significant in 78%, 5%, and 1%, respectively. Patients were taking a mean of 10.9±3.9 medications and 14.5±6 doses/d before the study and 10.7±4 medications and 14.4±5.8 doses/d at the end of the study</td>
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<td>Possidente et al., 1999 (17)</td>
<td>31 HD; 6 PD patients</td>
<td>Prospective observational study over 14 wk of HD and PD patients admitted to a teaching hospital</td>
<td>Evaluate the continuity of drug therapy in long-term dialysis patients who required hospitalization; identify and resolve MRPs during the transition between the outpatient and inpatient settings</td>
<td>161 MRPs were identified in 30 patients during 32 admissions (4.1 ± 3.9 per patient); of the MRPs, 48% were identified at time of admission, 27% were identified during hospitalization, and 26% were identified at discharge; number of MRPs at admission versus discharge was 77 versus 41 (P = 0.01) Physicians accepted 96% of pharmacist recommendations, and 75% of the accepted recommendations were determined to be significant or very significant clinically</td>
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<td>Manley et al., 2003 (24)</td>
<td>63 HD patients</td>
<td>Prospective observational study of randomly selected HD patients over 5 mo</td>
<td>Evaluate the accuracy of the electronic medical record system at an outpatient HD facility compared with monthly drug interviews</td>
<td>113 drug record discrepancies were identified in 38 patients, which placed patients at risk for adverse drug events and dosing errors 50% and 35% of the time, respectively; inverse association between patient’s age and number of drug discrepancies (r = -0.27, P = 0.04)</td>
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<td>Manley et al., 2003 (56)</td>
<td>133 HD patients</td>
<td>Retrospective chart review of patients undergoing HD at an outpatient dialysis facility</td>
<td>Describe the number, type, and factors associated with MRPs</td>
<td>Patients were prescribed an average of 11.0 ± 4.2 medications; a total of 475 MRPs were identified in 98% of patients (average 3.6 ± 1.8 MRP per patient) MRPs were more likely in patients with diabetes and positively correlated with number of patient comorbidities (r = 0.35, P &lt; 0.001)</td>
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<td>Manley et al., 2003 (10)</td>
<td>66 HD patients</td>
<td>Prospective observational study in which randomly selected HD patients received monthly counseling by a pharmacist over 10 mo at a single dialysis facility</td>
<td>Determine the number, type, severity, and appearance rate of MRPs</td>
<td>354 MRPs were identified in 66 different patients in 5373 medication orders for an overall appearance rate of $0.68 \pm 0.46$ per month per patient; the most common MRPs were medication dosing problems (34%), adverse drug reactions (21%), and failure to prescribe medication despite medical indication (14%)</td>
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<td>Manley et al., 2005 (12)</td>
<td>395 HD patients</td>
<td>Pooled analysis of data from published articles on MRPs in HD patients</td>
<td>Gain insight on MRP type, frequency, appearance rate, and significance</td>
<td>1593 MRPs were identified The most common MRPs were inappropriate laboratory monitoring (24%) and indication without drug therapy (17%)</td>
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<td>Ong et al., 2006 (23)</td>
<td>27 HD; 14 PD; and 9 patients admitted to initiate dialysis</td>
<td>Single center, prospective, clinical assessment of MRPs in patients admitted to a tertiary care teaching hospital over 3 mo</td>
<td>Identify and characterize the MRPs at hospital admission to investigate their relationship to gaps in medication information transfer</td>
<td>199 MRPs were identified in 47 patients; 92% of patients had ≥1 MRP The most common MRP was indication without drug therapy (51% of total MRPs) Of the total MRPs, 65% were related to gaps in medication information transfer</td>
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<td>Pai et al., 2009 (11)</td>
<td>104 HD patients</td>
<td>Prospective, randomized, controlled 2-y pilot study in which patients were assigned to receive either pharmacist counseling (drug therapy reviews) or usual care (brief drug therapy reviews conducted by a nurse)</td>
<td>Investigate the impact of patient counseling on MRPs, drug use, drug costs, and rate of hospitalizations in HD patients</td>
<td>530 MRPs were identified and resolved Pharmacist counseling was associated with use of 14% fewer drugs compared with usual care ($P&lt;0.05$), fewer all-cause hospitalizations ($1.8 \pm 2.4$ versus $3.1 \pm 3$ hospitalizations, $P=0.02$), and shorter cumulative hospital days ($9.7 \pm 14.7$ versus $15.5 \pm 16.3$ days, $P=0.06$)</td>
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HD, hemodialysis; PD, peritoneal dialysis; MRP, medication-related problem.
medications was 2.2 (18). Of the patients using antihypertensive agents, 62% used more than one agent, indicating that the medication burden and likelihood of MRPs are similar in peritoneal dialysis patients and patients undergoing in-center hemodialysis.

A single center study of 35 patients suggested that transitioning patients from in-center to nocturnal home hemodialysis may not result in a significant change in the number of medications (10.5 versus 11.8, P=0.05) (4). Although the use of antihypertensives and drugs for mineral and bone metabolism decreased, pill burden from vitamins and anti-infective medications increased. Interestingly, the medication regimen complexity index, determined by dosage form, administration frequency, and special instructions, increased during the study period. The increase in medication regimen complexity index score was attributed to the burden of dialysate preparation at home.

Pediatric patients are a subgroup with unique and complex needs regarding medication therapy. These needs include but are not limited to special dosing (e.g., weight based), need for compounded pharmaceutical formulations, off-label use of medications, sociodemographic issues extending beyond the patient themselves, and adherence issues (19). To our knowledge, there are presently no published data on MRPs in pediatric dialysis patients (20). Only one study to date evaluated the potential scope of MRPs in 283 pediatric patients who made a total of 374 nephrology and hypertension clinic visits (21). Each visit included a pediatric clinical pharmacist team member. The mean number of interventions by the clinical pharmacist was 2.3 on the first visit. These data suggest that focused MRP evaluation by a pharmacist could potentially be valuable in improving total costs and outcomes in pediatric patients with ESRD. However, more data are needed to determine the optimal models for care provision.

Systematic Medication Reconciliation Is Not Performed in Dialysis Facilities

It is important to note the difference between medication reconciliation and medication review. Medication reconciliation is the process by which an accurate medication list can be constructed (22). Medication reconciliation is preparatory to a medication review. Given the complex pharmacotherapy regimens and frequent primary and specialist health care professional visits, patients should be queried about medication changes each time that they present for dialysis treatment by a member of the dialysis facility interdisciplinary team. Complete medication reconciliation should occur at periodic intervals (e.g., monthly or bimonthly) but minimally, with each short-term care plan and after transitions in care. Accurate medication reconciliation does require training, and ideally, a pharmacist would provide this function or specifically train other members of the dialysis team to perform this function. Medication review is the process by which the patient’s medication regimen is evaluated for appropriateness and safety, and it requires advanced clinical pharmacotherapy skills to assess drug therapy in the context of the individual patient’s comorbidity, health literacy, and sociodemographic issues. It is well established that pharmacists possess these skill sets.

Management of an accurate medication list in dialysis patients is complex because of the high medication and pill burden and the involvement of multiple prescribers (2,3,9). In addition, this population experiences frequent care transitions, with an average of 1.9 hospitalizations per year (1). In a small single-center study, 65% of MRPs identified in hospitalized dialysis patients were associated with gaps in transfer in medication information between the patients, caregivers, and different health care settings and caregivers (23). In another study, medication discrepancies were noted in 60% of hemodialysis patients when information gathered from patient self-report and interview were compared with outpatient dialysis facility electronic medical records (24). Similarly, in the general population, discrepancies in medication lists generated from comprehensive patient interview and physician-acquired medical history were reported in up to 67% of cases at the time of admission to the hospital (25).

A consistently applied medication reconciliation process that occurs regularly in the dialysis facility as well as during care transitions could undoubtedly address many of these issues. Consistent with this recommendation for dialysis patients, the Joint Commission on Accreditation of Healthcare Organizations selected medication reconciliation as one of its top issues in 2005 and set the goal to “accurately and completely reconcile medications across the continuum of care” (26). The commission noted that pharmacists should be involved and provide advice to optimize medication reconciliation. There is some evidence that involving a pharmacist may reduce errors arising from inadequate medication reconciliation (27–29). In a randomized study, the rate of adverse events with a pharmacist-led medication reconciliation process at hospital discharge was lower compared with usual care (28). Another study showed that a multidisciplinary discharge process using clinical pharmacists and nurses for discharge planning, medication reconciliation, and postdischarge telephone follow-up reduced rehospitalization (29).

Evaluation of appropriate education in pharmacology, pharmacokinetics, and other related aspects of drug therapy for the individual conducting the medication reconciliation has generally been limited. Although medication reconciliation is often delegated to dialysis nursing staff, they have other priorities, and their education does not include sufficient training in pharmacology, pharmacokinetics, therapeutic application, or therapeutic substitution. A recent review pointed out that nurses’ overall limited drug knowledge was a major contributor to medication errors in nursing practice (30). Although a recent study of pharmacist literacy-sensitive interventions during a hospital admission did not a reduction in actual or potential adverse drug events, the study noted that a limitation was lack of postdischarge follow-up and surveillance, processes that are easily incorporated into medication management services delivery models at the dialysis facility (31). More recent data indicate that dialysis patients have variable levels of medication label literacy and numeracy (32). Evaluation of health literacy should be part of medication management services and will promote focused strategies for patient medication counseling.

Regulatory requirements to perform medication reconciliation periodically do exist. The Centers of Medicare and
Medicaid Services (CMS) Conditions of Coverage require that the dialysis patient’s comprehensive plan of care include a medication history and that it should be developed within 30 days of patient admittance to a dialysis facility, at least annually for stable patients, and at least monthly for unstable patients defined as extended hospitalization (>15 days), frequent hospitalizations (more than three episodes within 30 days), marked deterioration in health status, significant change in psychosocial needs, concurrent poor nutritional status, unmanaged anemia, or inadequate dialysis (33). Furthermore, medication history is a component of the Measures Assessment Tool (34). Codified via V506, it states that medication history should include a review of the patient’s allergies and all medications, including over-the-counter medications and supplements that the patient is taking. The assessment should show that all current medications were reviewed for possible adverse effects, interactions, and continued need.

Current barriers to providing comprehensive medication reconciliation in most dialysis facilities in the United States include lack of staff training on the importance and process of medication reconciliation, nonexistent or poor interfaces in electronic health information between care facilities (outpatient dialysis facilities, hospitals, skilled nursing facilities, and rehabilitation centers), and absence of clinical pharmacists in most dialysis facilities. St. Peter (22) recently suggested a minimal set of data to maintain a current, accurate medication list for dialysis patients and suggested a standardized process to evaluate patient’s medications.

**Significant Total Cost of Care Savings Could Be Realized through Systematic Delivery of Medication Management Services, Especially during Care Transitions**

Dialysis patients are hospitalized frequently, and many patients face one or more care transitions during the course of a year, putting them at risk for MRPs. Nevertheless, data suggest that many MRPs are present even in the absence of care transitions. One study estimated that, of the MRPs identified at the time of hospitalization, nearly 50% were preexisting, and 26% occurred at the time of discharge (17). This result suggests that more than 70% of MRPs could be prevented by systematic MTM at the dialysis facility during routine care and at transition back to the dialysis facility, potentially preventing readmission. In a 2-year randomized, controlled trial of 104 hemodialysis patients assigned to receive pharmaceutical care (in-depth bi-monthly medication therapy reviews conducted by a clinical pharmacist) or usual care (brief medication therapy reviews conducted by nurse), the former was associated with fewer hospitalizations (1.8 ± 2.4 versus 3.1 ± 3, P = 0.02); the trend for reduced lengths of stay did not achieve statistical significance (9.7 ± 14.7 versus 15.5 ± 16.3 days, P = 0.06) (11). A recent study showed that integrated pharmacy services in hemodialysis patients receiving Medicare and Medicaid were associated with lower rates of death and hospitalization (35). Program services were rolled out over time and included medication reconciliation and review at the time of program enrollment as well as medication delivery and refill management. In addition, patients had round-the-clock access to pharmacists who provided telephonic medication management services. Future studies are needed to measure patient use of various pharmacy services and outcomes associated with use.

Clinicians need to be aware of what medication regimen a patient is currently taking or previously exposed to before initiating new or modifying existing medication therapy (i.e., medication reconciliation). Therefore, medication reconciliation could be considered the foundation or primary function to be performed before any clinical intervention is implemented. The clinical and/or economic benefit in dialysis patients attributed solely to medication reconciliation is unknown. However, in an ESRD demonstration program by DaVita, nurse practitioners, pharmacists, and case managers collaboratively coordinated dialysis patient care with emphasis in four key areas: preventive care, regular immunizations, vascular access, and medication management. Three of four interventions, (preventive care, regular immunizations, and medication management) required medication reconciliation practices. Overall, the demonstration project resulted in 5% total lower costs in year 1, 10% total lower costs in year 2, and 11% total lower costs in year 3. Unfortunately, the impact of individual interventions on total cost per year is not known (36). Another structured quality improvement program (RightStart by Fresenius Medical Care) that was delivered to 918 patients who were new to hemodialysis included a review of medications (37). The RightStart program provided one-on-one care management to educate and empower new dialysis patients. The program was initiated within 2 weeks of dialysis start by a designated care coordinator and continued for 3 months. Although specific medication and MRP data were not reported, there were reductions in hospitalization days (7.2 versus 10.5 days at 12 months) and mortality (17 versus 30 deaths per 100 patient-years) in the RightStart patients compared with the control patients.

**Medication Management Services Available for ESRD Patients with Medicare Part D Prescription Drug Plans Are Suboptimal and Underused**

The Medicare Modernization Act of 2003 created the provision for prescription drug coverage for Medicare beneficiaries through Medicare Part D (38). Most dialysis patients in the United States are Medicare beneficiaries, and almost 70% are enrolled in a Part D plan (1). Beyond providing drug coverage, Medicare prescription drug plans are mandated to provide MTM services to high-risk enrollees. Program requirements for MTM are listed in Table 3. CMS requires the involvement of pharmacists in the creation of MTM programs and allows Part D MTM program services to be provided by pharmacists or other qualified providers (39). In 2012, almost all (99.9%) Part D MTM programs used pharmacists to provide the services. Physicians, registered nurses, and support staff (e.g., pharmacy technicians, patient care coordinators/case workers, pharmacy students, and MTM assistants) were used 9.3%, 28.9%, and 64.5% of time, respectively, in the provision of MTM services (40). Targeted beneficiaries for MTM services are enrollees in a specific Part D plan who meet all of the following criteria: (1) have multiple chronic diseases, (2) are...
taking multiple Part D drugs, and (3) are likely to incur ≥$3144 annual Part D drug costs in 2013 and subsequent years [drug cost threshold specified by CMS §423.153(d)(1)] (39). CMS has increased Part D MTM program standardization and requirements and increased beneficiary MTM eligibility through reduction in the threshold of the number of comorbidities and annual expenditure on prescription drugs (41). However, it has been estimated that only 12% of eligible Medicare Part D beneficiaries use MTM services (42).

At present, there is significant heterogeneity among the various Part D prescription drug plans regarding patient selection criteria, provider type (e.g., nurse versus pharmacist), and level of care (e.g., telephonic versus person to person) (43). CMS focused on improving MTM and mandated that every targeted patient who meets Part D plan criteria for MTM be offered a complete medication review that is documented in a standard format that was implemented in January of 2013. This standard format is required for all Part D MTM providers. About 10% of Medicare Part D plans already target ESRD patients, and it is expected that this percentage will increase during 2013 and in subsequent years, because CMS added ESRD and Alzheimer’s disease to the current list of seven targeted conditions (41).

The future eligibility of dialysis-dependent patients participating in the Medicare Part D program, however, is uncertain. Currently, the average dialysis patient’s total per beneficiary per year medication costs (Parts B and D combined) far exceed the $3,144 threshold to qualify for MTM services. Despite the high total medication costs experienced by nearly all patients on dialysis, many may still not qualify for MTM services in the current system, because Part B costs (e.g., Erythropoiesis stimulating agents, calcitriol, and intravenous iron) are not included in the qualifying criteria. Congress recently passed legislation delaying the inclusion of oral ESRD-related drugs under the ESRD Prospective Payment System (PPS) or bundle from 2014 to January 1, 2016 (44). When this legislation is implemented, the costs of phosphate binders and cinacalcet will financially impact dialysis units and affect ESRD patient eligibility for MTM services. Because phosphate binders and cinacalcet comprise almost 50% of total Part D costs for dialysis patients, the implications for dialysis patients qualifying for MTM are clear (1). It is estimated that, with exclusion of phosphate binders and cinacalcet from Part D costs, fewer than 30% of patients without the low-income subsidy and fewer than 45% of patients with the low-income subsidy will meet the threshold for MTM in 2014 (45). Therefore, although the need for MTM for dialysis patients will not diminish, fewer patients will meet the thresholds for number of medications and cost to qualify for such services when oral ESRD drugs are included in the PPS in 2016.

Recommendations for Policy Change to Support Systematic Cost-Effective Medication Management Service Delivery in Dialysis-Dependent Patients

The current Medicare ESRD PPS does not include the resources to establish and maintain a model of patient care that includes comprehensive medication management services. Because health care models are evolving in the general population, there is an opportunity to design and assess innovative models of care in dialysis patients in collaboration with practitioners, dialysis providers, and the CMS.
In addition to the potential loss of eligibility of dialysis patients to participate in MTM offered by Medicare Part D programs, with the inclusion of dialysis-specific oral medications in the bundle, many of these patients will begin receiving prescription medications from multiple pharmacies, further fragmenting medication management services. For many community pharmacists, the only indication that a patient has kidney disease or is dialysis-dependent has often been the presence of a phosphate binder or cinacalcet in the medication profile. When these medications are not filled by a patient’s community pharmacist, MRPs, such as necessary dosage adjustments of other medications, may not be identified at the time that the prescription is dispensed. Providing medication management services in conjunction and alignment with dialysis services is essential to overcome these challenges (Figure 1). The dialysis facility can serve as the central medication coordination center, and the dialysis health care team can serve as the medication coordination team for each patient. The dialysis facility is the most logical and convenient location for integrated pharmacy services, including medication pick-up, medication reconciliation, and person-to-person medication management services, to occur. This model could also be used by home dialysis patients who make trips to the dialysis facility for routine care. Including a clinical pharmacist as an integral part of the dialysis facility team to help provide these medication-related services within the construct of the existing team would substantially facilitate medication management services. In Canada, clinical pharmacy services funds one pharmacist per 100 hemodialysis patients, 200 peritoneal or home hemodialysis patients, and 300 CKD (stages 3–5) patients, and this system has been shown to reduce costs and improve care (46). Although the structure and costs of the Canadian health care system differ from the United States health care system, these data help identify potential pharmacist to practitioner ratios that could be successful in impacting patient outcomes. Proposed steps to achieve comprehensive medication management for the primary care, patient-centered medical home model could be adopted by dialysis facilities in the United States (47). Using available data regarding reduced lengths of hospital stay, a sustainability model could be developed that uses a portion of net savings from reduced lengths of stay (Medicare Part A), which could support medication management services under Medicare Part B (11). Approved Current Procedural Terminology codes for MTM exist (99605, 99606, and 99607), and the pharmacists’ salaries could be covered by billing under these codes if provided at adequate reimbursement rates. There is currently no standard reimbursement rate for each Current Procedural Terminology code. Different payers, such as Part D prescription drug plans
(PDPs) or commercial health care plans, establish their own payment guidelines and rates for services on a plan-to-plan basis. Pharmacists bill each Part D PDP or commercial health plan separately after providing MTM services. Reimbursement rates vary based on complexity of medication review and time spent conducting the medication review. McDonough et al. (48) performed a financial analysis of billing for MTM services in a community pharmacy setting and found that, over a 16-month period, performing 103 initial visits and 88 follow-up visits was cost neutral when the pharmacist performed all aspects of the visits. This analysis included pharmacist salary, program support (e.g., computers, etc.), and overhead. Additional sensitivity analyses were performed that showed that the use of ancillary personnel would significantly improve financial gain to the pharmacy. As previously mentioned, CMS requires Part D PDPs to provide MTM services for high-risk, high-cost patients. Preliminary data also suggest that dialysis staff believe medication management services are needed and valuable (49). Given the complexity and health care use of these patients, delivery of MTM to dialysis patients is warranted.

Some dialysis organizations are already poised to implement and evaluate comprehensive medication management services if a reasonable cost structure is established (36,37). Establishing comprehensive medication management services, including face-to-face review by a pharmacist and regularly scheduled medication reconciliation to all Medicare-enrolled dialysis patients, would necessitate compensation for these services. CMS should encourage programs like MTM to develop strategic programmatic growth through cost-sharing mechanisms that would allow dialysis organizations to offset additional costs of comprehensive medication management services by sharing in any potential cost reductions (reduced hospitalizations, clinic visits, etc.). The Affordable Care Act created the Center for Medicare and Medicaid Innovation to test payments and service delivery models, reduce costs, and improve quality (50). CMS proposes to partner with groups of health care providers and suppliers to form ESRD Seamless Care Organizations (ESCOs) to test and evaluate a new model of payment and care delivery specifically for ESRD patients. Participating ESCOs will be clinically and financially responsible for all care offered to a group of matched beneficiaries, not simply the provision of dialysis care or the care specifically related to a beneficiary’s ESRD. Medication management is an expected component of the proposed ESCOs, and participants in this initiative will be able to provide more data to inform growth of medication management services for ESRD patients (51).

Using existing data and data from participating ESCOs, CMS could also consider whether incentivizing dialysis facilities to use medication management services in the form of MTM or otherwise by incorporating a metric regarding medication management into the Quality Incentive Program would be feasible and effective. Indeed, savings from reduction in total costs of care (resulting from, for instance, reduced hospitalizations) could provide a powerful incentive in shared savings.

Optimal Model for Medication Reconciliation and Therapy Management in ESRD

In summary, dialysis patients have complex medication regimens, with large pill burdens and multiple prescribers involved in their care. Available evidence suggests that MRPs are highly prevalent in dialysis-dependent patients and associated with poor outcomes and high cost. Medication reconciliation and a delivery of medication management services that could consistently and systematically identify and resolve MRPs would be likely to improve ESRD patient outcomes and reduce total cost of care. Thus, the optimal model for systematic, cost-effective medication management services could be developed around these basic tenets.

1. Medication management service delivery should be structured around the dialysis facility and be treatment-centered.
2. Medication reconciliation should be performed preparatory to comprehensive medication review by a pharmacist or pharmacist-trained member of the interdisciplinary health care team (e.g., nurses, dieticians, medical social workers, nephrologists, and dialysis or pharmacy technicians).
3. A dedicated and adequately trained clinician, such as a pharmacist, is needed to provide consistent high-quality medication review and management services.
4. Medication management services need to be consistently coordinated with other care providers both internal and external to the dialysis facility.

Innovative practice models that incorporate medication management services in ambulatory dialysis units need to be further evaluated, scaled-up, widely implemented, and maintained to fully realize improved cost effectiveness and impact clinical and patient-reported outcomes.

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