Acute Kidney Injury Patients Requiring Outpatient Dialysis

Executive Summary
Traditionally, much of the focus on kidney disease epidemiology and management has been on chronic kidney disease (CKD) and end-stage renal disease (ESRD). Policy discussions and guidelines for care related to kidney disease have mostly addressed these specific, vulnerable patient populations. These efforts have contributed to the development of a robust and highly effective Medicare-based system to provide renal replacement therapy for those with ESRD.

Until recently, patients with acute kidney injury requiring dialysis (AKI-D) fell outside the Medicare scope of coverage, and they could not receive dialysis treatments in outpatient ESRD facilities. However, new legislation effective January 2017 will permit patients with AKI-D to receive dialysis services in ESRD outpatient facilities, and authorizes these services for Medicare beneficiaries as a Medicare covered service. These changes represent important progress by increasing access to outpatient dialysis care for AKI-D patients.

These regulatory changes, plus the increasing number of AKI-D patients, suggest the need for a reassessment of the care model for AKI-D patients in outpatient ESRD facilities. AKI-D patients differ from ESRD patients in key ways. AKI-D patients are by definition in a transitory state, heading toward either renal recovery or ESRD, with weak predictive markers and no finite time frame to a decision point. In addition, many AKI-D patients are recovering from critical illness and multi-organ system failure; the functioning of various non-renal organs is also in transition, and their overall clinical care needs are substantial. They require close monitoring to determine if renal recovery is developing, to avoid nephrotoxic medications and diagnostic studies, and to assure that as renal and other organ functions change, the necessary adjustments in medications, nutrition and clinical care are continuously implemented.

The presence of AKI-D patients in a dialysis care system whose care model is structured around ESRD patients raises important questions and challenges. Clinical quality-of-care measures that are well vetted for the ESRD population (e.g. avoiding dialysis catheters) may not be applicable to the AKI-D population. Expectations for intensity of care by dialysis facility staff and nephrologists may require re-examination. Indeed, even the determination of ESRD ceases to be straightforward in this patient population. A reassessment of clinical,
regulatory and economic aspects of outpatient dialysis services for AKI-D patients may be valuable to assure that these critical services are tailored to the unique characteristics and needs of this special population.

This paper describes the unique characteristics of the AKI-D patient population, identifies areas in which application of the ESRD care model may create barriers to optimal dialysis care for these patients, and offers recommendations for how the ESRD care model can be revised to reflect the needs of AKI-D patients to facilitate their transition from AKI-D to recovery or ESRD.

Background

U.S. National ESRD Program and AKI-D Patients

In October 1972, Section 2991 of Public Law 92-603 created the U.S. National ESRD Program that extended Medicare coverage to individuals with ESRD who require dialysis. This legislation was not intended to cover outpatient dialysis for Medicare patients with AKI-D.

Prior to 2012 CMS neither expressly approved nor prohibited dialysis care to non-ESRD AKI-D patients in ESRD facilities. Because outpatient dialysis treatments for these AKI-D patients were not covered by the Medicare ESRD Program, hospitals in many regions of the country developed contractual arrangements with outpatient dialysis companies to provide this care in outpatient dialysis facilities. Claims for these services were routinely processed by CMS.

This policy was reinterpreted in 2012 when CMS issued the following guidance:

*ESRD facilities cannot furnish acute dialysis to hospital outpatients.* The Medicare regulations provide that all therapeutic services furnished to hospital outpatients, whether directly or under arrangements, must be furnished in the hospital or in locations that qualify as provider-based departments of the hospital (42 CFR 410.27(a)(1)). Our regulations prohibit ESRD facilities from being provider-based departments of hospitals (CFR §413.65(a)), and while an ESRD facility may be located on a hospital’s campus and may share certain overhead costs and administrative functions with the hospital, CMS does not consider it to be part of the hospital. Therefore, a hospital may not enter into an arrangement with an ESRD facility for the ESRD facility to provide, outside of the hospital, outpatient dialysis or any other therapeutic service for which the hospital would bill Medicare. [Emphasis added].

This new interpretation prohibited AKI-D patients from receiving outpatient dialysis in ESRD facilities, and effectively restricted treatment for AKI-D patients to facilities with the capacity to provide dialysis in the provider-based hospital (outpatient) setting, or to inpatient care in long-term acute care or rehabilitation hospitals. While a subsequent re-interpretation may have unofficially indicated that the prohibition only applied to Medicare beneficiaries with AKI-D and not privately insured patients, it was problematic nonetheless.
On June 29, 2015, the Trade Preference Extension Act of 2015 was signed into law and will, as of January 1, 2017, provide Medicare reimbursement for renal dialysis services to Medicare beneficiaries with AKI-D in outpatient ESRD dialysis facilities. The key language on AKI-D is as follows:

“Renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid (under the end-stage renal disease—ESRD—program) to an individual with acute kidney injury”; (2) that “the amount of payment under this part for such services shall be the base rate for renal dialysis services”; and (3) “the term ‘individual with acute kidney injury’ means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made (under the ESRD program)”.

Therefore, beginning in January 2017, AKI-D patients will gain the opportunity, depending on clinical stability, to dialyze in outpatient ESRD facilities. Treatment will also remain available, as clinical circumstances dictate, in skilled nursing facilities (SNF) with dialysis capability, long-term acute care facilities, rehabilitation hospitals, and outpatient or inpatient hospital-based units with dialysis capability.

As this rulemaking is developed, several key questions must be addressed.

- How will these AKI-D patients be integrated into the outpatient ESRD dialysis milieu?
- Will AKI-D patients be subject to the same regulatory requirements and quality measures as ESRD patients?
- Will AKI-D patients receive the same services, require the same record keeping and have the same oversight as ESRD patients?
- How will the existing dialysis care model be modified to accommodate the distinctive clinical needs of this patient population and the physicians, dialysis facility and others who are involved in their care?
- How will economic issues be addressed?

**Acute Kidney Injury Requiring Dialysis (AKI-D)**

**Etiology and Natural History**

AKI-D is the abrupt loss of kidney function, resulting in the retention of urea and other nitrogenous waste products and in the dysregulation of extracellular volume and electrolytes. Patient risk factors for development of AKI-D include older age; underlying CKD, with increased risk associated with both lower baseline glomerular filtration rate (GFR) and greater severity of proteinuria; comorbidities including congestive heart failure (CHF), peripheral vascular disease, and diabetes mellitus; medication use, including use of inhibitors of the renin-angiotensin system such angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB), and non-steroidal-anti-inflammatory drugs (NSAIDs). AKI-D is common in patients admitted to the ICU with a primary diagnosis of infection or sepsis and in post-surgical patients, particularly after cardiothoracic and vascular surgical procedures and after non-renal solid organ transplantation. Several studies have implicated male gender, older age, black race, sepsis, shock, CHF,
mechanical ventilation coagulation/hemorrhagic disorders, liver disease and cardiac catheterization to be responsible for the increased temporal trend in AKI requiring dialysis.3-4

The most common histologic cause of AKI-D is acute tubular necrosis (ATN), from ischemic, septic or toxic causes; acute interstitial renal disease, intrinsic glomerular diseases and small and large vessel disease are uncommon causes of AKI-D. A recent study utilizing the USRDS database showed that in 2009-2010 ATN (presumably associated with AKI-D) accounted for 3.5% of incident ESRD patients, a doubling of the incidence rate compared to 2001-2002.26

Data on the natural history of AKI-D are limited, and characterized by substantial variability. Among the issues are lack of baseline renal function before the onset of AKI-D; wide variation in the cause and severity of the AKI-D; selection bias, in that some studies are limited to patients with critical illness, or use of continuous renal replacement therapy; incomplete data due to patient death; and use of USRDS data base, in which entry may delayed for 45 days after starting outpatient dialysis, and which classifies patients by cause of renal failure, but does not specifically identify AKI-D.

A recent review provides a general description of the course of AKI-D.10 Approximately 20% of hospitalized patients will develop AKI, of whom only 1-2% will require dialysis. Of those AKI-D patients, 40-60% will not survive. Of those who do survive to discharge, only 10-30% will still require dialysis. Of those AKI-D receiving outpatient treatment, up to 50% will not survive for 3 months; during that period 20-60% will recover kidney function, and the remainder are considered ESRD. However, another 1-6% may still recover over the ensuing 9 months.

Renal recovery is more likely to occur early after AKI-D, and decreases in likelihood as weeks and months pass. Recovery following AKI-D from ATN has been reported in one study as 23% at 3 months and 34% at about 6 months, after which no further recovery was observed.8 As noted above, other studies suggest that recovery may continue for up to a full year.

Predicting Renal Recovery versus ESRD in the Individual AKI-D Patient

Certain risk factors have been shown to have an adverse effect on the probability of renal function recovery including increasing age, diabetes mellitus, heart failure, increasing number of co-morbidities, and the presence and severity of underlying CKD.10 To date, there are no well-validated tools to predict whether an individual patient is likely to recover renal function or remain dialysis dependent and evolve to ESRD.11

Given the wide variability in the incidence and rate of recovery of renal function in AKI-D, and the absence of validated predictive tools, there is limited clinical guidance for the nephrologist when considering prognosis in the individual AKI-D patient. At present there are few definitive clinical parameters short of bilateral nephrectomy and no time point before one year that firmly establishes a diagnosis of ESRD in this scenario.
This issue poses a substantial challenge for the nephrologist. Typically, the patient hopes that the nephrologist will support his/her optimism regarding the chance of renal recovery. Indeed, an unfounded pessimistic prognosis by the nephrologist may represent an unnecessary psychological setback for the patient. The nephrologist does not wish to arrange surgery for permanent access creation if it is not needed, and does not want to delay its creation unnecessarily and prolong the risk of catheter-related infection. Similarly, a diagnosis of ESRD and completion of the 2728 Medicare ESRD Evidence Form provides entry into the multiple beneficial care pathways established for ESRD patients. However, the nephrologist’s signature on that form could raise a concern regarding false attestation if the diagnosis of ESRD is subsequently considered unjustified or unsupportable, or simply shown to be incorrect.

Conversations with patients about ESRD, long term care plans and end of life issues are influenced by quality of life expectations. Patients who remain dialysis-dependent after an episode of AKI-D often have a high burden of acute comorbidities, physical deconditioning, impaired functional status and diminished self-reported quality of life. In a large series of patients surviving critical illness complicated by an episode of AKI-D, health utility at 60 days after hospital discharge was markedly lower than population norms, with 27% of surviving patients rating their health quality as equal to or worse than death, even if they had recovered kidney function.15

There are no clinical practice guidelines to determine how or when an AKI-D patient has transitioned to ESRD. The nephrologist’s best professional judgment remains the widely accepted standard of care. In common practice, many nephrologists will declare ESRD after 90 days of dialysis-dependence if there is no evidence for recovery; some may use shorter or longer intervals. In specific patients with multiple risk factors indicative of poor potential for renal recovery, many will make that determination earlier than 90 days.

Clinical Status, Burden of Disease and the Clinical Care of AKI-D Patients

AKI-D as a State of Transition and Instability

For some patients, AKI-D may have developed following nephrotoxin exposure, a limited episode of sepsis or hypotension, or another renal disorder that necessitated only a short hospital course and caused only mild debility.

Others may have developed AKI-D as a complication of critical illness with multi-organ system failure. This critical illness may have been precipitated by malignancy, infection, major surgery, or complications of underlying heart, respiratory, cardiovascular or gastrointestinal disorders or systemic conditions such as diabetes. Hospitalization for weeks or longer is not uncommon, and some patients may have required tracheostomies, peripherally inserted central catheter (PICC) lines and gastric feeding tubes. They may come to dialysis with open wounds, amputations, bedsores and wound vacuum-assisted closures (VACs). Some may require continuous medications by infusion pumps, frequent suctioning and the use of portable medical devices including ventricular assist devices (i.e., external heart pumps). Patients are often weak, unable to stand or even sit without assistance, and in need of substantial help with activities of daily living. They may be
receiving narcotics for pain control, and other non-renal medications on a frequent and strict schedule. These constitute some of the added challenges that the dialysis facility may face when providing care to AKI-D patients.

In a more general sense, AKI-D patients are not in a steady state. Rather, they are in transition with regard to two important and related biologic processes: 1) they are either in some phase of recovery of kidney function, or are evolving toward ESRD; and 2) they are recovering from an acute illness, with ongoing changes in the status and function of various non-renal organ systems damaged during the that acute illness. By definition they are not stable, but rather are continuously changing in response to their recent acute illnesses.

Changes in kidney function may be reflected in increases or decreases in urine output and blood levels of electrolytes, as well as overall fluid balance, appetite, nutritional intake and the clearance of medications.

Alterations in the function of other organs may be reflected in fluctuations in mental, respiratory and cardiovascular status, in bowel function, appetite and nutritional status, in integrity of the skin, and in liver function and hepatic metabolism of various medications. Indwelling lines, open wounds and incisions carry an increased risk of infection. In addition, indwelling lines and devices can malfunction or become dislodged. Patients may need substantial assistance to transfer from wheelchair or stretcher to the treatment chair. Patients with decreased mental status from neurologic disease or unresolved delirium may require constant attendance to minimize the risk of needle dislodgment or other inadvertent injury.

None of these care needs is beyond the capability of most dialysis facilities, but the cumulative degree of care and attention required for the AKI-D patient typically exceeds that for a patient with ESRD. Additional staff time per patient, and specialized staff training, may be needed to address the increased needs of these patients.

AKI-D patients may require more frequent lab testing to review kidney function, and assess drug levels, nutritional status, infection, and other organ function. They may require antibiotic administration and monitoring for infections unrelated to the dialysis procedure. Intercurrent illness, hospital based treatments and debility may increase the frequency of missed treatments.

The non-renal care team for such patients often is extensive, and can involve primary care and specialist physicians, nursing home staff, family, physical and occupational therapists, pharmacists and home care nursing, as well as the dialysis facility staff. Sharing of laboratory information, changes in medications and other instructions for care are crucial to an effective treatment plan. Coordination of dialysis care with the other domains of care required by the AKI-D patient is a complex and time-consuming effort. Since the dialysis nursing staff often sees the patient more frequently than others, the dialysis unit often becomes the nexus of care coordination.

In this context, the care provided by the rounding nephrologist and associated mid-level providers may extend well beyond that envisioned in the existing ESRD monthly capitated
payment (MCP) framework. Visits to other care providers may be unrealistic for patients with severe debility and a three-times (or more) per week dialysis schedule, so more of the burden of care may fall to the nephrology providers. These issues may necessitate more face-to-face visits from the nephrologist than is typically the case for the ESRD patient, and could appropriately exceed four visits per month. An appropriate visit frequency should be dictated by the patient’s severity of illness and level of active medical problems.

In addition, some AKI-D patients may require more than average intensity of dialysis treatment. Some may be hypercatabolic and require additional clearance. Others may have dramatic excess of fluid resulting from the fluid resuscitation required during critical illness or associated with advanced liver disease or severe heart failure. Some may have chronic hypotension or cardiac instability that renders them poorly tolerant of even modest fluid removal during dialysis. In these circumstances prolongation of dialysis treatments, or the addition of a fourth or more treatments each week may be needed.

Much of the discussion in this section references hemodialysis. However, peritoneal dialysis (PD) may represent an effective treatment modality for some patients with AKI-D, particularly those with hypotension and cardiac instability. Peritoneal dialysis is associated with less hypotension and may offer more opportunity to regain endogenous renal function. Urgent start PD programs may offer advantages in this setting. Even though PD treatments would be performed at home after initial training, the requirements for monitoring, coordination of care and medication adjustments by nursing staff and nephrologists are likely to be substantially higher than those needed for ESRD patients on home PD.

In summary, AKI-D patients are by definition continuously evolving, both in their renal status and their response to recent acute illness, often with severe multi-organ system failure. They are likely to have a higher burden of illness, and more substantial ongoing medical problems and may require higher levels of monitoring, increased lab testing and more attention and support from facility staff and nephrologists than the typical ESRD patient.

Special Issues in the Care of AKI-D Patients

As previously stated, there are no established guidelines, metrics, or protocols for the care of patients with AKI-D. Nevertheless efforts to protect existing renal function and facilitate renal recovery are widely accepted components of renal management. General principles for the management of AKI-D, including avoidance of nephrotoxic medications (e.g. NSAIDs, radiocontrast agents, and aminoglycosides) and prevention of hypotension should be followed.

There is also no evidence that existing ESRD clinical practice guidelines for anemia management, metabolic bone disease, vascular access management, dialysis adequacy, and nutrition are applicable to AKI-D patients. However the specific recommendations in existing guidelines for infection prevention as related to tunneled dialysis catheters (TDCs) and peritoneal catheters are pertinent and should be applied to AKI-D patients.

Management of patients with AKI-D must include provision of adequate dialysis in a manner that minimizes the risk of further renal injury. Multiple studies have documented the
potential adverse effects of aggressive dialytic fluid removal on the recovery of renal function in AKI-D.\textsuperscript{19,20} Volume management, target weight and blood pressure goals must balance prevention of volume overload and associated complications with avoidance of hypotension and intravascular hypovolemia. In contradistinction to the management of ESRD patients, in whom the volume management goal is generally to keep the patient as “dry” as possible to optimize blood pressure management, a more liberal fluid management is generally required in AKI-D patients. Similarly, antihypertensive medications should be adjusted so as to limit hypotension.

The optimal means of monitoring for recovery of kidney function is uncertain. Suggested methods include: trending of pre-dialysis lab work; assessment of the change in creatinine between dialysis treatments; monitoring of urine volume; and periodic measurement of creatinine and urea clearance using timed interdialytic urine collections.

Given the possibility of recovery of kidney function, vascular access is generally provided via TDCs. Permanent vascular access placement is generally inappropriate, unless the patient had substantial underlying CKD before the onset of AKI-D and ESRD is anticipated soon even if the patient were to recover from the immediate episode of AKI-D.

At present, there is no consensus on the most appropriate approach for discontinuation of dialysis in a patient with nascent recovery of kidney function. Uncertainties exist regarding the minimal renal clearance needed, and how volume status, urine output and electrolyte parameters influence these decisions. Whether to stop or taper dialysis treatment (and how rapidly) in an individual patient is a clinical judgment based on provider practice and/or various clinical parameters such as urine volume; the levels and interval changes in blood urea nitrogen (BUN) and creatinine; clearances of urea and creatinine; electrolyte (particularly potassium) and volume status; nutrition; and overall clinical status. Discontinuation of dialysis is often a clinical evaluation, necessitating close monitoring of many of the above parameters for days or weeks thereafter. Some patients may fail and require resumption of dialysis, perhaps for another trial discontinuation later.

Behaviorally, AKI-D patients often expect to recover from kidney failure, and they may be reluctant to accept ongoing dialysis treatment or, as hope for recovery fades, a more permanent access or modality change. These patients are likely to experience hope and denial and anger, and may present extra challenges for care givers. It is likely they may require increased intervention on the part of the social worker; nursing and administrative staff as well as outside psychiatric support.

Goals of Care for the AKI-D Patient

The clinical care issues described above can be summarized as goals of care that apply to the nephrology team, dialysis facility staff, and the broader health care team. Goals of care should:

1. Recognize the patient’s burden of disease, disability and care requirements.
2. Recognize that the patient is inherently unstable, with evolving renal status and changes reflecting convalescence from acute illness.
3. Focus on measures to minimize risk to residual renal function and optimize conditions for renal recovery.
4. Preserve veins in case renal recovery does not occur and arteriovenous access is needed.
5. Monitor for changes in renal function, recognize incipient recovery and facilitate the discontinuation of dialysis when appropriate.
6. Address the need for medication dosing adjustments as kidney function changes.
7. Facilitate care of ongoing medical problems, including coordinating with other providers for the care of a range of ongoing medical problems common to patients with AKI-D and those recovering from acute illness and multi-organ system failure, including special dietary needs.
8. Recognize changes in the patient’s condition due to non-renal clinical issues.
9. Address the frequent need for physical rehabilitation following severe acute illness.
10. Address the unique psychosocial needs of patients who have survived an episode of severe life-threatening illness and are facing the possibility of ESRD.
11. Identify those patients with non-recovery of renal function and coordinate a timely transition to ESRD care, including timing of conversion from catheter access to permanent arteriovenous access and/or consideration of conversion to home dialysis modalities.

Medical Record Documentation, Provider Communication, and Care Transitions

For most AKI-D patients, kidney failure and initiation of dialysis occurs during admission to an acute care hospital. When sufficiently stable, the patient may be discharged to the home, skilled nursing facility, long-term acute care hospital or rehabilitation hospital. Subsequent transitions among these sites may also occur as the patient’s course evolves. At some point the patient is likely to receive dialysis in an outpatient dialysis facility. Because the dialysis facility is a focus of frequent, high intensity care for the AKI-D patient, it must be fully engaged in, and aware of, the patient’s ongoing care.

Throughout the course of the patient’s care, high quality clinical services will require comprehensive medical documentation, effective communication among care providers and facilities, and meticulous hand-offs between facilities and between providers. These aspects of communication and documentation should be as robust as those provided to ESRD patients.

AKI-D and the ESRD Care Model

The above sections provide a description of the distinctive clinical characteristics of the AKI-D patient population. It is in this context that the new policy permitting AKI-D patients to receive dialysis treatments in outpatient dialysis facilities warrants examination.

Specifically, to what extent can the care model for ESRD patients be appropriately applied to AKI-D patients in the dialysis facility? The ESRD care model is built upon federal law, regulation, policy, practice guidelines, dialysis operator policies and procedures, medical literature and clinical standards of care. Certain aspects of the existing care model may create barriers to care, or create unanticipated disincentives to appropriate care for AKI-D
patients. For example, current quality measures promote and reward use of a dialysis fistula or graft, rather than a TDC, an incentive that is not appropriate for AKI-D patients who may not need long-term dialysis.

While the existing care ESRD model is not perfect, it has been able to effectively provide dialysis services to the population of U.S. citizens certified as having ESRD. However, not all aspects of the current U.S. ESRD care model will facilitate the delivery of effective and appropriate care for AKI-D patients, and CMS’ policymaking affecting the care delivered to Medicare beneficiaries with AKI-D should account for that circumstance.

**Principles**

1. RPA acknowledges facility reimbursement for dialysis services to AKI-D patients is legislatively mandated to match the reimbursement for ESRD patients. That payment is intended to include dialysis-related expenses for laboratory testing and medications. RPA believes that certain laboratory tests for AKI-D patients can be appropriately billed separately under ICD and CPT codes related to acute renal failure or other diagnoses pertinent to the patient’s clinical diagnoses. Similarly, medications used for treatment of infections unrelated to dialysis access, and for treatment of non-renal clinical problems, would be billable separately.

2. RPA supports a nephrologist fee-for-service payment system utilizing E&M codes 90935/90937, for nephrologist services provided during dialysis treatments, recognizing that frequent physician visits during dialysis may be required, based upon patient acuity. If necessary, nephrologist visits outside of dialysis treatment times may also be required, and can be billed under the relevant E&M codes with appropriate documentation. To the extent that nephrologist services involve coordination of care among various members of the care team, use of the appropriate coordination of care modifier should be supported.

3. RPA emphasizes that the transition point from AKI-D to ESRD may be arbitrary and subject to substantial clinical judgment, given difficulty in predicting future recovery of kidney function. Administrative policies (such as those governing completion of the 2728 ESRD Medical Evidence form) not in alignment with this clinical reality should be revised in favor of the widely accepted standard of practice of individualized physician decision-making based upon best clinical judgment. With the allowance for dialysis of AKI-D patients in outpatient dialysis facilities, administrative considerations which previously fostered premature certification of patients as ESRD will diminish. However, the renal community, in conjunction with CMS, may wish to consider whether, for AKI-D patients, a specified time on dialysis without evidence of recovery of kidney function (perhaps 90 days) is appropriate and satisfactory, from a legal perspective, to establish eligibility for the Medicare ESRD system.

4. RPA recognizes that quality of care measures are an essential component of an optimized care delivery system; however, there are currently insufficient data and limited consensus related to the treatment of AKI-D to form the basis for specific quality metrics. RPA believes that new quality measures are appropriate for AKI-D
patients; however, new measures should not be implemented until relevant data have been obtained and validated, and consensus on appropriate measures developed.

Recommendations

1. Certain dialysis facility services should be the same for ESRD and AKI-D patients, including:
   - the dialysis treatment per se;
   - the medical record;
   - documentation by facility staff, nephrologists and mid-level providers;
   - services by dietitians and social workers;
   - medication reconciliation;
   - discussions regarding advance directives, goals of care and designation of surrogate decision makers;
   - care conferences, (multidisciplinary team meetings) as appropriate for unstable patients
   - infection control;
   - vaccination programs;
   - participation in patient education and social activities;
   - medication counseling and guidance;
   - Medical Director responsibilities;
   - in-house physical therapy program, as clinically appropriate;
   - communication with outside care providers;
   - quality measures pertaining to TDC infections and peritoneal dialysis;
   - routine pre-specified monthly laboratory testing:
     - CMS should recognize that the amount of laboratory testing associated with treating AKI-D patients will typically exceed the components of the laboratory panel included in the ESRD bundle.

2. The following components of dialysis facility services and care should not apply to AKI-D patients:
   - CMS Form 2728 (ESRD Medical Evidence Report);
   - Quality measures pertaining to:
     - adequacy of dialysis
     - anemia management
     - vascular access (except TDC infections)
     - nutrition
     - metabolic bone disease
     - hospital readmission rate
     - morbidity and mortality

3. Certain components of services should be modified as they may apply to AKI-D patients:
   - ESRD Network services
     - Network services that pertain to patient advocacy and grievance resolution should apply to AKI-D patients.
• Network services pertaining to quality of care should apply to AKI-D only to the extent that the quality measures are those identified above as appropriate for this patient population.

• Data collection and tracking
  o RPA recognizes the value of data collection from AKI-D patients for epidemiologic, administrative and clinical purposes.
  o RPA also recognizes the dearth of clinical data for AKI-D patients, including data that may help predict this course of renal function in such patients.
  o RPA strongly supports development of a robust clinical data collection system including baseline data and ongoing reporting for AKI-D patients.
  o New methodology may need to be developed, in conjunction with epidemiologists and clinicians, to implement appropriate and effective data collection and tracking relating to AKI-D patients.
  o Specific baseline clinical data that might be collected may include:
    ▪ Baseline renal status
    ▪ Cause of AKI
    ▪ Accompanying critical illness(es)
    ▪ Onset of AKI and dialysis
    ▪ Current clinical status
  o A robust data collection and reporting system for AKI-specific patient data should be developed.
  o RPA believes the data collection must not be excessively burdensome or excessively prescriptive.
    ▪ Reimbursement to the facility needs to consider the extra burden for data collection.
References


