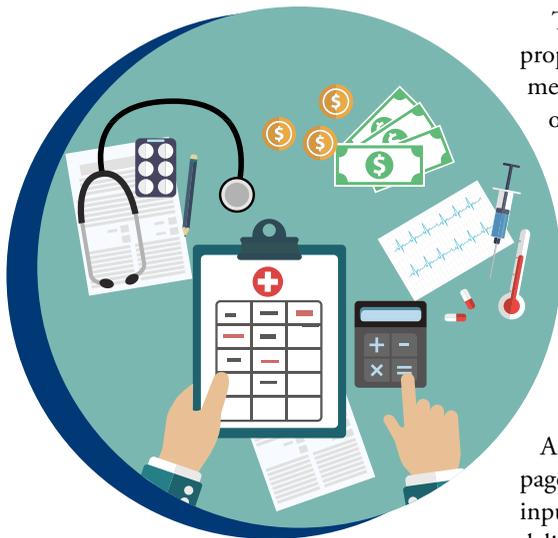


# Kidney News

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## Innovative ESRD Care and Payment Models: CMS Seeks Input

By Eric Seaborg



A request from the Centers for Medicare & Medicaid Services (CMS) for input on new care and payment models has ASN gearing up to weigh in on what could be significant changes in the way that Medicare treats kidney disease.

The CMS request came in its annual proposed updates of policies and payments related to renal disease. Published on June 24, 2016, other noteworthy parts of the updates include permitting acute kidney injury (AKI) patients to be treated in end stage renal disease (ESRD) clinics, introducing equivalency payments for more frequent dialysis treatment, and offering higher payment for home dialysis training.

The provision that has many in ASN excited is on page 204 of the 260-page proposed rule, where CMS “seeks input on innovative approaches to care delivery and financing for [Medicare] beneficiaries with end stage renal disease. This input could include ideas related to innovations that would go above and beyond the Comprehensive ESRD Care (CEC) Model with regard to financial incentives, population or providers engaged, or the scale of changes, among other topics.”

CMS requests responses to 10 questions covering a broad range of issues, including how providers who participate in alternative payment models could:

- coordinate care for beneficiaries with chronic kidney disease (CKD) and improve their transition to dialysis;
- target key interventions for beneficiaries at different stages of CKD;
- promote increased rates of renal transplantation;
- help reduce disparities in rates of serious kidney disease and adverse outcomes among minority groups; and
- facilitate changes in care delivery to improve patient quality of life.

“ASN is thrilled that CMS is seeking input to develop and refine innovative payment models in the kidney space,” said ASN President Raymond C. Har-

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## Ultrafiltration Rate Reporting Could Lead to Longer Dialysis Times

The Centers for Medicare & Medicaid Services (CMS) has proposed introducing an ultrafiltration rate quality measure into its End-Stage Renal Disease Quality Incentive Program (QIP). A study of competing models of this quality measure found that meeting the standard is likely to require lengthening dialy-

sis treatment times by durations that could prove challenging to dialysis unit operations.

CMS has been considering adding this measure for some time because fast ultrafiltration rates are associated with adverse outcomes, although data on direct links is far from definitive.

After CMS first proposed its model

for the standard, the Kidney Quality Care Alliance (KQCA) responded with a proposal of its own. Both proposals use a benchmark of 13 milliliters per hour per kilogram of body weight as the upper acceptable limit, but there are two major differences in the plans. First, the CMS model relies on data from a single treatment, whereas KQCA uses the mean of three treatments in a week. Second, the KQCA proposal gives a facility credit for dialysis sessions that last four hours or more, regardless of the actual ultrafiltration rate.

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One disease or many?

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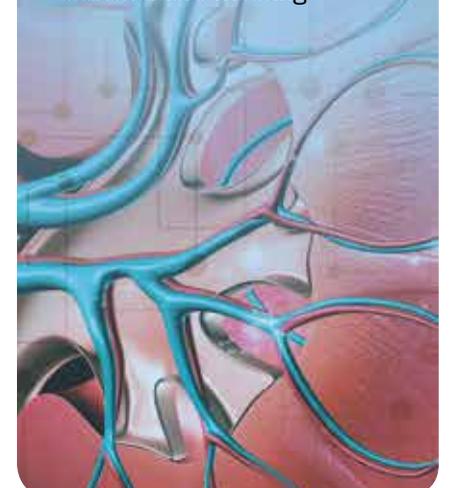
A case of metabolic acidosis

#### Policy Update

Kidney Research Advocacy Day a success

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Telehealth, clinical trial recruitment among topics at fourth annual KHI stakeholders meeting



## CMS Requests Input

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ris. “We are particularly enthused about the possibility of expanding beyond the focus on dialysis to potentially include CKD and transplant care. The society strongly supports more integrated care for kidney patients across the spectrum of kidney disease, and looks forward to providing input to CMS and encouraging the agency to explore truly comprehensive models ranging from CKD through transplant and end of life.”

Rachel Meyer, associate director of policy and government affairs, said that ASN is already promoting the need for these kinds of innovations. ASN included the outline of a comprehensive model for care of CKD in a letter it sent to CMS on June 27, 2016, detailing its comments on the agency’s proposals for implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). That law ended the Sustainable Growth Rate formula for determining Medicare payments to providers and was designed to create a framework for rewarding providers for supplying better care rather than more care.

### AKI treatment in ESRD facilities

Another potentially significant change proposed in the rules is that Medicare and Medicaid patients with AKI will be able to receive dialysis services in ESRD facilities beginning next year. CMS will provide payment based on the ESRD prospective payment rate, as adjusted by the wage index. However, CMS said in a press release that “drugs, biologicals, laboratory services, and supplies furnished to beneficiaries with AKI that are not considered to be renal dialysis services but that are related to the dialysis as a result of their AKI would be separately payable.”

ASN will certainly seek to influence

the shape of this new program, said John R. Sedor, chair of the ASN Public Policy Board: “As CMS begins to implement this new law, it will be tremendously important for them to take into account the many ways in which patients with AKI are unique from patients with ESRD. Their care will need to reflect those differences, and be reimbursed accordingly. On the quality front, what constitutes optimal care for patients with ESRD is often not even appropriate care for patients with AKI, so keeping the new AKI patients out of quality reporting systems such as the Quality Incentive Program is vital. At the same time, we need better data to inform what exactly optimal AKI care looks like.”

This change in coverage of AKI was mandated by a provision tucked into the Trade Preference Extension Act of 2015. Although AKI care would seem to have nothing to do with international trade, the provision was probably included as a budget offset to save money and keep the trade bill budget neutral.

### Change in payments for more treatments

CMS is also proposing a change in the payment system when an ESRD facility provides a patient with more than three hemodialysis treatments per week, which is often the case for hemodialysis patients who are dialyzing in their homes. Payment is generally capped at three dialysis sessions per week, with more sessions reimbursable if they are deemed medically necessary by a physician, such as in the case of congestive heart failure or pregnancy.

The proposed rule’s intent is to “provide a mechanism for payment for evolving technologies that provide for a different schedule of treatments that accommodate a patient’s preference and thereby improve that patient’s quality of life,” and it notes that more frequent dialysis allows for shorter treatments, affording patients greater flexibility in managing their illness. CMS seems to justify the capped payment proposal by noting that the same level of toxin

clearance can be achieved in three treatments, and “there is a lack of objective data to justify additional payment for HD treatments beyond three treatments per week.”

However, CMS notes that ESRD facilities have expressed concern that because of the limit, they are not able to report additional treatments on their monthly claim forms and are not paid for each treatment. To encourage facilities to report all treatments, CMS is proposing a payment equivalency formula for these treatments similar to the one used in peritoneal home dialysis, in which patients receive more than thrice weekly treatment sessions, but the total payment is capped.

CMS proposes to “calculate a per treatment payment amount that would be based upon the amount of treatments prescribed by the physician” regardless of how many actual treatments the patient receives. Thus, the equivalency payment would be based on three treatments a week. Because allowing more bills would represent “a substantial change for the ESRD facility’s billing systems and for the Medicare Administrative Contractor,” the change would not be fully implemented until July 1, 2017.

### Home dialysis training increase

The proposed rule also contains a provision that could improve the climate for home dialysis by paying more for training. CMS proposes to increase the number of reimbursable hours for training for a registered nurse for home dialysis and self-dialysis teaching from 1.5 hours or \$50.16, to 2.7 hours, to \$95.57. (CMS assumes that the hourly wage for a nurse providing dialysis training in 2017 will be \$35.93.)

### Little change in prospective payment

Although the updates contain some big changes in other areas, it’s pretty much the status quo when it comes to the base

bundled payment rate for renal dialysis services to treat ESRD in Medicare beneficiaries. CMS proposes increasing it by 65 cents, from this year’s \$230.39 to \$231.04 in calendar year 2017.

### Quality Incentive Program

Under the ESRD Quality Incentive Program (QIP), facilities that fail to achieve a minimum score on quality measures face a reduction in their payment rates of up to 2%. The new rule does not propose any changes in quality measures for next year, but does propose changes for 2018, 2019, and 2020.

For 2018, for example, CMS proposes two changes to the hypercalcemia clinical measure. The changes involve including plasma as an acceptable substrate in addition to serum for calcium and a technical change to the denominator definition to account for periods during which a facility reports no calcium values.

The proposed QIP for 2019 adds a new Safety Measure Domain, so it includes seven clinical/outcome measures and five to six reporting measures, a large increase from the two to three measures in the early years of the QIP, according to Daniel E. Weiner, chair of the ASN Quality Metrics Task Force. “The struggle for CMS and the community is trying to find reliable measures that evaluate truly important aspects of dialysis patient care,” Weiner said. “This is very difficult when clinical trials lack dialysis data to support any of the currently existing measures, not to mention any measures that may be proposed in the future. Ironically, this lack of evidence seems to have led to more measures being applied to the QIP, a trend that runs the risk of diluting the impact of high performance on measures that may be more important and better supported, such as the vascular access measures. Ultimately, the ideal QIP is both more parsimonious, containing fewer measures, as well as more important, containing the measures that, if achieved, are most likely to make meaningful differences in patients’ lives.” ●

## Ultrafiltration Rate Reporting

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A study in the August *Clinical Journal of the American Society of Nephrology* drew on the database of a large dialysis organization to analyze how some 150,000 patients would have fared against each measure. It found that 21–23% of patients would have exceeded the 13 mL benchmark under the CMS rules, and about 16% would have exceeded it under the KQCA rules. Although limiting fluid gain through diet is in many ways the better option, the most likely way facilities will lower ultrafiltration rates is by extending treat-

ment times—and the researchers calculated that a 100-patient facility would need to add 33 treatment hours per week to get all its patients below 13 mL—and that’s using a treatment duration cap of 4 hours (per the KQCA measure).

“That number tripled—up to 98 hours per week—when we removed the 4-hour treatment cap,” said lead study author Jennifer Flythe, MD, MPH, assistant professor of medicine at the University of North Carolina. “So there are some very interesting patient and facility implications that need to be thought through to ensure that there are no unintended consequences from implementation of the ultrafiltration rate measure.”

The study identified some other pitfalls of applying a uniform standard to all patient groups. For example, ultrafiltra-

tion rates rose in winter and fell in summer, probably because patients’ hydration levels vary during colder and hotter seasons.

“Certain patient groups tended to have had higher ultrafiltration rates, including patients that were younger, women, nonblack, of Hispanic ethnicity, and smaller in body weight,” Flythe said. Higher rates for smaller patients are not surprising, considering that the measure is by definition indexed to body weight, but the implication of higher rates among these patients is an open question.

### Why an ultrafiltration standard?

Flythe said that the physiological underpinnings for the desirability of low-

er ultrafiltration rates are sound: “The thought is that the faster you pull the fluid off during dialysis, the more cardiac and other organ stress you may be causing.” And the negative consequences are backed up by observational data, but the evidence base is not strong.

“We have an absolute lack of clinical trial data looking at the effects of ultrafiltration rates,” said Daniel Weiner, MD, MS, a nephrologist and associate professor of medicine at Tufts University School of Medicine, and chair of the ASN Quality Metrics Task Force. “Just like pretty much every other metric in dialysis, there are not good randomized trial data comparing different interventions and looking at important clinical outcomes”

Just the same, Weiner believes that

volume control “is the next big thing” in dialysis management: “It is much more important in my opinion than anemia management and hypercalcemia.”

He said that when KCQA surveyed the dialysis community about developing new quality measures, fluid management was the top priority.

But he acknowledges the uncertainty of any standard at this point. The 13 mL threshold was endorsed by the National Quality Foundation, but “for some people, 8 mL may be too high, and for some people, an ultrafiltration rate of 18 mL may be OK. But you had to start somewhere. Importantly though, we need a continuing iterative process by which we reassess what may be the optimal filtration rate.”

Eduardo Lacson Jr., MD, MPH, also from Tufts, is not as enthusiastic about the prospect of an ultrafiltration rate measuring standard. He noted that the most direct evidence has come from studies using technologies to prevent intravascular volume depletion—and these studies found that the avoidance of depletion had no effect on outcomes.

Weiner and Lacson co-wrote an edi-

torial that accompanied Flythe’s study and concluded that proposals like this one epitomize the balancing act between the two aphorisms, “the perfect should not be the enemy of the good” and “first do no harm.” But they also note that the QIP already exists, so the kidney community must be ready for new measures being added regularly.

### CMS says it is coming

And CMS’ latest draft updates to policies and payment rates for end stage renal disease make it clear that this one is coming. Released on June 24, 2016, the updates propose incorporating an ultrafiltration rate reporting measure into the QIP in payment year 2020. That timing is actually a year’s postponement—the 2015 updates proposed beginning the program in 2019.

The 2016 CMS proposal moves toward parts of the KCQA model, including reliance on a week of testing instead of a single measure. Although this requirement actually increases a facility’s data reporting requirements, Weiner and Lacson said that one reason the KCQA included it was not only to get a more accurate picture of a patient’s sta-

tus, but also to prevent dialysis facilities from gaming the system. As long as patients are scheduled for three sessions in a seven-day week, there are going to be shorter and longer periods between dialysis sessions, with more fluid building up during the longer breaks. “Patients who come in after the 72-hour gap are probably going to have more fluid taken off than those who come in after the 48-hour gap,” Weiner said. “So if you are a dialysis facility that draws its labs on a Wednesday or Thursday, you are going to look better under the [original] CMS measure than if you draw your labs on a Monday or Tuesday.” In addition, Lacson said that a facility could tailor a single treatment to meet the reporting requirement, temporarily leave the patient slightly fluid overloaded, and remove excess fluid at the next session.

Flythe’s study did in fact find that ultrafiltration rates varied according to the time between treatments, “with greater ultrafiltration rates occurring after the long interdialytic break.”

The updated CMS version did not include an exemption for dialysis sessions of four hours or more. This ex-

emption in the KCQA model was part of the reason more facilities met the guideline compared with the CMS proposal. Weiner said that a session of this duration shows that “the dialysis facility is doing what they can to minimize the ultrafiltration rate. You don’t want dialysis units to limit the amount of fluid they take off someone, leaving them fluid overloaded, just to hit a measure.”

Lacson noted that not only would longer treatment times pose challenges for the operation of a dialysis facility—such as longer hours and juggling patient schedules when treatment durations are unknown—but many patients will not happily greet the prospect of longer treatment.

### Implementation plan

CMS plans to score facilities on whether they successfully report the required data in a timely fashion, not on the values reported. Weiner said that CMS often phases in a measuring standard in this fashion to make sure that the data capture is feasible and reliable. He said the ASN Quality Metrics Task Force will be submitting comments on the latest CMS proposal. ●

# MD Anderson Onco-Nephrology Symposium 2016

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