

September 6, 2018

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1691–P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Secretary Azar and Administrator Verma:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program” (Proposed Rule). ASN represents more than 19,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society’s concerns is the preservation of equitable patient access to optimal quality care for kidney diseases and kidney failure, and the integrity of the patient-physician relationship.

The society appreciates CMS’s ongoing efforts to improve the quality and efficiency of dialysis care in the Medicare ESRD Program. Reflecting the society’s commitment to patient access to the highest quality of dialysis therapy, and to preserving the ability of nephrologists to provide and patients to receive individualized care, ASN submits the following comments regarding the proposed modifications to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and the ESRD Quality Incentive Program (QIP). In summary, ASN:

- Commends CMS on its focus on fostering and incentivizing innovation on behalf of people with kidney failure
- Believes a non-budget neutral methodology must be created to incorporate novel or improved technologies, including drugs and devices that will better the lives of patients with kidney failure, into the dialysis payment bundle
- Requests that some future novel products or technologies for with kidney failure that do not yet exist will require different reimbursement pathways than the PPS
- Urges CMS to aims for a highly meaningful yet parsimonious set of quality measures to enable providers to focus quality improvement efforts on factors that are most important to patient success
- Requests clarification regarding three important aspects for patients with acute kidney injury requiring dialysis (AKI-D) who do not recover kidney function and are subsequently deemed as having kidney failure

- Suggests CMS continue to focus on increasing access to transplantation and home dialysis for appropriate patients as important goals, but avoid creating measures assessing wait-listing rates or artificially selected counts or percentages of patients who should select specific modalities
- Recommends CMS remove, or revert to reporting-only, the current National Healthcare Safety Network (NHSN) Bloodstream Infection measure, which as currently structured fails to foster a culture of quality improvement, is not validated, and penalizes facilities that accurately report infections

Improvements to the Drug Designation Process

ASN commends CMS for its focus in this proposed rule on revising the drug designation process, including determining when products are no longer oral-only. This approach is particularly important for including how new drug products will be added into the bundled payment system. The society appreciates that these proposed changes come at time when the administration is undertaking broader efforts to foster and accelerate the development and availability of new products to improve the lives of the more than 40 million Americans affected by kidney diseases. This commitment is exemplified by KidneyX, the new public-private partnership between ASN and the Department of Health and Human Services (HHS).

People affected by kidney diseases, particularly by kidney failure, have seen too few novel therapies and almost no transformational advancements in kidney medicine in decades. While current structure of the PPS is perceived as a barrier to investment in products that could benefit patients, ASN believes many of the proposed revisions in this rule will help overcome that barrier. By implementing payment policies that incentivize needed development in this field, CMS can help improve patient lives. ASN views itself as a partner in helping to achieve this critically important objective and offers the following comments in support of this shared goal.

Ultimately, a non-budget neutral mechanism to incorporate into the bundle novel or improved technologies, including drugs and devices, that will not only better the lives of patients with kidney failure but also will encourage innovation must be created.

ASN supports CMS's proposal to extend the Transitional Drug Add-on Payment (TDAPA) to any new renal dialysis drug or biological approved on or after January 1, 2019. This change is an important step in creating a predictable, transparent pathway for the smooth addition of new products to the bundle, a step that is both fair and necessary to facilitate kidney patient access to these medications. Because generics and biosimilars perform the same or equivalent functions to drugs that are already incorporated into the PPS bundle whose use and pricing is established, ASN agrees that it is not necessary to provide a TDAPA payment for generics and biosimilars.

Ensuring patient access to affordable prescription medications is one of the most significant challenges our healthcare system currently faces, and ASN compliments CMS on its attention to reducing the overall cost of prescription drugs. Indeed, many Americans with kidney failure struggle with, and are sometimes unable to afford, their co-payments for dialysis and other medical care, which includes a substantial amount of prescription medication costs.

A strong supporter of the goal of improving patient access to lower-cost drugs, ASN is very concerned that CMS's proposal to reduce the Average Sales Price (ASP)+6% payment in TDAPA to ASP+0%. Rather than reducing payments for prescription drugs, this proposal reduces payments to dialysis facilities for administering prescription drugs. Facilities will have to reconcile potential differences in the amount that CMS reimburses in TDAPA and the amount that the facilities actually pay for new prescription drugs and associated costs of administering them to patients (overhead). This discrepancy could have the unintended consequence of discouraging dialysis providers from including new therapies on their formularies.

As the Medicare Payment Advisory Committee (MedPAC) has noted, the overhead costs to dialysis providers associated with actually making products available to patients exceed the precise cost of the product itself. For dialysis organizations that are unable to secure purchase of the product at or below the average sales price, providing this product to patients would result in a financial loss, thereby disincentivizing their use. ASN urges CMS to maintain the current ASP+6%, which the society believes will help signal that the agency encourages the development of new therapies in this space and will appropriately reimburse dialysis facilities that adopt them.

As we all agree, it is unfortunate that more novel therapies for people with kidney failure have not come to market. ASN recognizes that one of the contributing factors is the perception that reimbursement is a uniquely difficult barrier in the ESRD space. Reducing the ASP to +0% would likely:

- a) be perceived as increasing the financial risk of entering the dialysis market to innovators and investors, conflicting with CMS' goal of fostering innovation; and
- b) make it more difficult for dialysis organizations to adopt any new medications that are developed for the care of patients with kidney failure.

Imperative Addition of New Money to Reflect Innovation New Therapies

ASN believes it is imperative for new money to be made available to adequately integrate innovative new products in the PPS, even if those products fall within an existing functional category. Currently, there are new medications in the development and testing pipeline that could improve the lives of patients with kidney failure, and hopefully more will emerge in the future.

To promote innovation and utilization of products to better dialysis patients' lives, ASN encourages CMS to revise the current position of not adding new money to the bundle for drugs and biologicals that are in existing functional categories. Novel products developed that target a condition or issue within a functional category but either provide a more effective treatment or have a different mechanism of action that results in either greater safety, efficacy or tolerability are not direct substitutes for existing products within a functional category. Instead, these products constitute innovation that will benefit patients, and this innovation should be recognized within the payment bundle.

For example, one of the most significant complaints of patients on dialysis today is itching (pruritus). Although products exist in the "Antipruritics" functional category, existing agents—that are marginally effective—come with significant side effects, including fatigue and somnolence; given this unfortunate quality of life trade-off facing patients with existing agents in the "Antipruritics" functional class, patients clearly need more effective products to meet their needs. However, were a new medication to treat pruritus to become available, the current policy would add it to the bundle under the "Antipruritics" functional category with no new funds added to the

bundle. At best, this approach constitutes a serious risk of these products not being adequately reimbursed relative to the cost of the development and dissemination to patients. More likely, it constitutes a direct disincentive to develop effective antipruritic agents or any other products that would be expected to fall into any of the functional categories.

From a patient perspective, this policy presents a barrier to having access to innovative therapies that would significantly improve their health and quality of life. Recent research shows that patients on dialysis have prioritized the need for product development to focus on their physical symptoms of insomnia, fatigue, and muscle cramping. [Flythe et al, Clin J Am Soc Nephrol 13: 735–745, 2018. doi: <https://doi.org/10.2215/CJN.10850917>] As we seek to foster innovation in symptom management among individuals on hemodialysis, it is important that reimbursement to help address these patient-identified priorities be predictably available and adequate.

ASN strongly believes that CMS should assess each new drug that is not a biosimilar or a generic version of a drug that is already included in the bundle, using all available information, including data from the Food and Drug Administration (FDA) and labeling information and focusing on agents with either greater efficacy, greater safety, or greater tolerability than existing agents, and provide new, additional money to the bundle to appropriately reflect the total costs for drug purchase and any associated overhead.. The society is strongly opposed to the possibility that new drugs that are not biosimilars or generics would be added to the bundle with insufficient funding to cover costs of its addition to the formulary.

Patients with kidney failure deserve the opportunity afforded to all other Medicare beneficiaries to benefit from advances in medical care, and expect that policy, in the form of a rigid payment bundle, will not stand between them and access to those products. In lieu of clarification from CMS that it will assess innovative new products with an intent to add new funds to the bundle to cover associated expenses, the society is deeply concerned that few if any new products will be developed, as industry will continue to perceive dialysis therapies as too risky.

As CMS considers how to assess novel drugs for addition the bundle, ASN suggests the following aspects be taken into account:

- Products that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug’s label; or
- Products for which there are multiple clinical outcomes as stated in the FDA labeling material (including within the clinical pharmacology and study portion of the FDA label); or
- Products that based on FDA labeling that have demonstrated clinical superiority to existing products in the bundle; or
- Products that improve priority outcomes, such as:
 - Decreasing hospitalizations;
 - Reducing mortality;
 - Improving quality of life and other patient reported outcomes;
 - Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);
 - Addressing patient-centered objectives (including any used by the FDA in its review); or
 - Reducing side effects or complications; or
 - Improving safety over products currently available in the bundle.

New Devices in the Bundle

ASN appreciates CMS' attention to revising TDAPA and other policies that pertain to the addition of new drugs and biologicals to the bundle, and the society believes revisions in this domain will substantially benefit patients in the future. However, ASN observes with concern that no similar pathway exists for adding new devices to the bundle. In the absence of guidance and clarity concerning reimbursement pathways, investors and industry are understandably wary of investing in the development of new devices for patients. Companies with existing products in this space that are not currently in use in the United States, but are used elsewhere, also experience confusion regarding how to bring these products to Americans with kidney failure. In each case, patients are potentially deprived of access, whether today or in the future, to devices that could improve their quality of life or longevity.

ASN urges CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the bundle. Similar to the society's view concerning the addition of new drugs to the bundle, ASN also contends that new money must be made available to appropriately reflect the cost of new devices added to the bundle. The society stands ready to collaborate on the development of such a pathway and the details of related payment policies such as transitional payments and the process for evaluating new products, but is firm in its belief that the establishment of a non-budget-neutral process to add new or improved device technologies that will better the lives of patients with kidney failure in the care of dialysis patients is an urgently-needed development.

Future Changes to Kidney Care

In future years, it is likely that new therapies and technologies that benefit people with kidney failure will be developed that do not resemble existing renal dialysis services. It will be critical that CMS state proactively that not every product that is developed for the care of people with kidney failure will be added to and reimbursed via the bundle. Other, more appropriate, payment pathways should be identified for products that do not fit the current thrice-weekly, in-center dialysis care paradigm on which the development of the bundle was predicated. As an example, an implantable or bioartificial kidney that patients use continuously would not likely be an appropriate fit for the bundle.

By signaling that it recognizes that other payment paradigms for novel products that treat of kidney failure may exist in the future, CMS can help to not only de-risk this area for innovation but also to create the environment of certainty that will help foster interest in the space. ASN recognizes and appreciates CMS's acknowledgment of its role in this regard.

Revisions to the case-mix adjusters in the ESRD PPS

ASN appreciates that CMS has proposed revisions to the case-mix adjusters, particularly its acknowledgement that the documentation burdens are significant. The society supports the laudable goal of the case-mix adjusters, which is to protect beneficiaries by ensuring that all beneficiaries, regardless of the cost of providing care to them, have access to health care services. Yet, as long noted by MedPAC, ASN, and other stakeholders, the case-mix adjusters are plagued with methodological problems. The changes proposed in this rule begin to address these concerns but there is still significant room for improvement.

CMS proposes to begin to use ICD-10 codes to document case-mix adjustor conditions. The society is concerned that without a clear, simple process to obtain detailed comorbid condition data and to document these data for submission to CMS, comorbid conditions that may impact the bundled payment will continue to be insufficiently documented. Consequentially, funds set aside for care of dialysis patients will not be expended. On principle, it is inappropriate that funds ostensibly set aside to improve care for the most complex patients remain unused due to a documentation hurdle, ultimately missing an opportunity to improve the lives of dialysis patients.

ASN recognizes that CMS works to make policy decisions that are in the best interest of patients and respectfully submits that further refinements to the case-mix adjustors would help achieve that goal. Overall, the case-mix adjustors fail to provide meaningful benefit to patients, do not serve a clinical need in the dialysis facility setting, and should be revised or eliminated. The society would be pleased to work with CMS on revisions to the case-mix adjustors and offers to draw on the expertise of its more than 19,000 members, including many of the physicians who both make these diagnoses and treat them, in service of this goal should the agency undertake this effort.

Efforts to improve transplantation and home dialysis modality education

ASN commends CMS for soliciting information regarding improving patient knowledge of their kidney failure treatment options and ability to access other kidney failure treatment modalities. As CMS notes, the number of people waiting for healthy donor kidneys far exceeds the number of available organs, and reducing that gap is among the highest public policy priorities for the society. The agency also correctly observes that, while dialysis facilities and dialysis professionals have no control over the total supply of kidneys made available for transplantation, they do have control over some of the components that are necessary for transplantation to occur. It is important to bear in mind that there are numerous factors contributing to patient referral, wait-listing and ultimately, transplantation, some of which are modifiable and identifiable on claim data and others which are either fixed or reflect difficult to quantify patient factors.

While acknowledging that there is no one easy solution to increase patient access to kidney transplantation, which is the best kidney replacement therapy option for many patients, ASN also believes that the kidney and transplant community and policymakers need to address factors affecting patients' likelihood of transplantation. We can and must do better on behalf of those patients who would benefit from kidney transplantation but, for a variety of reasons, may be unable to access transplantation.

In this proposed rule, CMS requests feedback regarding ways it can increase kidney transplant referrals and improve the tracking of patients on the waitlist. ASN offers several observations for consideration.

Currently, some dialysis facilities track their patients' referral status and how their progress through the transplant evaluation system is progressing. However, there is significant variation across facilities and this information is not tracked in any kind of central database. Recent research published in the *Journal of the American Medical Association* describes the variability in referral for transplantation and highlights some of the underlying factors that need to be elucidated in order to improve transplant access. (Patzer et al, *JAMA*. 2015; 314(6):582-594. doi:10.1001/jama.2015.8897) ASN believes that documentation of referral rates in a public, transparent manner across dialysis facilities would be a significant step forward in the

understanding and awareness of transplant referral patterns. As noted in this article, “the collection of national transplant referral surveillance data by CMS among all... US dialysis facilities is needed to identify poorly performing facilities on which to focus quality improvement interventions. A CMS Technical Expert Panel recommended the collection of these data nearly a decade ago, yet there is still no national benchmark for transplant referral in the United States.”

It is premature to implement a quality metric examining referral rates until the non-modifiable individual factors that impact transplant referral can be sufficiently captured within a performance measure. ASN suggests that it would be a significant step forward for referral rates, with a statement regarding the precision of this rate (as expected, better than expected, worse than expected), to become more readily available in the public domain.

As part of this discussion, it must be acknowledged that transplant centers’ quality metrics and incentives are not aligned with dialysis facility quality metrics and incentives, and this misalignment is to the detriment of patients. In addition to any changes considered to put pressure on dialysis facilities to foster access to transplantation, there should also be parallel changes to realign the factors that influence transplant centers’ willingness to perform kidney transplants.

These changes are outside of the scope of this proposed rule, but they are nonetheless critical for CMS to consider in tandem with any changes to dialysis facility policies that are within the scope of this proposed rule in order to maximally benefit patients. For example, some transplant centers are currently working to reduce the numbers of patients waitlisted to improve the ratio of number of patients waitlisted versus ultimately transplanted, a transplant center metric that is assessed by the Scientific Registry for Transplant Recipients (SRTR). Thus, as the kidney community frets about low rates of wait-listed patients and seeks to increase that number, the transplant community, responding to incentives that impact the transplant center, frets about subpar ratios of wait-listed to transplanted patients. This lack of alignment is bad for patients.

Similarly it must be acknowledged that there is an inherent disincentive for dialysis facilities to promote referral of dialysis patients for transplantation. As transplant eligible candidates are successfully transplanted, dialysis facilities’ populations are increasingly comprised of the non-eligible patients; these patients tend to be sicker and/or less adherent and/or more difficult to help achieve quality standards. In essence, dialysis facilities are losing their least expensive patients and keeping their most expensive patients, a financial pattern that inherently disincentivizes kidney transplantation. In recognition of this paradox, and as data about referral rates become available and expected referral rates can be developed, ASN suggests that CMS consider a strategy to account for characteristics of recently transplanted patients in QIP scores.

Frequent, iterative patient education is a critical component of optimizing transplantation rates as well as rates of transplant referral and wait-listing. ASN recognizes that the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey asks questions about transplant education. As discussed in prior comment letters, the ICH-CAHPS has significant methodology issues, contains poorly worded questions, and is most likely to be completed by a certain patient type. The recently convened Technical Expert Panel on transplant education offered several potential ideas for consideration.

CMS also inquires how it can better ensure that dialysis facilities are meeting their obligations concerning patient education about home modality options, particularly with an eye to increasing home dialysis utilization to appropriate levels. ASN concurs with CMS that increasing access to home dialysis care is an important goal, and one the kidney community has significant room to improve upon. The society observes that it is difficult to assess the availability of peritoneal dialysis (PD) and home hemodialysis (HHD), and that lamentably not every facility offers these options to patients at all.

Additional causes are systemic, and include lack of hospital expertise in peritoneal dialysis and a lack of skilled nursing and rehabilitation facilities that have sufficient experience with peritoneal dialysis. The society is actively working to improve nephrology trainees' education in PD and HHD and to provide access to continuing education about these modalities and calls on CMS to promote the wider availability of peritoneal dialysis expertise in acute and sub-acute medical care settings.

Using purely administrative data, assessing education about home dialysis modalities would be quite challenging. As such, the society suggests that CMS encourage survey and certification inspectors to engage in more qualitative efforts to assess dialysis modality education. Admittedly, this approach takes more resources and time, but it is something that inspectors should be examining. Patient interviews about modality education, including transplantation and home dialysis, would better elucidate the frequency and quality of that education.

ASN also suggests that CMS urge the ESRD Networks to focus on improving modality education through the Quality Assurance and Performance Program (QAPI). At present, ASN members have observed that the ESRD Networks may be able to make better use of the \$0.50 per treatment fee. Rather than selecting a random percent target of patients to use home dialysis or raw number of patients to do so, the ESRD Networks should focus on helping facilities improve their educational processes on an individual patient level.

Fistula First was successful in using this approach and could serve as a model for alternative modality education. In contrast, a Network in the Northwest recently mandated a 15% increase in home dialysis use among in-center patients without the supporting infrastructure to facilitate this edict. Blunt instruments like this Network mandate that seemingly randomly selected a percent-increase goal are unlikely to foster meaningful change, and in some cases could result in pressure on patients to adopt modalities that are not appropriate for them. While more challenging to attempt to improve educational efforts about alternatives to in-center dialysis, ASN believes this greater targeting of individualized care would be a better and safer use of ESRD Network resources.

II. Acute Kidney Injury

Requested clarifications concerning patients with Acute Kidney Injury

In prior comments on AKI care, ASN requested clarification regarding three important aspects for patients with AKI-D who do not recover kidney function and are subsequently deemed as having ESRD:

- 1) When does the four-month modifier for incident ESRD patients apply for patients with AKI- D who go on to receive a diagnosis of ESRD and begin receiving maintenance dialysis? Does the modifier take effect on the date that the 2728 form is signed for the patient who did not recover kidney function, or another point in time?
- 2) What is the date that determines patient Medicare eligibility due to kidney failure?
- 3) What is the date that determines patient transplant waitlist time?

These questions are still outstanding, and ASN urges the agency to provide clarity in this final rule. Questions two and three carry tremendous patient importance, and ASN strongly urges that the first dialysis date, regardless of whether a patient is deemed ESRD or AKI-D at that time, be used to establish the start date of transplant waitlist time and waiting time for Medicare eligibility as this is in the best interest of patients and promotes the most accurate reporting of patient likelihood of recovery.

III. Quality Incentive Program

Meaningful Measures Initiative

ASN commends CMS for prioritizing regulatory reform and reducing regulatory burden, including through the Meaningful Measures Initiative. The society has advocated for focusing on the use of fewer, more meaningful measures in the QIP and other programs and is pleased that CMS is in agreement. Several of the proposed changes to the QIP, which are addressed later in this letter, align with the objectives of the Meaningful Measures Initiative, and ASN thanks CMS for taking steps to implement this philosophy in the proposed rule.

CMS also notes that it continues its efforts to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences. The elimination of health disparities is a top priority for ASN, particularly since they are so pronounced in the kidney patient population, where African Americans are four times as likely and Latino Americans are twice as likely to have kidney diseases. Last year, the society submitted recommendations regarding opportunities and strategies to improve health equity. The society encourages CMS to revisit those as the agency begins to move beyond its initial focus, as described in the proposed rule, of efforts to reduce disparities in the Inpatient Prospective Payment System/Long-Term Acute Care space.

New factors for QIP measure removal

For Calendar Year 2019, CMS proposes new factors for measure removal or replacement. ASN commends CMS for proposing to remove several measures from the QIP. This proposed change is consistent with ASN's longstanding belief that the QIP will be most effective (maximally benefitting patients while minimally generating administrative burden) when it is comprised of a small number of measures that are highly meaningful to patients and patient care.

Reflecting the importance of the patient-physician relationship, the importance of patient autonomy, and the heterogeneity of patient health and patient preferences, ASN stresses that it is critical that the QIP allow for the ability and flexibility for patients and their physicians to appropriately individualize care. This approach requires maintaining sufficient latitude in performance standards to allow some patients to *not* achieve the quality metric without pitting the physician who is practicing patient-centered care against the facility that is striving to avoid payment penalties. Actual current patient examples are presented below:

Mr. A was previously treated with in-center hemodialysis and transitioned to home peritoneal dialysis 18 months ago. Since transitioning to home peritoneal dialysis, he has felt much better than when he was undergoing in-center hemodialysis and is more satisfied with his health and independence. He has had no hospitalizations since beginning peritoneal dialysis. His only issue with peritoneal dialysis is that he does not like the feeling of having a lot of fluid in his abdomen during the day when he is active, limiting the number of daytime exchanges that he can do while maintaining his active lifestyle and quality of life. His prescription includes multiple cycler-assisted nocturnal exchanges as well as a morning dwell and a low volume long-daytime dwell. He has no residual kidney function. With a regimen that meets his lifestyle needs, he is able to achieve a Kt/V of 1.60, short of the 1.70 threshold in the metric for dialysis adequacy, a value that is not supported by clinical trial data and that is not followed by other countries that more widely utilize PD. His nutritional status/inflammatory status is good, as evidenced by a serum albumin consistently 4 g/dL or higher.

Because Patient A is attributed to a modestly sized facility, because PD patients are less likely to meet dialysis adequacy targets and because the performance of dialysis adequacy is very high in HD-only facilities, his failure to achieve the Kt/V performance standard hinders the facility's overall ability to perform well on this QIP measure. Were the leadership of the unit to focus on achieving an optimal QIP score the obvious choice would be to move Mr. A off of his preferred home PD modality and back into the unit where an HD treatment would likely achieve a more preferable Kt/V. Yet clearly, this would not be in the best interest of Mr. A. The society underscores that leaving a margin for flexibility to allow people like Mr. A and his nephrologist to make the best individual decisions is an important, patient-centered principle for the overall QIP program. This approach also includes removing *clinically* topped-out measures, rather than relying overly rigorous statistical criteria for defining when a measure is *statistically* topped out, a step the society is encouraged that CMS is beginning to undertake in this proposed rule.

Mr. B receives in-center hemodialysis. He has chronic hypercalcemia above the threshold value of 10.2 mg/dL due to metastatic prostate cancer. His PTH is suppressed and his phosphate is well controlled on non-calcium containing binders. He is treated with a 2 Ca bath (although he has significant cardiac issues as well). To achieve the hypercalcemia metric in this setting where there are no dialysis-related options to achieve this threshold, his dialysis facility draws and submits post-dialysis serum calcium levels. These results, which meet the threshold, are a transient effect of the low dialysate calcium concentration rather than of Mr. B's serum calcium levels. Of note, hypercalcemia in the setting of metastatic does not cause death but is a marker of a severe cancer that is likely to cause death.

Mr. B's situation highlights four factors, all of which most relevant to a clinically topped out metric that is based on observational data that show associations of a lab value with outcomes rather than causality. First, the current low rates of hypercalcemia result in a benchmark of 0% and an achievement threshold of 2.41%. In a 40 beneficiary facility, Mr. B's hypercalcemia, even

if no other patient ever has a serum calcium level above 10.2 mg/dL, will result in that facility receiving 0 points on the hypercalcemia metric; this reflects Mr. B's cancer. Despite this fact, the hypercalcemia metric is not statistically topped out. Second, the facility is using a very low calcium bath to attempt to achieve calcium control; in an individual with ischemic heart disease: this may be more dangerous than beneficial. However, the metric prevents individualization of care. Third, the metric is being gamed through submission of a post-hemodialysis serum calcium level; this is allowed under the measure specifications. Lastly, the hypercalcemia is caused by a metastatic cancer; this is not a function of dialysis and has nothing to do with safe dialysis or appropriate use of medications that address kidney failure dependent mineral bone disease.

ASN is very supportive of the proposal to include new factors for measure removal or replacement overall. However, as illustrated by the actual patient cases above, ASN believes that the agency is using an overly-stringent and non-patient-centered definition for Factor 1 (topped-out measures). The society very much concurs with the concept that topped-out measures should be removed, but suggests CMS revise its mathematical definition to better account for a measure being clinically topped out such that the ability to individualize care is disincentivized.

ASN lauds the overall shift in this direction, and, beyond the examples above, offers the following suggestions on the proposed removal of the four specific measures:

- **Healthcare Personnel Influenza Vaccination:** ASN supports the removal of this measure due to Factor 1 (topped-out). While the society strongly believes that every effort should be taken to reduce the transmission of influenza in dialysis facilities, the data suggest that compliance with healthcare personnel vaccination is close to 100%. Consequently, this measure is no longer necessary for inclusion in the QIP.
- **Pain Assessment and Follow-Up:** Similarly, the society believes that patient pain management and palliative care are an important aspect to provide throughout patients' time on dialysis. However, because performance on this measure is uniformly high and reflecting the need to develop better knowledge on how to treat chronic pain in patients with kidney failure, the society concurs that it no longer needs to be included in the QIP.
- **Anemia Management:** Anemia management is a critical aspect of dialysis care and, in fact, motivated the current PPS and QIP. While ASN agrees that data do not support a performance measure based upon hemoglobin level at this time, anemia management maintains importance as a reporting measure.
- **Serum Phosphorus:** Lauding CMS's proposal to reduce QIP measures in concept, ASN opposes the removal of the serum phosphorus reporting measure and would prefer that CMS instead eliminate the hypercalcemia performance measure. There is minimal variability in calcium levels, and, as presented in the case above, the measure is clinically topped-out. Moreover, there are no clinical trial data demonstrating that lowering elevated serum calcium levels improves outcomes, while there are observation data utilizing 'natural experiments' suggesting that use of low dialysate calcium may increase patient risk of adverse heart outcomes.

In contrast, phosphorus management is very important for dialysis patient care, and there is significant clinical ability to control phosphate levels, using binders. While there

is no agreed upon level that is optimal for dialysis patients and there is considerable variability on phosphorus levels based upon the timing of ascertainment, it is nonetheless an aspect of care that providers can affect. ASN suggests that CMS retire the hypercalcemia measure and maintain a reporting-only serum phosphorus measure.

Again, ASN commends CMS for taking the important step of removing measures from the QIP and believes this approach to streamlining the QIP should be continued in subsequent years. ASN would be pleased to participate in refining the methods for selecting measures to be removed and would be pleased to provide physician expertise and experience in discussing the most important measures that are available.

NHSN Infection Measures and Dialysis Facility Surveying

CMS proposes to increase the number of facilities surveyed to validate the NHSN bloodstream infection measure from 150 to 300. Unfortunately, increasing the numbers of facilities audited will not resolve the substantial underlying problems with the NHSN BSI measure that ASN has commented on extensively in the past.

ASN applauds CMS's focus on the importance of reducing infections for all ESRD patients. The reduction of dialysis-related infections is critical to the health, safety, and overall quality of life of these patients. This is a point that cannot be stressed enough. However, ASN strongly believes this measure is fundamentally flawed and that this measure should be removed and replaced either with a reporting measure or the superior measure on this topic endorsed by the National Quality Forum (NQF).

ASN strongly disagrees with using this measure as a clinical measure and urges CMS to consider reverting this measure to a reporting-only approach with no penalties associated with self-reported infection rates. Problematically, this measure aims to both achieve full and transparent reporting of all dialysis events and to grade facilities on BSI rates in order to improve clinical practices and reduce infection rates. Including this measure as a clinical measure runs counter to the goal of a quality improvement program and fails to foster the goal of patient safety. More frequent assessment of blood cultures inherently exposes facilities to more false positives that represent contamination rather than infection than facilities that assess less frequently. As such, the current program financially penalizes facilities that assess blood cultures more often as well as facilities that seek out and then report accurate infection data. This outcome is diametrically opposite to the goals of the QIP.

Unless CMS turns the measure into a reporting-only metric, it is not reasonable to expect that the measure will ever be validated if based on facilities reporting on themselves. Even if the measure were to be fully validated, combining accurate reporting with a scoring formula that penalizes facilities' reimbursement when infections are accurately reported as such appears likely to produce less than desirable results. ASN believes that the proposed approach will not foster a culture of infection prevention in the future, which is the true purpose of the QIP, thereby jeopardizing true quality improvement in this crucial aspect of care.

ASN also notes that the median has hovered near zero BSIs. This is implausible given the clinical realities of dialysis care and the experience of the ASN membership in caring for dialysis patients. Validation efforts that involve penalties if a facility accurately reports and shows BSIs are unlikely to yield useful results, and ASN encourages CMS to reconsider this study as part of an overall re-evaluation of this measure.

Until CMS can develop a system for complete reporting that does not create disincentives for obtaining blood cultures, accurately reporting results, or fostering a culture of quality improvement focused on improving those results, this measure actually harms patients. In sum, representing nephrologists, ASN strongly urges CMS to remove or revert to reporting-only the current NHSN Bloodstream Infection measure because it is bad for our patients.

Proposed new transplant measures

As noted above, ASN concurs with CMS that fostering improved access to transplantation, the optimal kidney replacement therapy for many patients with kidney failure, is a top public policy priority. In this regard, the society commends CMS for considering how it can appropriately incorporate this important measure of overall quality of care into the QIP. However, the society has concerns about the two proposed measures (PPPW and Standardized Kidney Transplant Waitlist measures) and offers an alternative for consideration.

ASN observes that there are many factors that are not within the control of the dialysis facility that influence whether or not a patient is wait-listed. From the time of referral to the time of wait-listing, many elements play a role including changes in the patients' health status, overall performance of the transplant center, and level of risk tolerance of a given transplant center just to name a few. So many things play a role in whether or not a patient is wait-listed that ASN believes it would be more effective to implement a reporting requirement for referrals to transplant centers.

ASN also notes that NQF declined to endorse the PPPW measure. Instead, developing a reporting-only measure on referrals would enable the development of a nationwide dataset on referrals that could help increase our awareness and understanding of referral patterns. This approach would allow researchers and policymakers to then develop appropriate policies and incentives in the future to promote transplant. The society also suggests that CMS explore the possibility of developing a process measure looking at whether and patient education about modality options—including transplantation—is documented in patients' plan of care.

As noted earlier, alignment between dialysis facilities and transplant centers' incentives is crucial for success. As such, ASN recommends that CMS collaborate with the community to develop measures that synergize across the dialysis and transplant settings.

Medication reconciliation management

CMS proposes adopting the new Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure in QIP, starting in Payment Year 2022. ASN concurs with the agency that medication management is an important and too-often incomplete process that has critical implications for patient safety. The society supports CMS' adoption of this measure, but, as in previous comment letters, highlights that dialysis facilities' ability to conduct a thorough medication management reconciliation would be greatly facilitated by requiring hospitals to provide data regarding patients' inpatient care to dialysis units. ASN recognizes that such data-sharing is hampered by the lack of truly interoperable EHRs, but urges CMS to consider how it can better prompt hospitals to provide this important patient safety information in a timely fashion.

Ongoing Concern Related to ICH-CAHPS Methodology and a Suggestion for Improvement

ASN remains concerned with the statistical validity of the ICH-CAHPS measure, specifically, that it requires a minimum of 30 responses from patients surveyed twice in a one-year period – one in the spring and one in the fall. A total of 30 responses with twice a year administration is, by statistical necessity, not valid as an “n” of 30 if the same patients are responding more than once; this reflects the fact that more than one response from the patient is not an ‘independent sample’. Stated plainly, 30 patients responding once is far more meaningful for this type of survey design than 15 patients responding twice, as the lack of independence of samples decreases the effective sample size. ASN encourages CMS to address the reasons for the low response rate rather than increasing the frequency of survey administration. These are concerns that CMS needs to address, and ASN would like to offer a solution for the agency’s consideration to do so.

ASN suggests that CMS, working in partnership with the ESRD Networks, concurrently pilots several different approaches to collecting ICH-CAHPS survey responses across the country. ASN knows that the current model is not effective in driving adequate or desirable response rates, in large part because the survey is quite burdensome. CMS could solicit ideas for how to improve response rates through a Request for Information, or it could work through the ESRD Networks and allow them, in conjunction with stakeholders, to design new ways to test obtaining ICH-CAHPS responses.

Because of the sheer volume of patients currently treated with dialysis, testing new approaches in real-time would not be a significantly time-intensive pilot. Within a year or so, CMS could have data to compare which approaches worked and which did not.

Alternatively, CMS could also pilot the use of different alternatives to the ICH-CAHPS, testing new patient experience of care survey tools or could explore whether administering smaller elements of the current survey is valid and effective while using other facilities as ‘controls’. Given the deeply suboptimal response rates at present, it would seem that there is little to lose in actively experimenting with alternative approaches. Such experimentation would also be a useful project to leverage the ESRD Networks’ capability in testing. ASN is excited to discuss this idea further with the agency as we think it could enable implementation a more meaningful and effective system in a relatively short period of time supported by generalizable, real-world data.

Lastly, ASN notes that the survey tool does not capture the experiences of HD patients, a shortcoming the society knows that CMS is actively considering. ASN would be pleased to continue to work with CMS to address this gap.

Revise Measures that are Reported as Ratios into Rates

CMS should modify three current QIP measures—the Standardized Hospitalization Ratio, the Standardized Readmission Ratio, and the Standardized Mortality Ratio—to be true risk-standardized rates, not as ratios. This modification allows accurate assessment of improvement as well as accurate benchmarking, elements that are critical to the quality program and to individual dialysis facilities as they seek to improve the care provided to individual patients.

Proposed Domain and Measure Weighting

ASN appreciates the careful attention paid to measure weighting within the proposed 2021 ESRD QIP. Measure weighting is important to emphasize those measures that are most meaningful to patients, most reliable for assessing dialysis facility care provision, and most useful for facilities to focus on for quality improvement. In this rubric, ASN has the following comments that can be viewed in conjunction with the following section titled 'Future Iterations of the QIP':

1. Vascular access is consistently ranked by patients as of critical importance, is modifiable by the dialysis facility, and is a key factor influencing infection risk, hospitalizations, and death. For these reasons, the minimal weight given to the VAT measure seems to inappropriately devalue this measure. While acknowledging that the VAT measure is moving closer to being topped out, ASN suggests that this can be addressed in other ways, including through modifying achievement thresholds to permit greater individualization and, as is proposed, incorporation of the newly revised VAT measures that account for some patient factors.
2. The safety measure domain weight appears appropriate overall, but ASN would suggest valuing reporting exclusively in this domain due to the lack of validity in the NHSN BSI measure discussed above. At a minimum, ASN suggests that the reporting aspect of this measure be valued far higher than the BSI Performance measure. This reflects the lack of validity in the BSI measure due to the need for facilities to report on themselves. More critical than a punitive performance measure that provides incentives to underreport is that facilities accurately track and examine their infection data. This quality assessment and performance activity will help patients live longer and better, and, therefore, will be far more meaningful to promoting high quality dialysis care. The current domain, as structured, disincentivizes accurate reporting, likely to the detriment of patients. ASN strongly supports a valid infection measure; however, until this exists, we feel that accurate reporting should be the priority in a program whose goal is to help improve patient care.
3. The STRR measure accounts for 22% of the TPS, and, in the frequent case of insufficient ICH-CAHPS responses, will account for more than a quarter of the QIP. The society agrees that transfusions should be minimized; however, transfusions are only a surrogate for very low hemoglobin, are not typically in the control of the dialysis facility, and may not be accurately ascertained due to hospital reporting patterns. ASN suggests reducing the weight of this measure in the proposed QIP.

Future Iterations of the QIP

As noted earlier, ASN is grateful for CMS's proposed removal of measures from the QIP. Looking ahead to future changes to the program, the society has developed a "model QIP" for consideration, reflecting what ASN believes are the essential aspects of care to assess in this program.

Measure	Reporting/ Performance	Comments
UFR/Time on dialysis	Reporting	The UFR is currently a reporting measure and, in this form, has been effective in driving change and conversation in the dialysis unit.
Vascular Access Type: Fistulas	Performance	Fistula placement remains one of the most important factors in ensuring patient safety and warrants inclusion in the QIP as a performance measure with clinically appropriate thresholds to avoid unintended consequences (such as a performance standard remaining at 60% or greater fistulas to allow individualization of care for patients for whom a fistula is not the optimal vascular access).
Vascular Access Type: Catheters	Performance	Reduction of catheters within reason is an important patient safety goal. ASN recommends maintaining this as a performance measure but with a performance standard remaining at 10% or fewer catheters to allow individualization of care for patients for whom graft or fistulas are not appropriate choices.
Standardized Transfusion Rate	Performance	ASN notes that the transfusion measure is effectively a marker of Hgb<7 g/dL. The society has concerns about the validity of this measure given the lack of communication between hospitals and dialysis facilities but believes transfusion rate is an important element to assess, albeit at a relatively low weight.
NHSN Bloodstream Infection Measure	Reporting	ASN supports inclusion of this measure as a reporting measure with subsequent transition to a performance measure when reliable systems to ascertain data are in place and validity can be assured.
Standardized Readmission Rate	Performance	Hospital readmissions are an important event to avoid. ASN would prefer this be reported as a simple rate rather than a ratio. Ideally, this measure could be combined with the SHR in the future to reduce the number of measures and better assess facilities with a single measure. This reflects that a facility with a very low hospitalization rate can then have a single patient with frequent readmissions, resulting in a high quality facility appearing low performing.
Standardized Hospitalization Ratio	Performance	Hospitalizations are an important event to avoid. ASN would prefer this be reported as a simple rate rather than a ratio. Ideally, this measure could be combined with the SRR in the future as discussed above.

Standardized Mortality Rate	Performance	Survival is important to many individuals. ASN supports inclusion of a mortality rate measure, but notes that a mortality measure should not result in a facility working to dissuade individuals from making a reasoned choice to withdraw from dialysis should the benefits of dialysis no longer exceed the burden of dialysis.
ICH-CAHPS	Reporting	A measure of patient reported experience of care is critical, but given the methodological issues with the ICH-CAHPS ASN prefers to maintain this as a reporting-only measure for now. In the future, CMS and ESRD Networks could pilot in real-time in national samples revised patient experience of care/PRO assessment tools and/or different methods of administering the current version in order to maximize the number of patients completing the ICH-CAHPS and thereby maximize its validity and utility.
Anemia management reporting measure of Hgb<10, sustained for three months	Reporting	ASN supports a reporting-only measure for anemia management but stresses that it should be based on the average of three months' of data. The society also notes that, within the pediatric population, data exist showing that that morbidity and hospitalizations rise when Hgb is less than 10g/dL, making this an especially appropriate measure for the pediatric population.

In the future, ASN would also like to see the measures on the following aspects of care developed:

1. Process measure assessing if the care plan documents education about transplant care and modality options
2. Reporting measure on referrals for eligible transplant patients
3. A PD-specific peritonitis measure, which would be a better indicator of the quality of care and dialysis adequacy for patients on PD than the current Kt/V measure
4. A measure assessing the nutritional status of patients on dialysis

Again, thank you for the opportunity to provide comments on this proposed rule. ASN would be pleased to discuss these comments with CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,



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President