August 15, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1651-P; Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and Comprehensive End-Stage Renal Disease Care Model; 81 Fed. Reg. 42802 (June 30, 2016)

Dear Acting Administrator Slavitt:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to share our comments on the Calendar Year (CY) 2017 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP) proposed rule.

We appreciate the opportunity to provide our comments on this important issue. ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 9,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis facilities, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.
ANNA is a member of Kidney Care Partners (KCP) and the Alliance for Home Dialysis and has actively participated in the development of their comment letters. The following comments are in addition to the comments submitted to the Centers for Medicare and Medicaid Services (CMS or Agency) by KCP and the Alliance for Home Dialysis.

ANNA is committed to improving the quality of outcomes for patients and providing greater healthcare efficiencies through care coordination that is centered on the needs and preferences of patients and their families. ANNA believes the coordination of care between inpatient facilities and outpatient facilities is essential to improving quality of care and outcomes of beneficiaries. Healthcare providers often struggle to satisfy CMS’ documentation requirements, and we applaud CMS for recognizing the burden on kidney dialysis facilities associated with meeting documentation requirements. ANNA encourages CMS to continue to develop initiatives that consider and diminish the administrative burdens placed on providers.

I. CY 2017 ESRD PPS

CMS proposes to set the ESRD PPS base rate for CY 2017 at $231.04, which reflects a reduced market basket increase and the application of the wage index budget-neutrality adjustment factor and the training budget-neutrality adjustment factor. ANNA joins with the broader kidney community in agreeing with the calculation of the CY 2017 ESRD PPS base rate. However, ANNA believes that the payment rate currently proposed does not provide the resources necessary to ensure the provision of quality care.

Provisions of the Proposed Rule

Payment for Hemodialysis When More than 3 Treatments are Furnished Per Week

Proposed Payment Methodology for Hemodialysis When More than Three Treatments are Furnished Per Week

ANNA encourages CMS not to adopt the proposed equivalency payment based on three hemodialysis treatments per week. There exists currently an effective, operational process to bill for additional hemodialysis treatments and we have concerns that implementing a new claims processing system would present an undue administrative burden on dialysis facilities. We reiterate KCP’s comments on this issue and urge CMS to maintain its current payment policy for additional treatments that are medically justified.

Applicability to Medically-Justified Treatments

ANNA supports CMS’ current payment policy for medically necessary treatments beyond the three treatments per week payment limit. However, we have concerns that despite the promulgation of local coverage determinations (LCDs) and other guidance detailing the documentation requirements for dialysis services, there are substantial differences in the Medicare Administrative Contractors’ (MACs) assessment of medical
justification for additional dialysis treatments. We understand that documentation requirements for services vary across the MACs’ regions. In our experience, however, there is significant variation among each of the MACs in determining whether payment for additional dialysis treatments is supported by the record, resulting in the denial of payment by the MACs for valid, medically justified additional treatments.

A small subset of our patients requires more frequent hemodialysis due to their medical condition(s), and it is imperative that CMS continue to educate the MACs on what constitutes medical justification and ensure the MACs are thoroughly examining each medical record in its entirety when assessing whether there is medical justification for additional treatments. The differences in documentation requirements necessitate additional work for our members, and it is imperative that the MACs exhibit greater consistency when determining the appropriateness of payment based upon the medical documentation.

**Home and Self-Dialysis Training Add-on Payment Adjustment**

**Analysis of ESRD Claims Data**

ANNA appreciates the efforts CMS is considering to improve the value of the data regarding the time required for home dialysis training treatments. We agree with CMS’ assessment that there is significant variation between ESRD facilities’ cost report data, and it is likely that CMS is collecting data that inaccurately assesses the adequacy of the home and self-dialysis training add-on. We believe CMS should update the cost reports and insert new fields with clear instructions on how to report training costs and labor. Such updates are critical to obtaining more accurate data in this area.

**Proposed Increase to the Home and Self-Dialysis Training Add-on Payment Adjustment**

While ANNA is supportive of the increase to the home and self-dialysis training add-on payment adjustment, we believe the add-on payment does not need to be budget neutral. We support KCP’s comments on this issue, and agree with KCP that the Agency has the authority to increase the training add-on without applying budget neutrality. ANNA encourages the Agency to increase the home and self-dialysis training add-on payment adjustment without the budget neutrality adjustment to the ESRD PPS base rate.

**Proposed Payment Policy for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)**

**Payment Rate for AKI Dialysis**

ANNA truly appreciates CMS’ efforts to provide payment for dialysis furnished by an ESRD facility to a patient with AKI. Patients with AKI require vigilant monitoring, additional drugs, more frequent laboratory sampling, and the administration of blood products as necessary. Allowing Medicare payment for patients with AKI permits dialysis facilities to provide patient-centered care that addresses the full spectrum of patients’ needs. It also helps to ease the financial and personal burdens on patients by allowing
them to receive treatment in an outpatient setting, more likely to be closer to their homes.

Renal Dialysis Services Included in the AKI Payment Rate

We applaud CMS for proposing to allow payment for all dialysis treatments furnished in a week to patients with AKI without requiring additional justification, while recognizing that it may be more common to see declining numbers of treatments per week as some of these patients recover kidney function. ANNA also is supportive of CMS’ proposal to allow ESRD facilities to separately bill for non-renal dialysis services, which will promote improved coordination of care and increased patient access to medically necessary services during dialysis treatments.

Applicability of ESRD PPS Policies to AKI Dialysis

Uncompleted Dialysis Treatment

ANNA supports CMS’ proposal to pay both the hospital and the dialysis facility for dialysis provided on the same day, even in instances when the dialysis is not completed. We urge CMS and/or the A/B MACs to issue guidance on what constitutes necessary documentation to support payment of dialysis when furnished by both the hospital and dialysis facility on the same day.

Home and Self-Dialysis

ANNA agrees with CMS’ assessment that patients with AKI are unlikely to receive dialysis in their home, given their unique medical needs. We support CMS’ proposal not to extend the home dialysis benefit to beneficiaries with AKI.

Vaccines and their Administration

ANNA supports CMS’ proposal to allow ESRD facilities to furnish vaccines to beneficiaries with AKI and bill Medicare. We strongly support efforts to ensure patients with AKI are vaccinated, and support providing adequate payment for services provided by ESRD facilities.

Monitoring of Beneficiaries with AKI Receiving Dialysis in ESRD Facilities

We applaud CMS for recognizing the distinct needs of patients with AKI and support CMS’ proposal to monitor utilization of dialysis and separately billable items and services furnished to patients with AKI. It is important to understand how patients with AKI utilize dialysis treatments, drugs, labs, and other services. We echo KCP’s recommendation that CMS work with the kidney community to determine whether the utilization of certain items or services should result in an adjustment to the payment rate for renal dialysis services furnished by ESRD facilities for individuals with AKI.
AKI and the ESRD Conditions for Coverage

ANNA generally supports CMS’ assessment that the current ESRD facility requirements are sufficient to ensure that patients with AKI are dialyzed correctly. However, we encourage CMS to work with the kidney community to develop a guidance letter for surveyors, and to share this with providers.

ESRD Facility Billing for AKI Dialysis

ANNA supports CMS’ proposal to identify claims for beneficiaries with AKI through a specific code. We encourage CMS to publish sub-regulatory guidance in the near future to allow sufficient time for ESRD facilities to prepare for the changes in billing requirements.

II. ESRD QIP

ANNA greatly appreciates the opportunity to provide comments on the QIP elements for payment years (PYs) 2018-2020 included within this proposed rule. ANNA is a strong proponent of the QIP and has supported the program’s implementation. We reiterate KCP and the Alliance for Home Dialysis’ comments on the proposals to modify the ESRD QIP, and recommend that CMS work with the Kidney Care Quality Alliance (KCQA) and the nursing community when developing and implementing quality measures to improve the quality of care provided to ESRD patients.

As the number and complexity of the ESRD QIP measures continue to grow at a rapid pace, dialysis facilities are required to devote an increasing amount of financial and personnel resources to collect and submit data. As CMS continues to modify and improve the QIP, ANNA encourages CMS to limit new measures to those that are evidence-based and promote the delivery of high-quality care and improved patient outcomes. We also encourage CMS to examine how data is currently reported to the Agency and develop and implement a single reporting system to simplify reporting and minimize unnecessary burdens on providers.1

Proposed Changes to the Requirements for PY 2018 QIP

Proposed Changes to the Hypercalcemia Clinical Measure

ANNA continues to believe the hypercalcemia measure does not provide value to the patient or relate to the provision of quality care. The National Quality Forum (NQF) Renal Standing Committee has determined the hypercalcemia measure is topped out and its initial recommendation is against current endorsement. We encourage CMS to work with ANNA and the kidney community to develop and seek NQF approval of an alternate measure specific to conditions treated with oral-only drugs.

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1 Letter from ANNA to CMS regarding ESRD PPS and QIP proposed rule (CMS-1352-P) (August 31, 2012)
Proposed Requirements for PY 2019 ESRD QIP

Proposed New Measures for the PY 2019 ESRD QIP


ANNA recognizes the importance of infection reduction in improving quality of care and patient outcomes and we appreciate CMS’ efforts to ensure more complete and accurate reporting of infections. However, we do not support CMS’ proposal to retain the NHSN BSI clinical measure and reintroduce the NHSN Dialysis Event Reporting Measure beginning with PY 2019 to address the accidental or intentional under-reporting of infections. As stated by KCP, recent studies have indicated that the reasons for under-reporting are related to the design of the NHSN BSI measure and how the data is reported. Accordingly, we echo KCP’s recommendations and encourage CMS to include the NHSN BSI measure as a reporting measure for PY 2018 and 2019, and not add the NHSN Dialysis Event Reporting Measure in PY 2019, eliminating the need for the new safety measure domain.

Proposed New Measure Topic Beginning with the PY 2019 ESRD QIP

Proposed NHSN Bloodstream Infection (BSI) Measure Topic

ANNA does not support CMS’ proposal to include the NHSN Dialysis Event Reporting Measure in the PY 2019 ESRD QIP and merge it with the NHSN BSI Clinical Measure under the same measure topic. Adding the NHSN Dialysis Event Reporting Measure to the ESRD QIP in an attempt to account for the lack of validity and reliability of the NHSN BSI clinical measure and address the under-reporting issue is not the most appropriate solution. Rather, we encourage CMS to take steps to resolve the validity and reliability issues related to the NHSN BSI clinical measure, and in the interim, utilize the NHSN BSI measure as a reporting measure.

Proposal to Establish a New Safety Measure Domain

While ANNA understands the need to increase patient safety in dialysis facilities, ANNA is not supportive of CMS’ current proposal to establish a safety measure domain. As stated above, due to the validity and reliability issues of the NHSN BSI measure, we do not believe the reintroduction of the NHSN Dialysis Event Reporting Measure is appropriate, nor should it be merged with the NHSN BSI Clinical Measure under one measure, rendering the establishment of the safety measure domain unnecessary.

Proposal for Scoring the Proposed NHSN Dialysis Event Reporting Measure

While ANNA does not support the adoption of the NHSN Dialysis Event Reporting Measure in PY 2019, ANNA appreciates CMS’ efforts to incentivize facilities to report the full 12 months of NHSN Dialysis Event data and reward reporting consistency. However, in the event of unanticipated circumstances, it is conceivable that a dialysis
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facility may be unable to submit 12 months of data. Therefore, we encourage CMS not to implement a scoring methodology that harshly penalizes facilities and instead implement a scoring methodology that scores facilities on a sliding scale. For example, CMS could provide 0 points for 0 months of data, 1 point for 1-2 months of data, etc. Although we do not believe the NHSN Dialysis Event Reporting Measure should be included within the PY 2019 ESRD QIP, should CMS choose to implement it, ANNA strongly urges CMS to revise its proposed scoring methodology for the measure.

Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2019 ESRD QIP

ANNA is supportive of CMS’ proposal to continue setting the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th, and 90th percentile, respectively, for the PY 2019 ESRD QIP. ANNA reiterates the comments provided by KCP on this issue and we urge the Agency to continue to maintain a consistent methodology for the ESRD QIP.

Proposed Requirements for the PY 2020 ESRD QIP

ANNA greatly appreciates having the opportunity to provide comments on the QIP elements for PY 2020 included in this proposed rule. Because nephrology nurses remain the linchpin in the collection and processing of these important data points, it is crucial that our members understand the Agency’s overall vision for the QIP, and that the Agency recognize that the burden of data collection may take time away from direct patient care.

Proposed New Clinical Measures Beginning with the PY 2020 ESRD QIP

Proposed Standardized Hospitalization Ratio (SHR) Clinical Measure

ANNA appreciates CMS’ efforts to measure hospitalization rates in an effort to improve care and reduce healthcare costs. We also are pleased that CMS acknowledged within the rule that there currently is no mechanism for correcting or updating patient comorbidity data on CMS’ Medical Evidence Reporting Form 2728. The Agency correctly noted that patients often develop additional comorbidities after they begin dialysis and facilities would be disincentivized to treat patients if recently developed comorbidities were not included in the risk-adjustment calculation. ANNA supports the Agency’s proposal to include a risk adjustment for 210 prevalent comorbidities in addition to the incident comorbidities from the CMS Medical Evidence Form 2728.

However, we object to the inclusion of the SHR clinical measure within the PY 2020 QIP until CMS adequately addresses several of the kidney community’s concerns. We support KCP’s comments on this measure and believe CMS should address the reliability issues associated with the SHR. Additionally, as stated by KCP, to ensure ESRD facilities are not penalized by both the SHR and standardized readmission ratio measures for the same hospital admission/readmission, we recommend CMS modify the SHR and exclude hospitalizations that occur within less than 30 days of the discharge.
Proposed New Reporting Measures Beginning with the PY 2020 ESRD QIP

Proposed Serum Phosphorous Reporting Measure

While ANNA supports CMS’ proposal to replace the Mineral Metabolism Reporting Measure with the Serum Phosphorous Reporting Measure, we echo KCP’s concerns that measurement in this area is topped out. We encourage CMS to work with ANNA and other kidney community stakeholders to identify more appropriate measures within this area.

Proposed Ultrafiltration Rate Reporting Measure

ANNA is supportive of CMS’ proposal to adopt the ultrafiltration rate reporting measure based upon the NQF-endorsed measure #2701, Avoidance of Utilization of High Ultrafiltration Rate (>=13 ml/kg/hour). We have concerns, however, with CMS’ definition of qualifying patients. Many of our patients may be assigned to the same facility for a calendar month but not physically present in the facility, as they may be in the hospital. We urge CMS to clarify how dialysis facilities should report patients who may be assigned to a facility for a full calendar month but not physically present during a portion of that month. We suggest that CMS use the same exclusion criteria as for other measures, that is, to exclude patients who dialyze at the facility less than seven (7) days during the applicable month.

Further, we support KCP’s recommendation that transient patients be excluded, and encourage CMS to include a standard specification for transient patients within the measure, as outlined in the Kidney Care Quality Alliance’s (KCQA) measure submitted to NQF for endorsement. Specifically, the KCQA measure proposed to exclude patients with <7 hemodialysis treatments in the facility during the reporting month.

Proposed Performance Period for the PY 2020 ESRD QIP

While ANNA supports the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure, we continue to have concerns the measure is not aligned with NQF-endorsed specifications for influenza measures, particularly in regards to the window for administration of immunizations. Nurses vaccinate healthcare personnel once the vaccine becomes available, which often occurs prior to October 1st. For example, in 2015, the vaccine was available in August and nurses began administering vaccines at that time. ANNA encourages CMS to modify the measure to ensure it has the capability of capturing all vaccinations of healthcare personnel, prior to the official start of flu season.

Proposal for Scoring the PY 2020 ESRD QIP

ANNA continues to have concerns that the ESRD QIP scoring and assessment methodology is so complex that facilities are unable to concurrently evaluate their progress so as to take action during the performance period to strengthen their facilities.
We urge CMS to consider ways of simplifying the scoring methodology or, as an alternative, develop a secure website that can provide each facility with an ongoing scorecard for this complex system.

*Scoring the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Clinical Measure*

While ANNA recognizes the importance of capturing the patients’ experience and supports the ICH CAHPS as a reporting measure, we continue to oppose the ICH CAHPS as a clinical measure. As previously stated, the twice annual survey requirement does not allow sufficient time for facilities to make improvements based on the first survey responses before the second survey is due to be conducted. We believe CMS’ purpose in requiring this survey is to improve the patient experience and the current required timing is contrary to that purpose. ANNA urges CMS to reconsider the requirement for two surveys annually and permit facilities to administer the survey once each year.

*Proposal for Weighting the Clinical Measure Domain, and Weighting the TPS*

*Proposal for Weighting the Clinical Measure Domain for PY 2020*

As stated above, ANNA does not believe the addition of the safety measure domain within the ESRD QIP is necessary; consequently, we do not support CMS’ modifications to the weighting of the safety measure domain and clinical measure domain. Additionally, as previously stated, we believe the Agency continues to propose an overwhelming number of measures that focus little attention on patient outcomes. We recommend CMS evaluate the existing and proposed ESRD QIP measures and remove measures that are less relevant to quality of care. ANNA also encourages the Agency to prioritize measures that promote patient outcomes during future modifications to the ESRD QIP.

*Future Policies and Measures under Consideration*

ANNA is supportive of CMS’ proposal to use rates rather than ratios and we support KCP’s recommendation that CMS use the year-over-year difference between normalized rates currently available from Dialysis Facility Reports data until they can be replaced by risk standardized rate measures. However, as previously stated, we continue to have concerns that including additional measures to the ESRD QIP may dilute the significance of each measure, add to the burden of data collection, and potentially reduce time available for direct patient care.  

Additionally, as previously stated, ANNA strongly supports efforts to ensure patients with ESRD are vaccinated. In the future, should CMS determine it is necessary to implement a clinical measure on patient-level influenza vaccination, we encourage CMS

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2 Letter from ANNA to CMS Regarding Proposed Rule on ESRD PPS and QIP (CMS-1628-P) (August 24, 2015)
include KCQA’s proposed NQF Measure #0226, *Influenza Immunization in the ESRD Population (Facility Level)* within the ESRD QIP.

*Medication Reconciliation Measure*

Generally, nurses in outpatient dialysis facilities perform medication reconciliation for their patients. Medication reconciliation helps to identify unnecessary medications, duplicate therapies, or incorrect dosages, reducing the risk of patients experiencing adverse drug events.\(^3\) We strongly encourage CMS include a medication reconciliation measure within a future version of the ESRD QIP. As the Medicare Payment Advisory Commission (MedPAC) acknowledged in comments to CMS regarding the post-acute care (PAC) medication reconciliation measure, medication reconciliation “can help reduce medication errors that are especially common among patients who have multiple health care providers.”\(^4\) ANNA strongly believes that incentivizing providers to perform medication reconciliation across the continuum of care will increase the focus on patient safety, resulting in improved patient outcomes.

ANNA participated in the development of NQF #2988: *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities* and supports this measure. Should CMS choose to adopt a medication reconciliation measure for the QIP, we encourage CMS to adopt NQF #2988.

*Comprehensive ESRD Care (CEC) Model*

ANNA appreciates CMS’ efforts to develop payment models designed specifically for beneficiaries with ESRD, such as the CEC Model. With the development of the CEC Model, in addition to other alternative payment models, nurses have assumed more responsibility to manage patient care across the continuum. Nurses in the CEC Model play an integral role in improving care delivery, communication, and coordination across settings, which can lead to an increase in patient-centered care and reduced healthcare spending.

However, we have concerns that despite the unique position of nurses and their role within the CEC Model, nursing participation in the development of the CEC Model is limited. To ensure the future success of the CEC Model, dialysis organizations participating in the ESRD care model should be encouraged to include nurses in decision-making roles when developing their care delivery model. Increased utilization of the unique perspective of nurses can lead to more successful care coordination and enhanced quality improvement strategies.

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\(^3\) *Agency for Healthcare Research and Quality Patient Safety Net: Medication Reconciliation* [https://psnet.ahrq.gov/primers/ primer/1/medication-reconciliation](https://psnet.ahrq.gov/primers/primer/1/medication-reconciliation) (Last accessed July 19, 2016)

Conclusion

ANNA greatly appreciates the opportunity to share our comments on CMS’ CY 2017 ESRD PPS and QIP proposed rule. As the leading professional association representing nephrology nurses, we look forward to continuing to work with your Agency on these important issues. Should you have any questions, please contact me or have your staff contact our Health Policy Representative, Kara Gainer (Kara.Gainer@dbr.com or 202-230-5649). We thank you for your consideration.

Sincerely,

Sheila Doss-McQuitty, MBA, BSN, RN, CNN, CCRA
ANNA President, 2016-2017