August 30, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1526-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1526-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule
78 Fed. Reg. 40836 (July 8, 2013)

Dear Administrator Tavenner:

On behalf of the American Nephrology Nurses’ Association (ANNA), we are pleased to offer comments on the calendar year (CY) 2014 End-Stage Renal Disease (ESRD) prospective payment system (PPS) and the payment year (PY) 2016 ESRD Quality Incentive Program (QIP). ANNA offers general comments on the 12 percent reduction in ESRD reimbursement. In addition, we offer specific comments on the ESRD QIP measures.

ANNA promotes excellence in and appreciation of nephrology nursing so we can make a positive difference for people with kidney disease. We are the only professional association that represents nurses who work in all areas of nephrology. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 10,000 registered nurses in almost 100 local chapters across the United States. Members practice in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis units, 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 the Kidney Care Partners (KCP) and has actively participated in the development of those consensus comments. The following comments are in addition to the comments submitted to CMS by KCP.

II. Calendar Year (CY) 2013 End-Stage Renal Disease (ESRD) Prospective Payment System

For calendar year (CY) 2014, CMS proposes updates to the ESRD PPS payment rate that are estimated to result in a 12 percent reduction in payment per dialysis treatment. ANNA is deeply concerned this proposed cut will negatively impact patient care for the 400,000 Americans currently living with kidney failure – 85 percent of which rely on Medicare as payor for their treatments.

According to the Medicare Payment Advisory Commission (MedPAC), dialysis facilities have an average profit margin of three to four percent in 2013.\(^1\) Given that for most dialysis facilities, Medicare represents the majority of their payor mix, a 12 percent reduction in Medicare reimbursement would be financially devastating. Moreover, this reduction comes at a time when dialysis facilities – like other Medicare providers – are faced with a 2 percent reimbursement reduction due to sequestration.

Proposed reductions will negatively impact patient care: ANNA is concerned that such reductions would negatively impact nephrology nurses’ ability to adequately care for their patients. Faced with these significant payment reductions, dialysis facilities will likely reduce their staffing ratios. CMS does not require facilities to maintain a minimum staffing ratio, choosing instead to leave that determination to the States. In the few states that mandate staffing ratios for dialysis facilities, most specify a ratio of no more than four patients to one direct care staff member. In the past year, even before the proposed 12 percent reduction, some of our members reported staffing ratios being increased to as high as one direct care staff member for every six patients. Such ratios make it challenging or impossible for a nurse to ensure safe and effective patient care is delivered.

Proposed reductions will limit availability of services: ANNA is also concerned that due in part to inadequate reimbursement, some dialysis providers will close their facilities – requiring patients to drive additional distances to an available dialysis unit. We have already seen some facilities that have chosen to limit their hours of operation. In some cases, evening and weekend dialysis appointments – those needed by individuals who are trying to maintain part- or full-time employment – may be eliminated. Patients are reporting it harder to find a facility with flexible appointment scheduling, making it challenging for a patient to fit the treatment into their work and family schedules. Significant reductions in Medicare reimbursement will only exacerbate this problem. Due to resource requirements to manage nocturnal and home hemodialysis services, ANNA is concerned about the potential reduction of the availability of these modalities, decreasing patient choice and further impacting patients’ ability to meet employment and family obligations.

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Proposed reductions will be harmful to pediatric patients: Pediatric patients often require more intensive staffing; it is not uncommon for smaller pediatric patients to need a staffing ratio of two nurses for one patient. The drastic payment reduction proposed by CMS will challenge pediatric facilities to provide safe care for these more vulnerable patients. Pediatric nurses must find ways to help their patients sit still for the three to five hours for each dialysis treatment. Many dialysis facilities that specialize in pediatric care offer patients and their family members distractions such as video games, televisions, and movies. While such items may seem trivial, they are vital to help keep the children distracted during the lengthy dialysis process. Reductions in Medicare reimbursement will hinder a facility’s ability to provide such items, negatively impacting patient care and making it more challenging for the pediatric nephrology nurse to provide care.

Proposed reductions will harm Medicaid patients: Approximately half of Medicare dialysis patients are dually eligible for Medicare and Medicaid. Implementation of the proposed Medicare cuts would be particularly harmful to the dual eligible population, who are often among the frailest beneficiaries. If these beneficiaries are unable to access dialysis treatment, they will likely seek care in a hospital setting, which unnecessarily and avoidably increases health care costs for both the Medicare and Medicaid programs.

Proposed reductions will impact the availability of qualified staff: Even if a facility were to keep their current nursing staffing ratios, some facilities have begun to reduce and/or eliminate other staff – such as dieticians, social workers, and clerical assistants – as a cost-cutting measure. These personnel are vital to the overall quality of care provided to the patients. The elimination and/or curtailing of work hours of these positions often results in nurses having to perform the non-nursing services traditionally provided by these other personnel, impeding the nurses’ ability to provide safe and effective nursing care. Given these reductions are already occurring in some markets, ANNA is concerned that further cuts to Medicare reimbursement – particularly as significant as the one proposed by CMS – would cause more facilities to cut the work hours of critical personnel.

Proposed reductions will negatively impact innovation: Any staffing reduction would impede a facility’s ability to implement innovative systems of care, including maintaining and developing electronic records systems, which hold great promise to improve care coordination and efficiencies of health care as well as reduce overall health care costs. Not only will the use of electronic records benefit patients, but also nurses who will be able to better coordinate the patient’s care and have real time access to the complete medical record. New technology that shows promise in improving fluid management and thus reducing hospitalizations will not be possible for facilities to afford if these reductions take effect. In addition, some facilities have begun comprehensive unit-based quality improvement programs, which could be halted due to the proposed reduction. Moreover, as facilities experience significant reductions in their Medicare reimbursement rates, they will likely eliminate existing programs such as nurse educators and/or access coordinator positions.

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2 MedPAC March 2013 Report, at 130. According to MedPAC analysis, 47 percent of traditional Medicare (e.g., beneficiaries not enrolled in a Medicare Advantage plan) dialysis beneficiaries are also dually eligible for Medicaid.
Proposed reductions are particularly harmful to small and rural providers: Small providers who operate on very small profit margins will be unable to absorb such a significant reduction in their Medicare reimbursement rates. If the proposed cuts were to be implemented, many small providers likely would be unable to operate and will be forced to close. Similarly, the proposed reductions would be particularly harmful to rural providers and the estimated nineteen percent of Medicare beneficiaries in rural areas who require dialysis. A closure of a dialysis facility in a rural area can result in patients having to drive a significantly longer distance in order to obtain dialysis services. This burden is multiplied by the requirement of multiple treatments (thus multiple trips) per week.

Proposed reductions will impede nurses’ education: For over 35 years, nephrology has been recognized as a specialty for nurses. It takes years of education, training, and experience for a nurse to become proficient in the complexity of care required by people with kidney disease. Approximately 35 percent of ANNA’s members have been involved in the field of nephrology for 20 years or more. ANNA is concerned the proposed reimbursement reductions will cause facilities to curtail the number of nursing positions, resulting in the loss of jobs for many of these highly skilled nurses. ANNA also is concerned about the ability to maintain staff education and competencies, with less time and resources that would be available. It is critical to have competent staff to ensure the delivery of safe and effective patient care, and to keep up to date with changes in technology, equipment, and workflow process.

Proposed reductions could harm the ESCO program: CMS’ Center for Medicare and Medicaid Innovation (CMMI) is in the process of launching the ESRD Seamless Care Organizations (ESCOs), a new comprehensive ESRD care initiative. It is not clear how these drastic payment reductions – such as the ones called for in the proposed rule – may impact the ESCO project. These cuts may hinder facilities’ ability to create ESCOs and test innovative models of care, thus denying nursing staff the ability to participate in these new innovative projects.

Proposed reductions will impact commercial payers: While CMS bears the responsibility to establish reimbursement rates for dialysis treatments under the Medicare program, we know that many other commercial payers use Medicare reimbursement rates as a basis for their reimbursement. As Medicare reduces its reimbursement, it becomes harder for facilities to “make up” the lost revenue from other payers, particularly if other payers follow Medicare’s lead and reduce their reimbursement in line with Medicare payments. Were such reductions to occur, it would be nearly impossible for many dialysis facilities to remain open, dramatically reducing patient choice and access to care.

ANNA recognizes the American Taxpayer Relief Act of 2012 required CMS to impose a payment reduction. Notwithstanding the statutory requirement ANNA urges CMS to reconsider the proposed 12 percent reimbursement reduction. ANNA urges CMS to limit any reduction in reimbursement to a level that ensures that patients can continue to have access to safe and effective dialysis care.

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3 MedPAC March 2013 Report, Ch. 6. According to the MedPAC report, 87 percent of Medicare dialysis beneficiaries are enrolled in traditional Medicare; thirteen percent of Medicare dialysis beneficiaries are enrolled in Medicare Advantage plans. Of those Medicare dialysis beneficiaries enrolled in traditional Medicare, nineteen percent reside in a rural area. See MedPAC March 2013 Report, at 130.
C. Discussion of Self-Dialysis and Home Dialysis Training Add On Adjustment and Request for Public Comments

Medicare will reimburse for self-dialysis or home dialysis after a patient has completed the appropriate training at an ESRD facility. Among other requirements, the Medicare Conditions for Coverage require the training be conducted by a registered nurse (RN) with experience in that dialysis modality, and ANNA agrees with and supports this standard. In addition to the bundled payment, Medicare reimburses facilities an add-on adjustment of $33.44 per treatment for training treatments. While ANNA appreciates this add-on payment, we continue to believe this additional payment fails to sufficiently reimburse facilities for the amount of RN time required to adequately train patients. While the length of time required to train each patient varies, generally for peritoneal dialysis, a minimum of 7-14 days are needed. For NxStage and conventional home hemodialysis, typically 25 days in-center are needed to train each patient, plus 5 additional days in the patient’s home. While some of this education can be done with small groups of patients, much of this training requires the commitment of one RN to one patient for about 6 hours per training day. These estimates for the RN time commitment to a single patient during the training do not include the time required for documentation of this care, which can add as much as two additional hours per day. A recent study demonstrated proper patient training can significantly improve patient outcomes by reducing the rate of infection.\(^4\) The add-on adjustment of $33.44 per treatment does not equal an RN’s salary for one hour, and certainly does not cover the cost of six hours of direct, one-to-one care during these training sessions. Due to the inadequacy of the add-on payment – coupled with the significant proposed reduction in reimbursement rates, as discussed above – we are concerned that facilities will refrain from or limit the offering of the option of self or home dialysis.

The proposed rule requests comment on a suggestion that Medicare impose a “holdback” payment methodology in which a portion of the add-on payment for training be withheld until the patient demonstrates a successful transition to a home treatment modality. ANNA does not support this suggestion, as we are concerned the withhold payment would unintentionally encourage facilities to offer self-dialysis or home dialysis only to those patients who appear to be more likely to successfully transition to home care. Specifically, as a result of the withhold payment scheme, facilities may be less likely to offer self-dialysis and home dialysis to patients who may be older, frailer, or have socio-economic or literacy limitations, even though these individuals have been successful in self therapies with individualized education. ANNA urges CMS to reconsider imposing a withhold payment. Facilities should be encouraged to make available to their patients different treatment modalities based on the best interest of the patient – not based on reimbursement issues.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program

As discussed in more detail above, ANNA is concerned that any reduction in reimbursement rates – particularly the drastic 12 percent reduction contained in the proposed rule – will result in cuts in both the numbers of registered nurses and the number of direct care staff available for care delivery. At the same time, CMS is proposing to implement new and revised measures as a part of the Quality Incentive Program (QIP). Already many nurses are overly burdened by multiple reporting obligations and often are unable to focus needed attention on direct patient care. ANNA is concerned that the proposed cuts in reimbursement coupled with the increased reporting requirements will prove unworkable in many real-world patient settings. As it finalizes the rule, ANNA urges CMS to consider the cumulative impact of the payment reductions and the increased reporting requirements on nurses and providers.

C. Proposed Measures for the PY 2016 ESRD QIP and Subsequent PYs of the ESRD QIP

As CMS works to develop and refine the ESRD QIP program, ANNA recommends that CMS adopt the following global exclusions and apply them to all current and future QIP measures – regardless of whether the measure is clinical or reporting in nature:

- Beneficiaries who are regularly treated by the facility and who fit into any of these categories:
  - Beneficiaries who die within the applicable month;
  - Beneficiaries who receive fewer than 7 treatments in a month;
  - Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month;
- Transient dialysis patients;
- Pediatric patients (unless the measure is specific to pediatric patients); and,
- Kidney transplant recipients with a functioning graft.

1. PY 2015 Measures Continuing in PY 2016 and Future Payment Years

As a general matter ANNA encourages CMS to ensure interested stakeholders are provided sufficient opportunity and adequate time to provide input on any changes to the QIP – including the addition of new measures, changes to existing measures, and the retiring of measures – that CMS may be considering. While we appreciate CMS providing stakeholders an opportunity to comment on the inclusion of future measures as part of its annual payment regulation process, we would not consider it a good practice for CMS to accept comments on a particular proposed measure during this comment period as representing the only opportunity to comment on that

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5 See, CMS, Transmittal 2311, “Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims” 50.9 (Sept. 23, 2011).
6 See, e.g., NQF #0261 Measurement of Serum Calcium Concentration (denominator exclusions include transient dialysis patients, pediatric patients, and kidney transplant recipients with a functioning graft). See 77 Red. Reg. at 40968 & 40971; Quality Measure Specifications for FY 2013 and FY 2014 ESRD QIP Final Rule (Nov. 1, 2011).
measure. We would expect that each annual Notice of Proposed Rule Making for the PPS and QIP would allow comment on all measures offered for the next Payment Year. As we are all aware, best practices and evidence-based medicine standards change and evolve as scientific knowledge is gained.

In the future, while we recognize that measures in defined areas are required by the statute (e.g., anemia and dialysis adequacy), we would encourage CMS to examine different quality measures for those areas and others, which have more effect on patient outcomes. For example, once an appropriate fluid management measure has been developed, we would encourage CMS to include it in the QIP as a measure for treatment adequacy and retire the existing Adult HD Kt/V measure, which is nearing “topped out” status with a performance standard of 93.6 percent.

2. Proposal to Expand One PY 2015 Measure and Revise Two PY 2015 Measures for PY 2016 and Subsequent Payment Years

a. Proposed Expanded ICH CAHPS Reporting Measure

CMS proposes that for PY 2016, each facility must arrange for a CMS-approved vendor to conduct the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. Under the CMS proposal, facilities will be required to have these arrangements in place by July 2014. For PY 2016, the facility’s vendor will have to administer the survey once during the performance period of 2014 and report the survey data to CMS by January 28, 2015. For PY 2017 and subsequent years, CMS is proposing that each facility’s vendor administer the ICH CAHPS survey twice during the year and report the results to CMS.

ANNA believes that feedback on the patients’ experience of care is vital to ensuring the delivery of high-quality health care. We recognize the ICH CAHPS measure is the single patient-centered measure included in the QIP. ANNA supports the inclusion of this measure as part of the QIP for in-center hemodialysis patients.

However, ANNA is concerned that CMS’ proposal to require twice annual surveying and reporting may prove to be a hindrance to facilities’ ability to provide high-quality care. Under the proposed measure, facilities will be required to contract with approved vendors to administer a patient survey twice annually. This requirement imposes an additional cost on facilities (who, as noted above are facing a significant proposed reduction in their Medicare reimbursement rates). The twice annual survey will not provide facilities sufficient time to act upon the results of each survey. The time spent surveying patients will usurp the facility’s ability to identify needed changes and implement and evaluate new practices to improve patient care.

In addition, ANNA is concerned with the proposed measure’s requirement that more than half of the survey questions be completed in order for the patient’s questionnaire to count for reporting purposes. This means each patient will have to complete more than 40 questions in order for the survey to be included. Hospitals are required to complete a similar measure on a monthly basis, but each patient is required to complete only twelve survey questions to be included. While ANNA supports patient feedback, we are concerned that in practice it can be challenging to get patients to complete 40 questions, as patients often skip or refuse to answer survey questions.
3. New Measures Proposed for PY 2016 and Subsequent Payment Years of the ESRD QIP

For PY 2016 and future years, CMS proposes to add five new measures to the QIP. ANNA appreciates the opportunity to provide comments on each of the proposed measures. ANNA supports the QIP. However, as CMS develops and refines the QIP measures, we urge the agency to selectively limit the included measures and to ensure those measures that are included in the QIP are specifically tailored to the ESRD population and will drive the achievement of desired outcomes. Requiring data collection and reporting for the sake of reporting serves no purpose and imposes an unnecessary burden on nurses, who are often tasked with both data collection and entry. As a practical matter, adding more quality measures to the QIP, may actually be less incentive for facilities to meet or exceed every measure because facilities may be able to “fail” some quality measures without significantly impacting their overall score.

a. Proposed Anemia Management Clinical Measure Topic and Measures

ii. Anemia of Chronic Kidney Disease: Patient Informed Consent for Anemia Treatment

CMS proposes to add a new clinical measure in the anemia management topic related to patient informed consent for anemia treatment. In order to meet this proposed measure, facilities would be assessed on: the percentage of qualifying patients who were provided information on the potential benefits and risks and alternative treatment options for anemia, and who completed an informed consent regarding anemia treatment. Facilities would be required to enter an attestation regarding this requirement annually in CROWNWeb.

ANNA urges CMS not to include this proposed clinical measure as part of the QIP. We are concerned the proposal to include this measure is predicated on the mistaken belief that facilities routinely obtain informed consent for Erythropoiesis-Stimulating Agents (ESAs) as part of their current practice. In fact, this is not standard practice in most facilities.

As the preamble to the proposed rule notes, currently the Food and Drug Administration (FDA) requires prescribers to educate their patients on the potential risks and benefits of ESAs. We would submit that the FDA requirement has been implemented in various ways by practitioners and has not routinely resulted in the dialysis facility assuming this responsibility. While ANNA agrees with the implied premise of the proposed measure (e.g., the importance of patient consent and involvement in his/her treatment), we are concerned that the measure as currently proposed duplicates the FDA requirement by mandating that dialysis facilities obtain a separate patient informed consent. The imposition of the proposed measure would require a considerable amount of nurse staffing time that could be better spent on providing safe and effective patient care. ANNA also is concerned that were this measure to be included in the QIP, it would create a precedent for future measures to require documentation of patient consent for other medications.
b. Hypercalcemia

CMS proposes to adopt a clinical measure that monitors hypercalcemia. As part of the PY 2015 QIP, CMS proposed a hypercalcemia clinical measure, but declined to adopt the measure recognizing the lack of baseline data. CMS notes that it now possesses sufficient baseline data and proposes to adopt NQF-endorsed measure #1454: Proportion of Patients with Hypercalcemia, for PY 2016 and subsequent years.

As stated in our comments to the PY 2014 QIP, ANNA does not support the adoption of a clinical measure for hypercalcemia. ANNA is concerned that focusing solely on hypercalcemia fails to also take into account the monitoring of phosphorous and intact parathyroid hormone (iPTH) levels as recommended by the Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) developed by the Kidney Disease Improving Global Outcomes (KDIGO) Initiative.

ANNA agrees with the importance of monitoring bone and mineral metabolism, however calcium, as a stand-alone measure, does not provide an accurate picture of this aspect of care. The contribution of hypercalcemia to vascular calcification has not been demonstrated, while plasma phosphorous has been identified as a risk factor for vascular calcification. Treatment of bone and mineral metabolism is not driven by an isolated calcium measure but in collaboration with monitoring of phosphorous and iPTH levels. The treatment of hypercalcemia, in isolation, can be complex, and patients may be treated by high risk therapies to meet the QIP. For example, providers may feel compelled to use low calcium dialysate, which may put those patients at risk for cardiac arrhythmias, or utilize major surgical interventions such as a parathyroidectomy, which creates an undue hardship on the beneficiary and unnecessarily increases Medicare spending.

As clinicians who are often responsible in collaborative practices for the management of mineral bone disease, we believe that hypercalcemia should not be used in isolation to manage bone mineral metabolism. We encourage CMS to work with ANNA and the kidney community to develop and seek NQF approval for metrics for other related mineral disturbances, such as phosphorous and PTH, to encourage more effective management of bone mineral metabolism. We support the continuation of the inclusion of calcium levels as a part of the mineral metabolism reporting measure.

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7 See, Letter from Glenda Payne, President, American Nephrology Nurses’ Association, to Marilyn Tavenner, Acting Administrator, Centers for Medicare and Medicaid Services, ANNA comments on End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for payment years 2014 and 2015 (Aug. 31, 2012) (available at regulations.gov).
9 KCP has supported both a phosphorous and PTH measure for endorsement by the NQF.
c. Use of Iron Therapy for Pediatric Patients Reporting Measure

CMS proposes to include NQF-endorsed measure #1433: Use of Iron Therapy for Pediatric Patients as part of the proposed anemia management clinical measure. CMS proposes that for PY 2016 and future years, facilities must enter into CROWNWeb on a quarterly basis seven data elements.

ANNA has several concerns about the inclusion of this measure. First, most of the pediatric facilities in the United States are hospital-based and do not subscribe to a system for batch data entry into CROWNWeb. In fact, only three pediatric programs subscribe to the National Renal Administrator’s Association Health Information Exchange. Manually gathering and entering seven data elements per patient per quarter for this measure is a significant burden, particularly since one of these elements includes the dose of oral iron, which may not be as well documented as the doses may be obtained over-the-counter. Additionally, there is no specification of the age/size of the child to determine if all seven points of data are required for even the smallest/youngest patients. Finally, if CMS includes this measure, it would also be critical to include the exception we have proposed for all clinical and reporting measures, and apply this requirement only to pediatric patients treated at a facility for more than seven times in a given month.

d. NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure

CMS proposes to replace the NHSN Dialysis event reporting measure adopted as part of the CY 2013 ESRD PPS final rule with a new clinical measure that would require facilities to report the number of hemodialysis outpatients with positive blood cultures. Under the proposed rule, facilities would be required to submit a total of 12 months of data to NHSN on a quarterly basis. Facilities who fail to provide a full 12 months of data within the timeline would receive a score of zero on the measure.

ANNA believes it is important for patients to be aware of a facility’s potential bloodstream infection rates. However, we are concerned the measure as currently proposed fails to provide facilities with a baseline upon which performance will be measured. Therefore, rather than requiring this measure as a clinical measure, ANNA urges CMS to consider including this requirement as a reporting measure and collect the baseline data. Collecting the baseline data prior to converting this reporting measure to a clinical measure allows for greater transparency with the dialysis community by providing achievement thresholds, performance standards, and benchmarks as a part of the rule proposing this as a clinical measure.
e. Comorbidity Reporting Measure

CMS proposes to adopt a comorbidity reporting measure to provide a more reliable source of data to be used in the development of a risk-adjustment methodology for the Standardized Mortality Ratio (SMR) and the Standardized Hospitalization Ratio (SHR). Under the proposed measure facilities would annually update in CROWNWeb information on 24 comorbidities10 for each “qualifying case”, which CMS defines as a hemodialysis or peritoneal dialysis patient.

ANNA appreciates that CMS is attempting to obtain information to provide better data for the development of appropriate case-mix adjustments. However, we are concerned that the measure as currently proposed by CMS is overly burdensome. The proposed measure would require facilities to annually report on the 24 co-morbidities of each patient. While this data is currently collected, it is only entered into any CMS accessed system at the time of each patient’s admission. Some of the requested data may be readily available in the patient’s record (e.g., whether the patient has had an amputation or is an insulin-dependent diabetic) while other data (e.g., alcohol dependence or whether the patient needs assistance with daily activities) may not be readily available in the patient’s record. In order to accurately capture data to report on the 24 co-morbidities as CMS proposes, facilities will need adequate time to update their data collection processes to add questions to the tools used for admission assessment and annual reviews.

Even if the requested information were readily available in patient charts, a nurse would have to review each individual patient chart, locate the information, and manually process the information. Such a task would be incredibly burdensome, particularly at a time when CMS proposes to significantly reduce the facilities’ reimbursement rates. In light of the proposed reductions, ANNA urges CMS to refrain from imposing this additional data collection burden at this time.

4. Other Measures Under Development

ANNA appreciates the opportunity to comment on additional measures CMS may want to consider in the future. ANNA urges CMS to consider including a fluid management measure, as successful fluid management has a greater probability of improving patient outcomes for mortality and morbidity than some measures currently included in the QIP. However, in creating a fluid management measure, we urge CMS to be strategic in the data elements required to be reported under the measure and to specifically limit those to a few key data elements that are demonstrated to be valid and reliable.

ANNA also encourages CMS to consider nurse-sensitive outcome measures. Currently ANNA has created a task force to identify and develop measures which demonstrate the value of nursing care in improving patient outcomes.

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10 CMS lists the 24 comorbidities in the preamble to the proposed rule. 78 Fed Reg. at 40862.
X. Economic Analyses

ANNA appreciates the opportunity to provide CMS with comments on the estimated economic impact of the QIP reporting requirements. As discussed in greater detail above, ANNA believes the proposed add-on payment for self-dialysis and home dialysis training is insufficient to adequately reimburse facilities for the amount of RN time required to adequately train patients.

In addition, we are concerned the systems issues related to the CROWNWeb program impose an additional burden on facilities and nurses (to whom the burden of collecting and entering the data into CROWNWeb often falls). As CMS estimates the economic impact of the various QIP measures, it should include a more realistic analysis of the time required to interface with the CROWNWeb system, not simply the amount of time it would take to interface with the program absent any systems issues. Specifically, one facility in Minnesota hired a full time data entry person in June of 2013 to help the current data entry person cut down on 20 – 30 hours of overtime every pay period for the past twelve pay periods. The burden to smaller dialysis organizations is high where they have limited resources and funding to handle this added responsibility. We are encouraged that CMS has identified several issues with CROWNWeb and are hopeful that it will be able to resolve the issues promptly. However, until the CROWNWeb program achieves routine optimal performance, we would encourage CMS to consider whether the addition of new measures is appropriate or whether such additional data burdens would overtax an already stressed system.

Conclusion

Thank you for the opportunity to comment on the proposed rule regarding the calendar year 2014 End-Stage Renal Disease Prospective Payment System and the payment year 2016 End-Stage Renal Disease Quality Improvement Program. If you have any questions or need clarification regarding any of our comments, please contact me or have your staff contact ANNA’s health policy associate Anna Schwamlein Howard at (202) 230-5681 or anna.howard@dbr.com.

Sincerely,

Norma Gomez, MSN, MBA, RN, CCN
President
American Nephrology Nurses’ Association