August 31, 2012

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1352-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC  20201  

Re: CMS-1352-P: Medicare Program; End Stage Renal Disease  
Prospective Payment System, Quality Incentive Program, and Bad Debt  
Reductions for All Medicare Providers Proposed Rule  

Dear Acting Administrator Tavenner:

On behalf of the American Nephrology Nurses Association (ANNA), we are pleased to offer comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for payment year 2014 and 2015. ANNA offers general comments related to data reporting, the development measures specific to patient outcomes, and the use of exclusions rather than a percentage of patients to be included in quality measures. In addition, we offer specific comments on the proposal related to the new measures proposed for payment year 2015 and subsequent payment years of the ESRD QIP.

ANNA is a nonprofit professional organization representing nurses who practice in nephrology. Our mission is to promote excellence by advancing nephrology nursing practice and positively influencing outcomes for individuals with kidney disease. Founded in 1969, we represent over 10,000 registered nurses and other health care professionals at all levels of practice. ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues affecting the practice of nephrology nursing.

We appreciate CMS’s work to implement the ESRD QIP. We support much of what is proposed and have actively participated in the development of consensus comments from Kidney Care Partners (KCP). The following comments are in addition to the comments submitted to CMS by KCP.
General Comments

Reduce the burden of data reporting: As CMS continues to modify and improve the program, we urge you to look at the program in totality, particularly with respect to how the data is reported to CMS. Currently multiple data systems are used to report the QIP measures. For example, reporting is conducted via claims data, CROWN Web, and National Healthcare Safety Network (NSHN). While we recognize currently there exists no single system that provides for the reporting of all QIP measures, we urge CMS to prioritize the development and implementation of a single reporting system in order to simplify reporting and minimize unnecessary burdens on providers, particularly staff members who provide direct care to beneficiaries.

Seek to develop and use measures that truly make a difference in patient outcomes: As CMS works to update and refine the QIP program, ANNA urges the agency to focus its efforts on the adoption of quality measures that truly affect patient survival and quality of life. Each QIP measure should be carefully chosen to ensure the measure is validated, and has a direct effect on patient outcomes. Simply having an NQF-approved measure does not mean it should be included in the QIP program. Each added QIP measure consumes resources, and potentially negatively impacts critical aspects of care as facility staff are pressured to try to improve each QIP measure in order to avoid payment penalties. ANNA shares CMS’s commitment to ensuring beneficiaries receive high-quality health care and believes that evidence based outcomes should be driving practice, rather than payment. We ask that CMS work closely with ANNA and the kidney care community to develop a comprehensive strategic plan for measure development, adoption, and retirement/removal of measures.

We also urge CMS to support work to develop a QIP measure for fluid management. Failure to successfully manage fluid volume is recognized as a major factor in hospitalizations, re-hospitalizations, and mortality in the dialysis population.\(^1\)\(^,\)\(^2\)

Use exclusions rather than a percentage of patients to be included: Regarding the use of percentage of patients to be included in the reporting measures: ANNA appreciates CMS recognition and reconsideration of the 2014 QIP requirement for reporting of 100% of patient’s values monthly.

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Rather than an arbitrary determination of a percentage of patients to be included, ANNA recommends that CMS adopt the following global exclusions and apply them to the PY 2014 measures, as well as those for PY 2015 and subsequent years (as appropriate):

- 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.

These recommended exclusions seek to target the measures to those beneficiaries who regularly receive care from a facility. They are consistent with exclusions included in CMS’s own measures that the NQF endorsed in 2007, CROWNWeb, and the urea reduction ratio (URR) reporting specification. Use of this set of exclusions would reflect the care received by the patient population for which the dialysis facility is responsible on a routine basis and recognize the over-penalization of smaller facilities that implementation of a percentage reporting system would have.

C. Proposed Measures for the PY 2015 ESRD QIP and Subsequent PYs of the ESRD QIP

3. New Measures Proposed for PY 2015 and Subsequent Payment Years of the ESRD QIP

b. Hypercalcemia

CMS proposes to adopt a new clinical quality measure related to proper bone mineral metabolism management. Specifically, CMS proposes to evaluate ESRD facilities using the NQF-endorsed measure (NQF #1454: Proportion of patients with hypercalcemia).

ANNA does not support the adoption of a clinical measure for hypercalcemia. While it is clear that disturbances in bone and mineral metabolism are associated with adverse cardiovascular (CV) outcomes and mortality, a more complete measure of this risk would include the additional monitoring of phosphorous and intact parathyroid hormone (iPTH) levels. This comprehensive approach is consistent with the Clinical Practice Guidelines for the Diagnosis, Evaluation,

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3 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).

4 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 Fed. Reg. at 40968 & 40971; Quality Measure Specifications for PY 2013 and PY 2014 ESRD QIP Final Rule (Nov. 1, 2011).
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Prevention, and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) developed by the Kidney Disease Improving Global Outcomes (KDIGO) initiative.\(^5\) 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,\(^6\) to encourage more effective management of bone mineral metabolism. We support the continuation of the use of calcium levels as a reporting measure.

5. Other Potential Future Measures Under Development

The Preamble discusses several proposed quality measures CMS is considering as it works to update and improve the ESRD QIP. ANNA encourages CMS to work with quality standard setting organizations and the nursing community at large to develop and implement quality measures that recognize the value nurses bring to improving the quality of care provided to ESRD patients. Nursing sensitive indicators reflect the structure, process and outcomes of nursing care. Numerous empirical studies have evaluated and documented the importance of the role nurses play in ensuring high quality health care. Nursing sensitive outcomes represent the effects of nursing interventions that result in changes in the patients’ experience, functional status, safety, psychological status, and/or costs. We look forward to working with CMS to implement an effective quality measure that takes into account the impact of nephrology nursing care.


\(^6\) KCP has supported both a phosphorous and PTH measure for endorsement by the NQF.
Conclusion

Thank you for the opportunity to comment on the Proposed Rule regarding the payment year 2015 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,

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