



**American Hospital  
Association**

Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
[www.aha.org](http://www.aha.org)

August 27, 2013

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1526-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

***RE: CMS-1526-P, Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; (Vol. 78, No.130), July 8, 2013.***

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2014 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP).

### **PROPOSED ESRD PPS BASE RATE ADJUSTMENT TO REFLECT CHANGE IN UTILIZATION OF ESRD-RELATED DRUGS AND BIOLOGICALS**

The *American Taxpayer Relief Act of 2012* requires that, for services furnished on or after Jan. 1, 2014, the Secretary of the Department of Health and Human Services (HHS) must reduce the ESRD PPS base rate to reflect the HHS Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals by comparing per patient utilization data from 2007 with such data from 2012. In conformance with this requirement, CMS proposes to reduce the ESRD PPS base rate by \$29.52 (12 percent), resulting in a proposed CY 2014 base rate of \$216.95.

**While the drug utilization adjustment is mandated by law, the AHA is concerned that a single-year reduction of 12 percent to the ESRD PPS base rate could have devastating repercussions for ESRD programs' financial stability and, therefore, could harm beneficiary access to ESRD care.** This cut would be particularly difficult for the smaller dialysis programs, such as dialysis facilities within hospitals and health systems, to absorb. For example, a cut of this magnitude on facilities that, according to the Medicare Payment Advisory Commission (MedPAC), have just 3-4 percent Medicare margins, could result in closure of dialysis facilities and a reversal of the many recent gains in improving quality of care and



mortality for dialysis patients. It also would be difficult for hospital-based dialysis facilities to adjust their budgets for these programs for next year on such short notice.

**Therefore, the AHA recommends that CMS phase-in the adjustment over several years. We agree with CMS's view that it has the authority to do so. In addition to a phase-in, we recommend that CMS provide for a short grace period in order to allow dialysis facilities to budget and prepare for this reduction in payment.**

## **ESRD QIP CHANGES**

*The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)* mandated that CMS establish a program, starting in CY 2012, under which ESRD facilities would receive payment reductions of up to 2 percent if facilities do not meet or exceed performance standards on specific measures. To determine ESRD facility performance, CMS uses a scoring methodology very similar to that of the hospital value-based purchasing (VBP) program. That is, facilities receive a Total Performance Score (TPS) between zero and 100 points based on their achievement versus national benchmarks and improvement versus their own baseline performance. However, unlike the hospital VBP, the QIP is not budget neutral; ESRD facilities must score at or above a CMS-designated minimum TPS to avoid a payment reduction. Thus, the best-case scenario for facilities under this program is avoiding the 2 percent penalty. For every 10 points below the minimum TPS, an ESRD facility receives a 0.5 percent reduction in payments, with a maximum reduction of 2 percent.

**The AHA supports several aspects of the ESRD QIP.** For example, the program's scoring methodology uses a mix of achievement versus national benchmarks and improvement versus baseline performance to assess penalties. We believe this incentive structure has the potential to reward high performers while encouraging improvement among low performers. However, the scores ESRD facilities receive must be based on rigorous quality measures that multiple stakeholders agree are important to improving the quality of ESRD facility care.

**However, the AHA is very concerned that four out of the five new measures proposed for the payment year (PY) 2016 ESRD QIP are not endorsed by the National Quality Forum (NQF). CMS's proposals are especially alarming given that there appear to be NQF-endorsed versions of some of these measures, and that the Measure Applications Partnership (MAP) reviewed these NQF-endorsed versions of the proposed measures in its pre-rulemaking activity this year. We ask the agency to provide additional rationale for selecting non-NQF endorsed versions of these measures. We also are concerned that the agency has ignored Congress's intent to obtain MAP input *before* measures are formally proposed for programs. We urge the agency not to finalize four of the proposed measures until it is able to implement NQF-endorsed versions of the measures.**

The five proposed measures, along with their NQF-endorsement and MAP review status, are summarized in Table 1. The table also notes which of the four measures the AHA does not support finalizing for the ESRD QIP at this time.

**Table 1: NQF Endorsement and MAP Review Status of Proposed PY 2016 ESRD QIP Measures**

Proposed Measure Title	NQF-endorsed version reviewed by MAP?	ESRD QIP uses NQF-endorsed version?	Did MAP review the version proposed in the rule?	Does AHA support measure for ESRD QIP as proposed?
Proportion of Patients with Hypercalcemia	Yes (NQF #1454)	Yes	Yes	Yes
Use of Iron Therapy for Pediatric Patients Reporting	Yes (NQF #1433)	No	No	No
Bloodstream Infection in Hemodialysis Outpatients	Yes (NQF #1460)	No	No	No
Anemia of Chronic Kidney Disease: Patient informed consent for anemia treatment	No	No	Yes	No
Co-morbidity Reporting	No*	No*	No*	No

\* NQF #1463 and #0369 were reviewed by the MAP in Jan. 2013; however, the proposed co-morbidity reporting measure was not. The agency states that reporting this measure would assist in the calculation of two NQF-endorsed measures of risk-adjusted hospitalization and mortality (NQF #1463 and #0369) it may propose in future years.

**NQF Endorsement.** The AHA has long urged that CMS use NQF-endorsed measures in its programs, and we believe that NQF endorsement should be viewed as a minimum standard for measures being used in a pay-for-performance program like the ESRD QIP. The NQF measure endorsement process constitutes an in-depth, multi-stakeholder review of a measure’s technical specifications and testing data. NQF endorsement provides all stakeholders with assurance that measures are important, scientifically sound, useable and feasible to collect. CMS has the authority to include non-endorsed measures in the ESRD QIP when it feels that there are not NQF-endorsed measures available to meet a high-priority measurement need. **However, given that there are NQF-endorsed versions of three of the proposed measures (NQF #1454, #1433 and #1460), we encourage CMS to use those measures rather than the non-endorsed measures the agency has proposed.** We are disappointed that the agency has proposed only one NQF-endorsed measure, and do not feel the proposed non-NQF endorsed measures are appropriate for inclusion in a pay-for-performance program.

**Furthermore, we are very concerned that the agency proposes measures that are only “based on” NQF-endorsed versions of the measures, and believe this practice compromises the credibility of measure results.** Of the four non-NQF endorsed measures proposed for the ESRD QIP, the agency claims that two are derived from NQF-endorsed versions of the measure with very similar titles. One other measure – co-morbidity reporting – is not based on any NQF-endorsed measure, but the agency feels that collecting it would enable the use of two other NQF-endorsed measures in the future. NQF-endorsed measures are subjected to thorough empirical testing to ensure that they give the public an accurate view of performance, and generate data that can be used by providers to benchmark and improve performance. For example, NQF endorsement review would allow stakeholders to examine what minimum sample sizes are needed to obtain accurate data. The review also would help determine whether a measure

requires risk-adjustment to ensure an ESRD facility does not perform poorly on measures simply because its patient population is sicker. When the agency deviates from the NQF-endorsed specifications, it is not clear if the measure generates credible results. We appreciate the agency's transparency in including the NQF-endorsement status of the measures in the proposed rule. We also acknowledge that it is possible to uncover limitations of NQF-endorsed measure specifications in the process of implementing them in programs. **Nevertheless, we do not believe the solution to these limitations is to simply use a non-NQF endorsed version of the measure. Instead, the agency should identify, test and seek NQF-endorsement of measure enhancements before proposing the measure for the program.** For example, the agency states that it considered using the NQF-endorsed version of the Iron Therapy for Pediatric Patients measure (NQF #1433), but ultimately decided not to because "not enough patients would qualify for this measure to establish reliable baseline data." Instead of adopting untested measure specifications, the agency could work with a subset of ESRD facilities to more fully characterize the data collection process and identify needed changes that would allow more reliable measure reporting.

**MAP Review.** As mandated by the *Patient Protection and Affordable Care Act*, the NQF convenes the multi-stakeholder MAP to provide input on measures being considered for federal quality measurement and reporting programs in advance of formal rulemaking. By Dec. 1 of each year, the HHS Secretary must provide the MAP a list of measures – known as the Measures Under Consideration (MUC) list – that the agency is considering for future use in its programs. By Feb. 1 of each year, the MAP must provide its report detailing its recommendation for each measure on the MUC list. The Secretary must then consider the MAP's input in selecting quality and efficiency measures she will subsequently propose for programs.

**The AHA is concerned that the agency has ignored Congress's intent to use the MAP to obtain multi-stakeholder input on measures being considered for the ESRD QIP before those measures are formally proposed in rulemaking.** Indeed, section 1890A(a)(4) of the *Social Security Act* states, "the Secretary shall take into consideration the input from multi-stakeholder groups described in paragraph (1) [i.e., the MAP] in selecting quality and efficiency measures described in section [1890\(b\)\(7\)\(B\)](#)." Section 1890(b)(7)(B)(i) of the act further states that the measures are "for use pursuant to" several programs, including the ESRD QIP.<sup>i</sup> However, as noted in Table 1, three of the five measures proposed by CMS in the rule were not reviewed by the MAP in its recent pre-rulemaking report.

**While the MAP reviewed NQF-endorsed versions of several of the proposed measures, it did not review the versions that CMS now proposes to use for the ESRD QIP, even though some of the proposed measures have the same titles.**<sup>ii</sup> For example, the MAP explicitly supported NQF #1433, which has the same title as the proposed "Use of Iron Therapy for Pediatric Patients" measure. However, as noted in the previous section, CMS is not proposing to use the NQF-endorsed version of the measure. Furthermore, the MAP did not review the "Co-Morbidity Reporting" measure proposed in the rule. The agency notes that it wishes to collect this measure to facilitate the future reporting of risk-adjusted hospitalization and mortality measures that were reviewed by the MAP – NQF #1463 and #0269. CMS also invokes its "exception" authority to use non NQF-endorsed measures in programs. However, the MAP can review both NQF-endorsed and non-NQF endorsed measures as part of its deliberations. The reporting of co-morbidity data alone was never discussed by the MAP as a discrete measure.

**Because the MAP process is predicated on reviewed measures being implemented as specified, the AHA is concerned that CMS's proposals for the ESRD QIP undermines the MAP's credibility.** The AHA strongly supports the premise of the MAP's work; that is, improvement in our nation's health care system can be catalyzed by selecting rigorous quality measures in federal reporting and payment programs focused on aspects of care that a broad array of stakeholders believe to be important. However, by proposing versions of measures not reviewed by the MAP, it creates the appearance that CMS is trying to bypass the MAP process rather than fully engage it. Thus, once the agency is ready to use NQF-endorsed versions of the proposed measures in the ESRD QIP, it should include those measures on a future MUC list. This will ensure that the MAP has fully evaluated CMS's intended use of the measures.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Rick Pollack  
Executive Vice President

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<sup>i</sup> The section specifically lists section 1881(h)(2)(A)(iii) of the *Social Security Act*, which is the statute for the ESRD QIP.

<sup>ii</sup> See National Quality Forum, *MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration*, available at <http://www.qualityforum.org/map>.