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August 26, 2011

Donald M. Berwick, M.D., M.P.P.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1577-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

***RE: CMS-1577-P, Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; (Vol. 76, No.131), July 8, 2011.***

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) and the ESRD Quality Incentive Program (QIP) for payment year (PY) 2013 and PY 2014.

### **ACCESS TO DATA NEEDED TO VALIDATE CMS'S PROPOSED PAYMENTS**

**The AHA urges CMS to make available its rate setting file and the proposed rule's impact file at the provider level.** We are concerned that CMS has not released the data necessary for dialysis providers to validate and comprehensively comment on the proposed payment rates and updates for the ESRD PPS system. The AHA supports the comments from the Kidney Care Partnership and the National Renal Administrators Association related to the need for additional transparency in the calculation of the proposed updates to the ESRD composite rate, the ESRD PPS base rate and the market basket update.

### **TRANSITION BUDGET NEUTRALITY ADJUSTMENT**

**The AHA supports CMS's proposal to retain the zero percent transition budget neutrality adjustment for CY 2012.** This proposal appropriately reflects the fact that a far larger percentage of the ESRD facilities than CMS had initially estimated elected to forgo the transition and instead receive the full ESRD PPS payment in CY 2011.



**We remain disappointed, however, that CMS did not use every available opportunity to remind all ESRD providers of the November 1, 2010, deadline to elect to be excluded from the transition.** There were numerous CMS ESRD PPS electronic mailing list e-mails between the date the CY 2011 final rule was published and the election deadline that CMS could have used to widely inform providers of this opportunity, but did not. Neither did CMS prominently highlight the deadline on its ESRD Web page. The AHA believes that, as a result, many hospital-based dialysis providers lost the opportunity to benefit from moving directly to payment based entirely on the ESRD PPS rate because they were unaware that they had this option.

## **EMERGENCY SERVICES FOR ESRD BENEFICIARIES**

The AHA applauds CMS's statement that the ESRD PPS consolidated billing rules do not apply to items and services furnished to ESRD patients in a hospital emergency department (ED) for reasons other than ESRD treatment and that these items and services can be paid separately under other Medicare payment systems. In particular, CMS clarifies in the proposed rule that laboratory tests that could be used during dialysis and ordered for the treatment of ESRD also may be ordered for ESRD patients in an ED for reasons other than ESRD – for instance, as part of the general ED workup of the patient. In these circumstances, the agency would not consider these laboratory tests as renal dialysis services under the ESRD PPS, and they could be separately billed.

**The AHA agrees with CMS's view that these services should be separately billable by the hospital. However, in practice, CMS's current policy often results in denials of appropriate claims.** That is, any claim from a hospital ED submitted for an ESRD beneficiary that contains ESRD-bundled items and services is denied, regardless of the diagnosis, unless the hospital, at the time of admission, is able to determine that the patient is receiving dialysis services (often furnished by a different provider) and adds the "AY" modifier to the line-item HCPCS codes to indicate that the hospital ED services are unrelated to ESRD treatment. Patients arriving in the ED are frequently unconscious, traumatized, or otherwise unable to communicate coherently about their medical history and conditions. Therefore, the hospital often will not be aware that the patient is undergoing dialysis and will submit a bill to CMS without using the required "AY" modifier. In the vast majority of such circumstances, the patient's care is unrelated to ESRD, and the services are paid according to CMS's policy. But again, without the appropriate modifier, the services will be denied. This creates an unnecessary administrative burden for the hospital, which then must re-submit the claim with the required modifier, and for the Medicare contractor, who must then process the claim a second time.

**Given that it is rare for a hospital ED to furnish ESRD services to a patient, the AHA recommends a different approach. We recommend that hospital ED services, which can be easily identified by the inclusion of the Uniform Bill (UB) Revenue Code 045X on the hospital's bill, should be, by definition, excluded from ESRD PPS consolidated billing unless a modifier is used to indicate that the services furnished are related to ESRD.** This approach would provide for correct payment for hospitals the first time without having to follow up on and resubmit a large number of inappropriate denials.

## QUALITY INCENTIVE PROGRAM

*The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)* mandated that CMS establish a program under which ESRD facilities would receive payment reductions if facilities do not meet or exceed performance standards on specific measures. In last year's ESRD proposed rule, CMS finalized three measures to begin the quality incentive program (QIP) that will be applied to the CY 2012 ESRD update. In a separate regulation, CMS finalized a scoring methodology based on a 30-point scale that is tied to a sliding scale of payment penalties. An ESRD facility may receive penalties ranging from zero up to two percent. Unlike other value-based purchasing programs, the QIP is not budget neutral, and ESRD facilities are not eligible to receive any bonus money. The best-case scenario for this program is avoiding a 2 percent penalty. This year's proposed rule includes several potential modifications to the QIP for CY 2013 and CY 2014.

### Proposed payment penalty scale for CY 2013

**The QIP penalties proposed for CY 2013 are too aggressive, and the AHA urges CMS to simplify the 2013 changes and lower the penalties.** We urge CMS to reconsider the penalties proposed for CY 2013. In CY 2012, the first penalty an ESRD facility may experience is 0.5 percent. This penalty is associated with earning between 21 through 25 points on the 30-point scale (see chart below). For CY 2013, CMS is proposing to double the first penalty to 1 percent. CMS is also requiring ESRD facilities to score many more points in order to avert a penalty. For CY 2012, an ESRD facility needs to score more than 25 points to avoid a penalty. For CY 2013, CMS is proposing that ESRD facilities must score more than 29 points to avoid a penalty.

Total Score	2013 Proposed Payment Reduction	2012 Payment Reduction
30 Points	0.0	0.0
26-29	1.0	0.0
21-25	1.5	0.5
16-20	2.0	1.0
11-15	2.0	1.5
0-10	2.0	2.0

CMS is proposing too many simultaneous changes to the sliding scale for CY 2013. Each approach, doubling the initial penalty and requiring facilities to earn more points to avoid penalties, is aggressive by itself. Applying both penalties at the same time will place undue hardships on ESRD facilities. We recommend that CMS consider either doubling the penalty or requiring more points to avoid a penalty, but not both. Unfortunately, we are unsure which of these approaches to recommend because we do not have enough impact information to make a recommendation. **In the future, we urge CMS to make the modeling results publicly available so that we can provide more detailed recommendations.**

Even without the modeling data, we are able to comment on the expectations built into application of the maximum penalty. In CY 2012, ESRD facilities that earn fewer than 10 points will receive the maximum penalty of 2 percent. For the CY 2013 QIP, CMS proposes to require

facilities to earn nearly twice as many points in order to avert the maximum 2 percent penalty. **It is unreasonable to expect that facilities have the experience and infrastructure in place to double performance rates in a one-year period in order to avoid the maximum penalty.**

This proposal is very alarming, and it indicates that CMS has unreasonable expectations for how quickly providers are able to change their performance on measures. We urge CMS to pursue research on how quickly measurement change occurs. Only after such research is completed can CMS justify proposing a change of this magnitude in the QIP or any other value-based purchasing program.

#### **Proposals for CY 2014**

For the CY 2014 QIP, CMS proposes to include seven new quality measures. Below we provide some overarching goals that CMS should aim to achieve prior to including these new measures.

*National Quality Forum endorsement.* **For the QIP, we urge CMS to use only National Quality Forum (NQF) endorsed measures.** The AHA is a staunch supporter of the NQF process because of the high level of review that each and every measure must undergo prior to achieving endorsement status. Of the seven QIP measures proposed for CY 2014, none is currently NQF-endorsed. CMS notes that three of the seven proposed measures are currently undergoing NQF review, though they are not currently endorsed. We commend CMS for the transparency it has included regarding NQF status in this proposed regulation. This level of transparency has not been included in other quality reporting regulations (such as the inpatient and outpatient quality reporting programs). **We urge CMS to use the same level of transparency regarding NQF status that has been used in the QIP program in all of CMS's quality reporting programs.** We urge CMS to include the NQF status of all proposed and finalized QIP measures in each ESRD regulation. However, since none of the CY 2014 proposed measures is NQF-endorsed, we are unable to support them at this time.

*Use of all-payer data.* **We urge CMS to require reporting of the ESRD measures for all applicable patient populations, including both Medicare and non-Medicare populations.** CMS intends to require reporting on Medicare patients only for the ESRD quality measures. The AHA has been a long-time supporter of collecting all-payer data. Providers have a much better understanding of their overall performance when they are measured across their full patient panels.

*Minimum sample of patients for clinical measures.* **We urge CMS to provide empirical justification, by publicly releasing analytic results, for the minimum threshold of cases needed to derive a consistent rate of reliability for all measures used in VBP programs.** CMS proposes a minimum threshold of 11 cases in order for a measure to qualify for the scoring in the QIP. We ask CMS to provide references that empirically support this minimum. Further, it is incumbent upon CMS to harmonize methodologies, such as the establishment of minimum thresholds, across its various VBP programs. One way in which CMS can do this is to establish a rate of reliability that a measure must achieve in order to ensure the measure is statistically accurate. There is a variety of conflicting research on what rate of reliability is needed. Therefore, it is incumbent upon CMS to consult experts and then obtain comment from the public prior to finalizing a rate of reliability. Once a rate is established, then CMS must conduct

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further research on what minimum threshold of cases (whether it be patients or claims) is appropriate in order to attain the rate. **It is incumbent upon CMS to make all of this research available to the public for review.** Currently, CMS has established the following minimum thresholds for measures used in its VBP programs:

- 30 patients for efficiency measures in the physician feedback program;
- 25 patients for the public reporting of quality measures reported on *Hospital Compare*;
- 11 patients for the ESRD Quality Incentive Program (*proposed*);
- 10 patients for clinical process of care measures in hospital VBP;
- Three patients for the patient safety composites in hospital VBP (*proposed*);
- One claim for the hospital-acquired conditions rates in hospital VBP (*proposed*).

While these measures are currently tied to payment now or soon will be and CMS has not done its due diligence to ensure these measures are producing statistically reliable information. CMS must rectify this immediately. In the absence of disclosing its research results on reliability rates, we are unable to assess the appropriate number for a minimum sample of patients for the QIP measures.

*Recognizing both achievement and improvement on quality measures.* **We commend CMS for implementing a process to score measures on both achievement and improvement for the CY 2014 QIP.** Even though MIPPA did not require this scoring process in the QIP, we applaud CMS for applying this best practice from hospital value-based purchasing into the ESRD program. Awarding performance points based on either comparison to a benchmark (attainment) or an internal year-to-year comparison (improvement) is far more equitable than using a sliding scale. We urge CMS to consider using this approach in CY 2013, if feasible.

*Simultaneous proposals.* **We commend CMS for proposing measures, proposing timeframes and proposing the weight each measure would have in the CY 2014 program within one regulation.** This level of planning and foresight has not been used in the other value-based purchasing programs, such as hospital VBP. **We urge CMS to take this best practice from the QIP and apply it to rulemaking for hospital VBP.**

Thank you again for the opportunity to comment. If you have any questions, please contact me, Roslyne Schulman, director for policy at (202) 626-2273 on ESRD PPS payment policy issues or Lisa Grabert, senior associate director for policy at (202) 626-2305 on ESRD QIP issues.

Sincerely,

/s/

Rick Pollack  
Executive Vice President