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Glenn M. Hackbarth, J.D., Chairman  
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August 15, 2014

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

**RE: CMS-1614-P**

Dear Ms. Tavenner:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed notice entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” published in the Federal Register, vol. 79, no. 133, pages 40208 to 40315. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2015 and the ESRD quality incentive program (QIP). We appreciate your staff’s ongoing efforts to administer and improve payment systems for physician and other services, particularly considering the competing demands on the agency.

Our comments address provisions in the proposed rule about the proposed rebasing and revising the ESRD bundled market basket. We comment also on the following provisions of the ESRD QIP for payment years (PYs) 2017, 2018, and beyond:

- Proposed ESRD QIP measures for payment years 2017 and 2018
- Calculating a facility’s total performance score
- Stratifying QIP measures for beneficiaries eligible for Medicare and Medicaid
- Future QIP considerations
- The ESRD QIP and the Dialysis Star Ratings System

**Rebasing and revising the ESRD bundled market basket**

The ESRD bundled (ESRDB) market basket forecasts how much providers’ costs would change in future years if the quality and mix of inputs they are to furnish care remained constant. For calendar year 2015, CMS is proposing to:

- Rebase the current ESRDB market basket (which is based on 2008 cost reports) by updating the cost category weights that are intended to reflect the distribution of input costs faced by providers using 2012 cost reports submitted by freestanding dialysis facilities and data from the U.S. Census Bureau's Services Annual Survey.
- Revise the ESRDB market basket by adding additional cost categories and by changing some of the wage and price proxies that assess the rate of price change for each cost category. CMS proposes to use U.S. Bureau of Labor Statistics indexes (Produce Price Index, Employee Cost Index, and Consumer Price Index).
- Update the labor-related share of the base payment rate from 41.737 percent to 50.673 percent (because the labor cost weight increases and the pharmaceutical cost weight decreases under the ESRDB market basket).
- Implement new core-based statistical area (CBSA) delineations.<sup>1</sup>

CMS projects that these provisions would decrease 2015 total payments for rural facilities by 0.8 percent and increase total payments for urban facilities by 0.1 percent. Because rural facilities generally have low wage index values, they are adversely affected by the proposed increase to the labor-related share of the payment rate. To moderate these effects, CMS proposes a 2-year transition to carry out the updated labor-related share and to implement the new CBSA delineations.

### ***Comments***

The Commission supports rebasing the ESRDB market basket using the most current and accurate data that are available because the market basket would better reflect the recent decline in dialysis drug use that has occurred under the ESRD PPS.<sup>2</sup>

To better ensure accuracy, CMS should use 2012 audited cost report data instead of the proposed unaudited reports. Historically, facilities' cost reports have included costs that Medicare does not allow. If facilities' reported costs are either overstated or understated, then the cost category weights that CMS derives to create the rebased ESRDB market basket could change. Earlier this year, the Commission recommended that the Congress direct the Secretary of Health and Human Services to audit dialysis facilities' Medicare cost reports.<sup>2</sup> The agency is initiating audits of cost reports submitted by a sample of dialysis facilities. The Protecting Access to Medicare Act of 2014 (PAMA) mandated the audits and provided \$18 million for fiscal year 2014 to fund the effort.

Delaying the implementation of the rebased ESRDB market basket to 2016 in order to use audited cost report data would not result in a change in 2015 total dialysis spending because PAMA sets the 2015 update to the ESRD PPS base rate at 0 percent. Other changes to the ESRD PPS could also be considered during the 2016 rulemaking process that might mitigate some of the payment

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<sup>1</sup> CMS also proposed to adopt the same new market delineations in the fiscal year 2015 proposed rule for inpatient PPS and long-term care hospitals.

<sup>2</sup> Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

redistribution that is projected to result from the updated labor share and new CBSAs. In this proposed rule, the agency announced plans to reevaluate all the patient- and facility-level adjustments using updated cost and claims data during the CY 2016 rulemaking process. The American Taxpayer Relief Act of 2012 requires that CMS, no later than January 1, 2016, analyze the ESRD PPS case-mix adjustments and make appropriate revisions to those adjustments.

We strongly recommend that CMS, during the 2016 rulemaking process, redesign the low-volume payment adjustment to consider a facility’s distance to the nearest facility. The distance requirement in CMS’s current definition does not prevent some facilities that are close to one another from receiving the 18.9 percent payment adjustment to their base rate.<sup>3</sup> The Commission’s analysis of 2012 claims found that nearly half of all facilities that received the payment adjustment were within 5 miles of the nearest facility.<sup>2</sup> We found that rural facilities tend to be smaller than urban ones (as measured by total treatment volume) and their 2012 Medicare margin was lower compared with urban facilities (–0.08 percent vs 4.7 percent, respectively).<sup>2</sup> Our analysis showed a strong correlation between lower treatment volume and higher cost per treatment. Our analysis also found that rural facilities tended to be farther from the next facility suggesting that a redesigned policy that considered distance between facilities might benefit rural, low-volume facilities, and help maintain beneficiaries’ access to dialysis services in rural areas.

**Proposed ESRD Quality Incentive Program measures for payment years 2017 and 2018**

The PY 2017, the sixth year of the QIP, would use 8 “clinical measures” and 3 “reporting measures.” The PY 2017 QIP would use 10 of the 11 measures from the 2016 QIP and would introduce the standardized readmission ratio. Beginning in PY 2017, CMS is proposing to retire the anemia measure that assessed the proportion of beneficiaries with hemoglobin level greater than 12 g/dL. The PY 2018 QIP would include 16 measures; 11 of them are from the PY 2017 program, 2 of them are new “clinical measures” and 3 of them are new “reporting measures.” The following table summarizes the measures proposed for PYs 2017 and 2018:

<b>Measure</b>	<b>Measure type</b>	<b>Payment year measure used</b>
<u>Low dialysis adequacy</u> Kt/V measure for adult hemodialysis patients Kt/V measure for adult peritoneal patients Kt/V measure for pediatric hemodialysis patients Kt/V measure for pediatric peritoneal patients	Clinical Clinical Clinical Clinical	PY 2016 measure PY 2016 measure PY 2016 measure Proposed for PY 2018
<u>Anemia management</u> Anemia management reporting measure Standardized transfusion ratio	Reporting Clinical	PY 2016 measure Proposed for PY 2018
<u>Vascular access type</u> Use of AV fistulas Use of catheters	Clinical Clinical	PY 2016 measure PY 2016 measure

<sup>3</sup> For facilities certified for Medicare participation as of December 31, 2010, CMS’s definition does not impose a distance requirement between the facility that receives the low-volume adjustment and the next closest facility.

Hypercalcemia	Clinical	PY 2016 measure
Standardized readmission ratio (SRR)	Clinical	Proposed for PY 2017
NHSN blood stream infection in hemodialysis outpatients	Clinical	PY 2016 measure
ICH CAHPS survey (patient experience)	Reporting (PY 2017) Clinical (PY 2018)	PY 2016 measure
Mineral metabolism	Reporting	PY 2016 measure
Clinical depression screening and follow-up	Reporting	Proposed for PY 2018
Pain assessment and follow-up	Reporting	Proposed for PY 2018
NHSN healthcare personnel influenza vaccination	Reporting	Proposed for PY 2018

Note: PY (payment year). Kt/V (dialyzer urea clearance x dialysis time/urea volume). SRR (standardized readmission ratio). NHSN (National Healthcare Safety Network). ICH CAHPS (In-center hemodialysis Consumer Assessment of Healthcare Providers and Systems survey).

*Comments on ESRD QIP “clinical measures” for PYs 2017 and 2018*

We support removing the anemia measure that assesses high hemoglobin levels beginning with the PY 2017 QIP. In our 2013 comment letter to CMS, the Commission suggested retiring this measure because there is little variation in facilities’ performance and because under the PPS, facilities no longer have an incentive to overuse erythropoietin stimulating agents.<sup>4</sup> We also support adopting the SRR measure in the 2017 QIP. The Commission’s 2013 comment letter suggested that CMS consider adopting a hospital readmission measure because hospital readmissions may be an indicator of poor access to follow-up primary care or missed opportunities for inpatient and ambulatory care providers to better coordinate care.

Regarding the PY 2018 QIP, we support adopting the standardized transfusion ratio. This proposal is consistent with the Commission’s recent recommendation that the ESRD QIP include a measure that assesses the poor outcomes related to anemia in the ESRD QIP.<sup>2</sup> We also support CMS’s proposal to convert the In-center hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey “reporting measure” into a “clinical measure” for the PY 2018 QIP, as facilities would be held responsible for their actual performance.

*Comments on ESRD QIP clinical depression and pain “reporting measures” for 2018*

For the PY 2018, CMS is proposing to adopt a “pain assessment and follow-up” measure and a “clinical depression and follow-up” measure. Both measures require facilities to report to CROWNWeb the screening of clinical depression (once a year) and the assessment of pain (twice a year) for qualified patients.<sup>5</sup>

<sup>4</sup> Medicare Payment Advisory Commission. 2013. Comment letter to CMS on the proposed rule entitled: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, August 30.

<sup>5</sup> Qualified patients are those treated at the facility for 90 days or longer and who are 18 years and older for pain assessment and 12 years and older for depression assessment.

We understand the importance of screening for these conditions and developing follow-up plans when appropriate. However, we are concerned that these measures overlap with Medicare's conditions for coverage for ESRD facilities (section 494.90(a)(6)), which require that in the patient's plan of care, facilities address patients' psychosocial status as measured by a standardized mental and physical assessment tool at regular intervals, or more frequently on an as-needed basis. In addition, the ICH CAHPS, a QIP measure, asks patients about the presence of pain.

We believe that CMS should instead consider using a clinical measure such as the standardized hospitalization ratio (SHR) that would capture the effective management of the dialysis patient. The SHR is a risk-adjusted measure of hospitalizations for dialysis beneficiaries, which could be defined as an all-cause or potentially avoidable. CMS has previously said that hospitalizations are an important indicator for patient quality of life and morbidity and proposed but did not implement the SHR for the PY 2014 QIP.<sup>6</sup> In a subsequent rule, CMS said that it would consider the SHR for future payment years, possibly beginning with the PY 2018 program.<sup>7</sup>

### **Calculating a facility's total performance score**

For the PY 2018 QIP, CMS is proposing to implement a new method to calculate a facility's total performance score. The proposed method would assign the facility's total performance score using two domains, the clinical measure domain and the reporting measure domain. Facility scores on "clinical measures" would be divided into subdomains that align with National Quality Strategy domains and weighted according to the number of measures in a subdomain, facility experience with the measure, and the measure's alignment with CMS priorities for quality improvement. These weighted scores would be summed to produce a facility's clinical measure domain score. Facility scores on "reporting measures" in the reporting measure domain would be summed and calculated to produce a facility's reporting measure adjuster, which would be subtracted from the facility's clinical measure domain score to produce a facility's total performance score.

If the new method is not adopted, the agency proposes, for PY 2018, to use the current method but weight "clinical measures" at 90 percent and "reporting measures" at 10 percent. For the PYs 2016 and 2017 QIPs, CMS will weight "clinical measures" at 75 percent and "reporting measures" at 25 percent.

We appreciate the agency's responsiveness to the Commission's comment to increase the weight of "clinical measures" under the QIP.<sup>4</sup> In our 2013 comment letter, we said that the 2016 QIP total performance score should be calculated by using weights of 90 percent for "clinical measures" and 10 percent for "reporting measures." As we have previously said, the Commission believes that

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<sup>6</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011. Medicare program; Changes to the end-stage renal disease prospective payment system for CY 2012, the end-stage renal disease quality incentive program for PY 2013 and PY 2014; ambulance fee schedule; and durable medical equipment; proposed rule. July 8.

<sup>7</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare program; Changes to the end-stage renal disease prospective payment system, quality incentive program, and bad debt reductions for all Medicare providers; proposed rule. July 11.

value-based purchasing programs should evaluate providers’ performance rather than their ability to track and report information, and that clinical outcomes are more important than simply tracking or relaying information to the Secretary.

If the agency adopts the new method in PY 2018 to calculate a facility’s total performance score, first, the method should not result in less weight for “clinical measures.” Second, we do not think that facilities’ experience with the “clinical measure” should affect the weight assigned to the measure. For example, CMS assigned a lower weight to the standardized transfusion ratio because PY 2018 would be the first program year in which facilities are measured on the measure. Third, the agency should re-evaluate the proposed assignment of measures to subdomains (as presented in the table below). The concern is that some measures span multiple subdomains. For example, the standardized readmission ratio measure, which was assigned to the patient and family engagement/care coordination subdomain, could instead have been assigned to the clinical care subdomain. Hospital readmissions are indicators of poor access to follow-up primary care, missed opportunities for inpatient and outpatient ambulatory care, and inadequate care coordination.

<b>Subdomain</b>	<b>Measure weight</b>	<b>Subdomain weight</b>
Safety		20%
NHSN blood stream infection measure	20%	
Patient and family engagement/care coordination		30
ICH CAHPS measure	20	
Standardized readmission ratio measure	10	
Clinical care		50
Standardized transfusion ratio	7	
Dialysis adequacy measure topic	18	
Vascular access type measure topic	18	
Hypercalcemia measure	7	

Note: NHSN (National Healthcare Safety Network). ICH CAHPS (In-center hemodialysis Consumer Assessment of Healthcare Providers and Systems survey).

### **Stratifying QIP measures for beneficiaries eligible for Medicare and Medicaid**

CMS is seeking comments on whether it is feasible to stratify ESRD QIP measures based on whether the beneficiary is dually eligible for Medicare and Medicaid (duals), the burden associated with reporting stratified measures, whether stratified measures should be reported publicly, and how the agency should factor these measures into the scoring method.

We do not support the risk adjustment of quality measures to reflect patients’ socioeconomic status. Risk adjusting based on socioeconomic differences obscures differences in facilities’ risk-adjusted quality scores, and would mask potential disparities in care. The Commission thinks that all facilities should be held accountable for the quality of the services they furnish, regardless of the socioeconomic status of the patients that they serve.

If CMS wants to stratify QIP measures based on dual status, a better approach is to evaluate a facility’s performance in relation to their peers. That is, the performance of a given facility that

serves a large share of dual-eligible beneficiaries could be compared against a group of peers with a similar share of dual-eligible beneficiaries. Such an approach adjusts for socioeconomic status without masking differences in quality. The expectation is that facilities will use this information in their quality improvement activities. The Commission's June 2013 report discussed such a strategy for hospitals' readmission ratings.

To minimize administrative burden to providers and the agency, CMS should select only QIP measures that are claims-based, including the dialysis adequacy and vascular access measures. CMS could compare each facility against its peers by linking the claims-based measures to administrative data with information about beneficiaries' Medicaid eligibility. The agency would have the flexibility of furnishing facilities' this evaluation thru the "Dialysis Facility Reports" effort as well as to the public thru the Dialysis Facility Compare website.

### **Future QIP considerations**

We repeat our concern about the overall number of measures used in the ESRD QIP. We urge CMS to remain vigilant in maintaining a reasonable number of outcomes-based performance measures for the program. As the number of measures grows, the administrative costs to providers and CMS also increase. The QIP should strive to include those measures that address multiple domains of CMS's value-based purchasing programs and are not duplicative.

### **The ESRD QIP and the Dialysis Star Ratings Systems**

On June 18, 2014, CMS announced (on its blog) that it would be adding star ratings to the Dialysis Facility Compare, Hospital Compare, and Home Health Compare websites. Nursing Home Compare already includes star ratings for facilities, and Physician Compare has just started to include star ratings in certain situations for physician group practices.<sup>8</sup> CMS is intending that the Dialysis Star Ratings System will begin October 2014.<sup>9</sup>

The Dialysis Star Ratings System and the ESRD QIP—the ESRD facility-level quality initiatives—will use different methods to calculate a facility's performance score. For the Star Ratings System, CMS will group the measures into three domains, calculate the average of the values for the measures in each domain, and then calculate the final score by averaging the domain scores. CMS will group final scores using a "bell-curve" method to assign each facility its star rating. Facilities with the top 10 percent of final scores will be given a 5-star rating, the next 20 percent will be given a 4-star rating, the middle 40 percent of final scores will be given a 3-star rating, the next 20 percent will be given a 2-star rating, and the lowest 10 percent of final scores will be given a 1-star rating. The ESRD QIP evaluates each facility's performance based on the combination of the facility's performance on improving on the care they furnish and exceeding national averages.

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<sup>8</sup> <http://blog.cms.gov/2014/06/18/star-quality-ratings-coming-soon-to-compare-sites-on-medicare-gov/>.

<sup>9</sup> Centers for Medicare & Medicaid Services. 2014. Dialysis facility compare star rating system. Medicare Learning Network. July10.

The measures used by both quality initiatives (as proposed) will vary. Of the nine “clinical measures” that the Dialysis Star Ratings System will use, seven of them are proposed for the PY 2018 QIP.<sup>10</sup> The PY 2018 QIP will not (as proposed) include the standardized mortality or hospitalization ratios that the star system will use. Unlike the PY 2018 QIP, the Dialysis Star Ratings System will not contain any “reporting measures.”

The differences in the methods and measures might result in a facility scoring high under one program and low under the other program. Beneficiaries and their families might be confused if a facility’s star and QIP scores diverge. CMS intends to post facilities’ star rating on the Dialysis Facility Compare website. The Medicare Improvements for Patients and Providers Act of 2008 requires each facility to post its QIP score in patient areas and the Secretary to post QIP scores on a CMS-maintained web site (currently Dialysis Facility Compare).<sup>11</sup>

We are also concerned that CMS intends to establish the Dialysis Star Ratings System beginning October 2014 without addressing public comments. CMS established the program through subregulatory guidance. Information about this program was presented during a July 2014 CMS-sponsored educational conference call, the Medicare Learning Network Connects™ National Provider Calls. During the conference call, CMS staff listened to comments from stakeholders but said that any comments they receive will be considered during next year’s process.<sup>12</sup>

We urge that CMS delay the implementation of the Dialysis Star Ratings System in order for the agency to issue a proposal to establish the system. In its proposal, CMS should describe why the agency believes a second quality measurement system for dialysis facilities—beyond the current QIP—is needed and address the comments they receive. The Commission believes the quality measurement process needs greater simplicity and clarity. Moving to two systems creates greater uncertainty. Furthermore, the Commission generally believes that the measurement of quality performance should be based on absolute standards rather than one calculated from the performance distribution. We believe this is fairer to providers and gives clearer targets for providers to meet. If CMS can establish the need for a Star Ratings System for dialysis facilities, the agency should then describe why it believes the measures in the QIP are an insufficient basis for establishing a Star Ratings Systems. The proposal will also give CMS an opportunity to provide an analysis of the correlation between the ratings calculated under the Dialysis Star Ratings System and the ESRD QIP and explain any discrepancies in measured facility performance between the two measures. Lastly, an open and transparent process will give beneficiaries, providers, and other members of the public the opportunity to submit comments to the agency’s proposal.

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<sup>10</sup> The Star Ratings Systems uses the following clinical measures: standardized transfusion ratio, standardized mortality ratio, standardized hospitalization ratio, adult hemodialysis adequacy, pediatric hemodialysis adequacy, adult peritoneal dialysis adequacy, hypercalcemia, use of AV fistula, and use of catheter.

<sup>11</sup> <http://www.medicare.gov/DialysisFacilityCompare/QIP/Total-Performance-Scores.html>.

<sup>12</sup> <http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/07-10-14-ESRD-FSR-Transcript.pdf>.

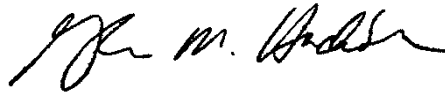


## Conclusion

The Commission appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. We also value the ongoing cooperation and collaboration between CMS and Commission staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth". The signature is fluid and cursive, with a large initial "G" and "H".

Glenn M. Hackbarth, J.D.  
Chairman

GMH/nr/wc