

August 6, 2015

Andrew Slavitt, Acting 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-1628-P

Dear Mr. Slavitt:

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, and Quality Incentive Program, Proposed Rules” published in the Federal Register, vol. 80, no. 126, pages 37807 to 37860. This proposed rule includes provisions that update the end-stage renal disease (ESRD) payment system for 2016 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.

We address the following issues concerning the proposed refinement of the payment adjustments under the ESRD prospective payment system (PPS):

- the model specification,
- including comorbid conditions as payment adjusters,
- the effect of separate adjustment factors for body surface area and body mass index,
- using unaudited cost reports, hospital-based cost reports, and data from 2012, and
- defining low-volume and rural adjustment factors.

We then address CMS’s proposed update to the calendar year (CY) 2016 ESRD PPS base payment rate and the proposed elimination of the reasonable compensation equivalent (RCE) limit for reporting an ESRD facility’s medical director fees on ESRD cost reports. Lastly, we comment on the proposed reporting measures for the ESRD QIP for payment years (PYs) 2018, 2019, and beyond.

Refinement to the ESRD PPS payment adjustment factors

The American Taxpayer Relief Act of 2012 required that the Secretary, no later than January 1, 2016, analyze the case-mix payment adjustments under the current ESRD PPS and make appropriate revisions to the adjustments. Based on new regression analyses of cost reports and claims data, CMS is proposing to revise the value of the adjusters used in the current PPS for: age, four comorbid conditions, body surface area, low body mass index, time since onset of dialysis (less than four months), and facility low-volume status. CMS also is proposing to remove two comorbid adjusters that are used in the current PPS, modify the definition of a low-volume facility, and add a new adjuster for ESRD facilities located in rural areas.

Payment adjuster	Current value	Proposed value
Age		
18-44	1.171	1.257
45-59	1.013	1.068
60-69	1.000	1.070
70-79	1.011	1.000
80+	1.016	1.109
Body surface area (per 0.1 m ²)	1.020	1.032
Underweight (body mass index < 18.5 kg/m ²)	1.025	1.017
Time since onset of dialysis (< 4 months)	1.510	1.327
Comorbidities		
Pericarditis	1.114	1.040
Gastrointestinal tract bleeding	1.183	1.082
Bacterial pneumonia	1.135	--
Hereditary hemolytic/sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	--
Facility low-volume status	1.189	1.239
Facility rural status	--	1.008

Note: Payment adjustment factors, age 18 and older. Source: Center for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Medicare program; End-stage renal disease prospective payment system, and quality incentive program. Proposed rule. *Federal Register* 80, no. 126 (July 1): 37807–37860.

The model specification

CMS is proposing to refine the payment adjustment factors using a two-equation regression methodology similar to the one used for 2011, the first year of the ESRD PPS. The two-equation methodology includes:

- A facility-level regression model that uses 2012 and 2013 ESRD cost reports. For independent (i.e., freestanding) and hospital-based facilities, the dependent variable is equal to the average cost per treatment for composite rate services.
- A patient-level regression model that uses 2012 and 2013 dialysis facility claims. For both facility types, the dependent variable is equal to the estimated average payment per patient for ESRD-related drugs and laboratory services. To derive the average payment per patient for previously separately billable services, CMS multiplied the resource use of such

services (e.g., drugs) reported on claims by the appropriate Medicare payment rate (e.g., average sales price plus 6 percent).

The Commission is concerned about continuing to use a two-equation model to estimate adjustment factors:

- The costs associated with separately billable services may be included in the cost centers that are used to derive the dependent variable—composite rate cost per treatment—for the facility-level regression.¹ The dependent variable for the patient-level regression is the payment per treatment for separately billable services. To combine facility- and patient-based estimates for a given variable, CMS weights each estimate by the proportion of cost or payment represented by the dependent variable in each regression, and then multiplies the two weighted estimates together to produce a final adjustment factor. If separately billable services are included in the dependent variable for both regressions, the weights will not accurately distinguish the relative cost or payment addressed by each regression.
- Multiplying factors from the facility- and patient-level regressions (with different bases) may diminish the accuracy of the combined factors. The distribution of average treatment cost across facilities is quite likely different than the distribution of payments for separately billable services across patients, and combining the two factors estimated on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment.
- Through various revisions of the model, the empirically-determined lowest-cost reference population for age category variables has shifted from ages 45 to 59 in the proposed rule for the CY 2011 PPS, to ages 60 to 69 in the final rule for the CY 2011 PPS, and now ages 70 to 79 in the proposed rule for the CY 2016 PPS. We would expect the relative cost of dialysis treatment across age categories to remain relatively stable over time, and are concerned that such shifts indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. The two-equation approach might contribute to these results.

CMS should develop payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle. Medicare has reimbursed dialysis facilities based on a single bundled rate since 2011. Given the availability of cost data for the full PPS payment bundle, it is no longer necessary to use pre-bundle service categories when developing the adjustment factors. We understand it may not be feasible to develop factors based on a single-equation model for CY 2016, but expect to see such a change in a future revision.

Finally, CMS should report all regression coefficients, including those for the control variables, from both the facility- and patient-based regressions, and should explain the calculation of the

¹ For example, the cost report instructions in CMS's Provider Reimbursement Manual for independent facilities states that the cost center for dialysis supplies includes supplies covered under the composite rate payment and separately billable supplies.

weights used to combine factors from each regression. This level of transparency is necessary to assess the validity and understand the relative importance of each aspect of the model.

Including comorbid conditions as payment adjusters

CMS has proposed to drop two of the six comorbidity adjustments (bacterial pneumonia and monoclonal gammopathy) that are used in the current ESRD PPS because of: (1) the burden on patients to undergo clinical testing to meet CMS's documentation requirements, (2) differences between CMS's requirements and the diagnostic practices of Medicare providers, and (3) stakeholder concerns about the burden associated with meeting the documentation requirements. CMS proposed to continue using the following four comorbidity adjusters: pericarditis, gastrointestinal tract bleeding with hemorrhage, myelodysplastic syndrome, and hereditary hemolytic/sickle cell anemias.

The Commission agrees with CMS's proposal to remove the two comorbidity factors given the differences between CMS's requirements and the diagnostic practices of Medicare providers and the burden on dialysis patients to undergo additional diagnostic procedures to meet Medicare's documentation requirements.

CMS should consider removing all comorbidity adjustment factors from the case-mix model because the comorbid conditions may result in undue burden on patients required to undergo additional diagnostic procedures for payment adjustment, are poorly identified on dialysis claims, and reflect only differences in the cost of separately billable services. It is not clear that differences in diagnostic requirements or in levels of burden for dialysis patients are unique to the two comorbidity factors that CMS has proposed to remove. Diagnostic requirements for the other comorbidity factors may include invasive imaging and bone marrow aspiration or biopsy.

Comparing the prevalence of each comorbidity reported on 2013 dialysis facility claims with the prevalence of each comorbidity reported on 2013 physician (carrier) and inpatient and outpatient hospital claims, we found that claims submitted by dialysis facilities do not accurately identify the presence of each comorbidity. The two comorbidities that CMS is proposing to remove were only identified on dialysis facility claims 11 percent (bacterial pneumonia) and 44 percent (monoclonal gammopathy) of the time they were identified on 2013 physician, inpatient, and outpatient hospital claims. The other four comorbidities were identified on dialysis facility claims 19 percent (pericarditis), 25 percent (gastrointestinal tract bleeding with hemorrhage), 36 percent (myelodysplastic syndrome), and 47 percent (hereditary hemolytic/sickle cell anemias) of the time they were reported on 2013 physician, inpatient, and outpatient hospital claims.

The poor identification of each comorbidity on dialysis facility claims has two implications. First, the adjustment factors may not be estimated accurately as costs associated with unreported comorbid conditions are not identified. In the proposed rule, each comorbidity was assigned a factor of exactly 1.000 in the facility-level regression indicating that these factors are only estimated based on differences in separately billable services.² To the extent that comorbid

² In the proposed and final rules for the CY 2011 ESRD PPS, CMS stated that when a variable is found to either lack statistical significance or lack stability over time, it is assigned a value of 1.000 for the purpose of estimating final adjustment factors.

conditions were not identified when estimating the adjustment factors, related costs would be incorporated into the base payment rate. Second, dialysis treatments were often not paid with a comorbidity adjustment when a comorbidity was present (according to physician and hospital claims).³ To the extent that unreported comorbid conditions increase the cost of treatment above the dialysis base rate, those costs are currently borne by the facility and the outlier payment pool.

The Commission supports the principle that case-mix adjustment should be implemented when identifiable exogenous factors affect the cost of treatment. However, the ESRD PPS already accounts for unreported comorbid conditions in the base rate and addresses high costs for separately billable services through the outlier payment policy.

The effect of separate adjustment factors for body surface area and body mass index

CMS is proposing to continue to adjust the base payment rate for body surface area (BSA) and low body mass index (BMI) using two separate adjustment factors. For BSA, CMS applies a formula that increases payment when patient BSA is larger than average, and decreases payment when patient BSA is smaller than average, providing adjustments of greater magnitude for patient BSA values further from the mean. For low BMI, CMS applies a single adjustment that increases payment by 2.5 percent when BMI is less than 18.5 kg/m², the value below which may indicate malnutrition. The Commission is concerned about the potential interaction between these two variables:

- Because BSA and BMI are calculated based on patient height and weight, their values are correlated such that patients with low BMI also have low BSA. For patients with low BMI, CMS applies an adjustment factor that increases payment by 2.5 percent; however, those patients tend to have BSA values less than the average, for which CMS applies an adjustment factor that decreases payment.
- The proposed adjustment factors do not accurately account for the inherent correlation between patient BMI and BSA. CMS has not stated exactly how each variable is incorporated in the facility- and patient-based regression models; however, the BSA adjustment factor is empirically estimated only in the facility-based regression, while the low BMI adjustment factor is estimated only in the patient-based regression.⁴ This specification does not address the joint effect of patient BSA and BMI in each regression.

Our analysis of 2013 freestanding ESRD cost reports indicates that BSA and low BMI jointly affect cost per treatment. In a facility-based regression, we defined the dependent variable as the average cost per treatment (for services included in the PPS payment bundle), included the same independent and control variables as the CMS model, and specified a set of BSA variables to take into account the distribution of patient BSA values at each facility, thus allowing us to assess the joint effect of low BMI and BSA. With this specification, we found that the low BMI factor is statistically significant and increases payment by enough to offset reductions in payment resulting from low BSA.

³ Our analysis of 2013 dialysis facility claims found that the four remaining comorbidity factors were only used as payment adjusters for 0.1 to 0.5 percent of Medicare dialysis treatments.

⁴ The BSA factor in the patient-based model and the low BMI factor in the facility-based model are listed as 1.000.

To account for this correlation, CMS should refine the low BMI and BSA adjustment to reflect the factors' joint effect on facility costs. One method could be to continue applying the same adjustment for BSA when patient BMI values are 18.5 kg/m² or greater, but for BMI values less than 18.5 kg/m², apply a single adjustment factor that takes into account the joint effect of patient BSA and low BMI. Our preliminary analysis suggests that a joint BSA and low BMI adjustment factor would be about 1.02 to 1.03.

Using unaudited cost reports, hospital-based cost reports, and data from 2012

We have three concerns about CMS's use of 2012 and 2013 unaudited cost reports and claims from hospital-based and freestanding dialysis facilities. First, we are concerned about using unaudited cost reports because historically, facilities' reports have included costs that Medicare does not allow. Based on the Commission's recommendation, the Protecting Access to Medicare Act of 2014 funded CMS to audit a representative sample of ESRD facility cost reports beginning in 2014. Although audited cost report data would better capture the most recent trends in ESRD facility costs than unaudited reports, we recognize that CMS is not yet finished with the mandated audit. Once audited data are available, the Commission urges CMS to report on whether there are differences in the payment adjustment factors that are derived from pre- versus post-audited data.

Second, we are concerned about using hospital-based cost reports to derive the payment adjustment factors. There is no guarantee of consistency in the methods used to allocate hospital costs to dialysis departments and to dialysis cost categories. CMS has said that expense data for hospital-based cost reports reflect the allocation of overhead over the entire institution, and that the expenses of each hospital-based component may be skewed.⁵ The inclusion of hospital-based cost reports likely increases statistical noise in the regression model. CMS should consider either: (1) not including hospital-based cost report data to derive the payment adjusters; or (2) reporting on the effect of including the hospital-based reports on the adjusters.

Third, data from 2012 may not reflect current practice patterns particularly with the use of ESRD-related drugs. During 2012, the second year in which dialysis facilities were paid based on the ESRD PPS bundle, dialysis drug use continued to decline. CMS should consider using data from 2013 and beyond to update the payment adjusters. Using only 2013 data would ensure better the accuracy of the payment adjusters.

Defining low-volume and rural adjustment factors

A low-volume facility would continue to be defined as one that: (1) provides fewer than 4,000 treatments in each of the three years before the payment year and (2) has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. CMS is proposing to revise the distance criterion that is used to determine eligibility for the low-volume payment adjustment by:

⁵ Center for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare program, End-stage renal disease prospective payment system, quality incentive program, and durable medical equipment, prosthetics, orthotics, and supplies. Proposed rule. *Federal Register* 79, no. 133 (July 11): 40207–40315.

- Including, for the purposes of determining a facility's eligibility, treatments furnished by the facility in question and other facilities under common ownership that are within 5 road miles from the facility in question. Under the current PPS, a 25-mile criterion is applied.
- Applying the proposed 5-mile distance criterion to all facilities (regardless of when a facility was certified by Medicare). Under the current PPS, the 25-mile distance criterion only applies to facilities certified on or after January 1, 2011.

In addition to adjusting payment for low treatment volume, CMS is proposing to add a new payment adjuster for all facilities located in a rural area, regardless of a facility's geographic proximity to the closest facility and treatment volume. A rural area would be defined as any area outside of an urban area.⁶ The proposed low-volume and rural adjustments are separate, meaning that a facility meeting both criteria would receive both payment adjustments.

The Commission is concerned that neither the low-volume adjustment nor the rural adjustment are targeting facilities that are critical to beneficiary access:

- The proposed low-volume adjustment only imposes a distance requirement for facilities under common ownership. According to our analysis, about 47 percent of the facilities that would receive the proposed low-volume adjustment are within 5 miles of the next closest facility.⁷ The median distance between the facility that would receive the proposed adjustment and the next closest facility is six miles. Eleven facilities that would receive the proposed adjustment have the same street address as another facility (according to Dialysis Facility Compare).
- The rural adjustment does not impose a distance requirement between a facility that would receive this adjustment and the next closest facility. About 28 percent of all rural facilities are within 5 miles of the next closest facility. We are also concerned that the rural adjustment does not consider facilities' total treatment volume. Nearly 20 percent of facilities located in rural areas are high-volume, and total volume is correlated with cost per treatment.⁸ Using 2013 cost reports submitted by freestanding ESRD facilities and CMS's impact file, high-volume facilities located in rural areas had lower total adjusted cost per treatment than low-volume facilities located in rural areas (median cost of \$239 per treatment and \$312 per treatment, respectively). (This analysis defined total cost as all services in the PPS payment bundle, and adjusted total cost per treatment to remove differences in the cost of labor.) Thus, the fact that the facilities are designated as rural does not in and of itself indicate that these facilities warrant special payment adjustments in order to ensure access to care. These findings suggest that there is great diversity among areas designated as rural.

⁶ Urban areas are Metropolitan Statistical Area (MSA) or a Metropolitan division (in the case where an MSA is divided into Metropolitan Divisions).

⁷ The low-volume and rural analyses used CMS's facility-level impact file for the CY 2016 proposed ESRD rule, 2013 Dialysis Facility Compare file, 2013 freestanding dialysis facility cost reports, and 100 percent 2013 claims from freestanding and hospital-based dialysis facilities. These analyses included facilities located in the 50 states and Washington, DC.

⁸ For this analysis, high-volume facilities were defined as those that furnished 10,000 or more treatments (Medicare and non-Medicare) and low-volume facilities were those that furnished fewer than 4,000 treatments.

The Commission recommends that CMS design a single payment adjustment that targets low-volume isolated providers instead of two separate adjustments for low volume and rural location. Dialysis beneficiaries and Medicare would be better served by a single adjuster that targets low-volume facilities that are not close to another facility. In our March 2014 report, we said that only low-volume ESRD facilities that are necessary to maintain access—those located in isolated areas—should receive enhanced payment, and recommended that the Congress direct the Secretary to redesign the low-volume payment adjustment to consider a facility’s distance to the nearest facility.⁹ In our June 2012 report¹⁰ (which CMS cites in the proposed rule), we said that:

- Payments should be targeted toward low-volume isolated providers—that is, providers that have low patient volume and are at a distance from other providers. Distance is required because supporting two neighboring providers who both struggle with low volume can discourage mergers that could lead to lower cost and higher quality care.
- The magnitude of special rural payment adjustments should be empirically justified—that is, the payments should increase to the extent that factors beyond the providers’ control increase their costs.
- Finally, rural payment adjustments should be designed in ways that encourage cost control on the part of providers.

As suggested by the Government Accountability Office, CMS should consider designing an adjustment that does not give facilities an incentive to limit services to avoid reaching the low-volume treatment threshold (the so-called cliff effect).¹¹ A payment approach that decreases the payment adjustment as facility volume increases might reduce this incentive.

Update to the CY 2016 ESRD PPS base payment rate

CMS is proposing to update the CY 2015 base payment rate based on the market basket increase factor (of 2.0 percent) less an adjustment for productivity of (0.6 percent) and 1.25 percentage points. The Protecting Access to Medicare Act of 2014 mandated the 1.25 percentage point reduction to the update of the base rate in CYs 2016 and 2017.

Comment

Our most recent analysis of the adequacy of Medicare’s payments to dialysis facilities found that outpatient dialysis payments are adequate. Most of our indicators of payment adequacy are positive, including beneficiaries’ access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. Based on this analysis, the Commission

⁹ Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

¹⁰ Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC: MedPAC.

¹¹ U.S. Government Accountability Office. 2013. *End-stage renal disease: CMS should improve design and strengthen monitoring of low-volume adjustment*. GAO-13-287. Washington, DC: GAO.

recommended that the Congress eliminate the update to the outpatient dialysis payment rate for CY 2016.¹²

Reporting medical director fees on ESRD facility cost reports

Beginning in CY 2016, CMS is proposing to eliminate the Reasonable Compensation Equivalent (RCE) limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. CMS established the CY 2015 RCE limit at \$197,500 per year (for a board-certified physician of internal medicine). According to CMS, RCE limits are generally used when determining payment for providers paid on a reasonable cost basis and the limits are no longer necessary because all ESRD facilities are paid under the ESRD PPS.

Comment

The goal of Medicare payment policy is to obtain good value for the program's expenditures, which means encouraging efficient use of resources while maintaining beneficiaries' access to high-quality services. The RCE limit on the medical director compensation creates pressure on facilities to constrain their compensation costs (to the extent possible) and make better use of beneficiaries' and taxpayers' resources. Eliminating the RCE limit may decrease some facilities' negotiating leverage with prospective medical directors, which, in turn, will lead to increased compensation costs. As providers' costs increase, all other things being equal, the resulting Medicare margin will decrease.

Therefore, the Commission urges CMS to maintain a limit for reporting an ESRD facility's medical director fees on ESRD facility cost reports. Options for CMS to consider include: (1) maintaining the current RCE equivalent limits or (2) adopting a limit used by other Executive branch agencies, such as the Title 38 Physician and Dentist Pay used by the Department of Health and Human Services (HHS).¹³ HHS uses five pay tables that are each arrayed into four tiers based on the management role of the physician or dentist in the covered clinical specialties. For example, HHS's Title 38 physician and dentist pay table 2 includes nephrology as a covered clinical specialty and the pay range for the most senior management level is \$140,000 to \$250,000.

The ESRD Quality Incentive Program

In PY 2019, the eighth year of the QIP, CMS would use a total of 15 measures, of which 8 are "clinical measures" that assess the outcome of care processes and 7 are "reporting measures." In PY 2019, CMS is proposing to

- Replace the four dialysis adequacy measures for adults and pediatrics used in PY 2018 with one clinical measure to assess dialysis adequacy; and
- Add two new reporting measures on the rate of hemodialysis ultrafiltration and influenza vaccination status.¹⁴

¹² Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

¹³ Instruction 590-1: Title 38 Physician and Dentist Pay. <http://www.hhs.gov/asa/ohr/manual/files/590-1-00.html>.

¹⁴ The ultrafiltration rate measures the rapidity with which fluid is removed at dialysis per unit body weight in unit time.

The following table summarizes the measures proposed for PY 2019:

Measure	Measure type	Payment year measure used
<u>Low dialysis adequacy</u> Kt/V measure for all patients	Clinical	Proposed for PY 2019
<u>Anemia management</u> Anemia management reporting measure Standardized transfusion ratio	Reporting Clinical	PY 2018 measure PY 2018 measure
<u>Vascular access type</u> Use of AV fistulas Use of catheters	Clinical Clinical	PY 2018 measure PY 2018 measure
<u>Hypercalcemia</u>	Clinical	PY 2018 measure
<u>Standardized readmission ratio (SRR)</u>	Clinical	PY 2018 measure
<u>NHSN blood stream infection in hemodialysis outpatients</u>	Clinical	PY 2018 measure
<u>ICH CAHPS survey (patient experience)</u>	Clinical	PY 2018 measure
<u>Mineral metabolism</u>	Reporting	PY 2018 measure
<u>Clinical depression screening and follow-up</u>	Reporting	PY 2018 measure
<u>Pain assessment and follow-up</u>	Reporting	PY 2018 measure
<u>NHSN healthcare personnel influenza vaccination</u>	Reporting	PY 2018 measure
<u>Ultrafiltration rate</u>	Reporting	Proposed for PY 2019
<u>Influenza vaccination (patient status)</u>	Reporting	Proposed for PY 2019

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).

Comment

In last year’s final rule, CMS adopted a reporting measure on the influenza-vaccine status of healthcare personnel—the National Healthcare Safety Network Healthcare Personnel Influenza Vaccination Reporting Measure—for PY 2018 and future years. We believe that all healthcare personnel, especially those dealing with immunologically vulnerable patients, must be immunized annually against influenza, unless the worker has a medical contraindication to the vaccine. Given the importance of this measure, we urge the agency to adopt the clinical version of this measure as soon as possible.

For the PY 2019, CMS is proposing to adopt an “ultrafiltration rate” measure and a “full-season influenza vaccination” reporting measure. Both measures require facilities to report to CROWNWeb qualifying patients’ ultrafiltration rate (once per month) and influenza vaccination status (once per performing period). CMS also is expecting that facilities will retain patient influenza immunization for their own records.

We understand the importance of these measures. According to CMS, higher hemodialysis ultrafiltration rates and lower influenza vaccination rates are associated with increased risk of

mortality. CMS cites data (from United States Renal Data System (USRDS)) that rates of seasonal influenza vaccination for ESRD beneficiaries have historically been lower than the Healthy People 2020 goal of 70 percent. According to USRDS, the rate of seasonal influenza vaccination for the most recent influenza season (2011-2012) that data are available was 72 percent for hemodialysis beneficiaries, 68 percent for peritoneal dialysis beneficiaries, and 51 percent for transplant beneficiaries.¹⁵

However, we are chiefly concerned about the continued reliance and proliferation of reporting measures, i.e., measures that rely on clinical process measures for assessing quality of care. We also are concerned that the influenza vaccination measure overlaps with Medicare's condition for coverage for ESRD facilities, which requires that facilities' quality assessment and performance improvement efforts include the development of recommendations to promote immunization, and the potential documentation burden this measure would impose on facilities.

Our standing position on quality measures is that CMS should use clinical risk-adjusted measures that capture the effective management of dialysis patients, such as the standardized hospitalization ratio (SHR) or the standardized mortality ratio. The agency previously considered but did not adopt either measure for the PY 2014 ESRD QIP.¹⁶ In a subsequent rule, CMS said that it would consider the SHR for future payment years, possibly beginning with the PY 2018 program.¹⁷ Both measures are included in the Dialysis Facility Compare star ratings.

Finally, 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.

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.

¹⁵ United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2014. *USRDS 2014 annual data report* (figure 3.12). Bethesda, MD: NIDDK.

¹⁶ 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.

¹⁷ 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.

Andrew Slavitt
Acting Administrator
Page 12

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 that reads "Francis J. Crosson M.D." The signature is written in a cursive style with a large initial 'F' and a distinct 'M.D.' at the end.

Francis J. Crosson, M.D.
Chairman

FJC/nr/wc