

August 31, 2018

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

**Re: File code CMS-1691-P**

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS" in the *Federal Register*, vol. 83, no. 139, p. 34304–34415 (July 19, 2018). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2019, updates the payment rate for individuals with acute kidney injury (AKI) when furnished in dialysis facilities, addresses the ESRD Quality Incentive Program (QIP), and revises the DMEPOS CBP. 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 ESRD-related comments address provisions in the proposed rule about:

- Revisions of the drug designation process,
- The ESRD PPS's comorbidity adjustment,
- The ESRD PPS's outlier policy,
- The ESRD PPS's wage index, and
- The ESRD QIP.

In addition, we reiterate our prior comments about the accuracy of the cost reports that dialysis facilities submit to CMS, the ongoing CMS audit, and the Dialysis Star Ratings System.

Lastly, we comment on several aspects of CMS's proposals to revise the CBP and adjust the DMEPOS fee schedule.

### **Revision of the drug designation process**

In the final rule for the ESRD PPS implemented in 2011, CMS categorized drugs and biologics (hereafter referred to as “drugs”) reported on ESRD facility claims into one of eleven functional categories,<sup>1</sup> and then used the definition of renal dialysis services (including drugs) from the Social Security Act to distinguish functional categories as always, sometimes, or not ESRD-related.<sup>2</sup> The functional categories that include drugs that are always or sometimes ESRD-related have been included in the ESRD PPS bundle since 2011.

The functional categories were defined to include drugs that were, before 2011, formerly paid under the prior ESRD payment system's prospective payment—the composite rate—and ESRD-related drugs that were separately billable (e.g., erythropoietin stimulating agents (ESAs)). In other words, all drugs in the ESRD bundle fit into a functional category. Under current policy, drugs that are formerly separately billable are eligible for outlier payment, but drugs and services formerly included in the composite rate are not eligible for outlier payment. Although the functional categories define the set of drugs in the PPS payment bundle, the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008—which broadened the composite rate payment bundle to include dialysis drugs, laboratory tests, and other dialysis-related services that were previously separately billable—did not require a policy to incorporate newly approved renal dialysis drugs into the PPS.

The Protecting Access to Medicare Act of 2014 (PAMA) required that CMS develop policies to determine how certain new dialysis drugs and biologics are incorporated into the PPS payment bundle. Under the current drug designation process:

- If the new injectable or intravenous product is used to treat a condition for which there is an ESRD-related functional category, the drug is included in the PPS payment bundle. CMS does not pay providers separately for the product nor does the agency modify the ESRD PPS base rate. The new drug is eligible for outlier payments. In addition, CMS uses the ESRD market basket, which accounts for price changes of the drugs reflected in the base rate, in the annual update process of the PPS base rate.
- If the new injectable or intravenous product does not fit into an ESRD-related functional category and has a billing (Healthcare Common Procedure Coding System (HCPCS)) code, then the drug is eligible for a transitional drug add-on payment adjustment (TDAPA) for at least two years, until ESRD use and spending data are available. CMS

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<sup>1</sup> The ESRD PPS functional categories are: access management; anemia management; bone and mineral metabolism; cellular management; antiemetic; anti-infectives; antipruritic; anxiolytic; excess fluid management; fluid and electrolyte management including volume expanders; and pain management.

<sup>2</sup> Center for Medicare and Medicaid Services, Department of Health and Human Services. 2010. Medicare program; End-stage renal disease prospective payment system. *Federal Register* 75, no. 155 (August 12): 49047-49053.

bases the TDAPA on the average sales (ASP) price plus 6 percent, or the wholesale acquisition cost (WAC) if ASP data are not available. When the TDAPA ends, CMS includes the drug in the PPS payment bundle (through a modification to the ESRD-related functional categories or by adding a new category), modifies the PPS base rate (to reflect changes to the functional categories), and considers the drug for outlier payments.

In the proposed rule, CMS states the current drug designation policy hinders high-value innovation and prevents the uptake of innovative new products. CMS is therefore proposing revisions with the goal of allowing manufacturers of new drugs and biologics to gain a “foothold” in the existing market for dialysis drugs and help facilities test and potentially transition to new drugs and biologics in their clinical operation. No later than January 1, 2020, CMS is proposing to expand the drug designation process for drugs and biologics that the Food and Drug Administration (FDA) approves on or after January 1, 2019:

- The drug designation process would apply to all new dialysis drugs, not just new injectable and intravenous products. Under current law, oral-only drugs and biologics are excluded from the PPS payment bundle until 2025 or when the FDA approves an injectable or intravenous-equivalent product.
- The drug designation process would apply to new dialysis drugs with a HCPCS code application submitted, regardless of whether a HCPCS code has been assigned.
- New dialysis drugs that fit into an ESRD-related functional category, including composite rate drugs, would receive the TDAPA for two years. After two years, the new drug would be included in the PPS payment bundle, but there would be no modification to the base rate as there would be no changes to the functional categories.
  - Consistent with the current outlier policy, new renal dialysis drugs that are considered to be composite rate drugs would not be eligible for calculation of outlier payments, but other new renal dialysis drugs would be included in the outlier payment calculation.
  - However, CMS has requested comment on whether the outlier policy should be expanded to include all composite rate drugs and supplies, including composite rate drugs that would receive the TDAPA under the proposed policy (on which we comment in the next section).

Finally, CMS is proposing to change the basis for the TDAPA to ASP plus 0 percent (i.e., ASP with no percentage add-on) for all drugs approved by the FDA after January 1, 2019. If ASP data are not available, then CMS proposes to use WAC or the manufacturer’s invoice price. Currently, calcimimetics are the only products receiving the TDAPA and would continue to be paid at ASP plus 6 percent.

*Comment*

The Commission believes that it is important to maintain the structure of the ESRD PPS and not create policies that would unbundle services covered under the ESRD PPS or create incentives that encourage high launch prices of new drugs and technologies. Access to new dialysis products is favorable under the ESRD PPS. For example, in 2015, nearly one-quarter of all dialysis beneficiaries received epoetin beta, which was introduced to the U.S. market in that year. Indeed, in the proposed rule, the agency states that “...the drug designation process does not prevent ESRD facilities from furnishing available medically necessary drugs and biologics to ESRD beneficiaries. Additionally, our position has been that payment is adequate to ESRD facilities to furnish new drug and biologics that fall within existing ESRD PPS functional categories.”

Consequently, CMS should not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into a functional category (including composite rate drugs, which have never been paid separately by Medicare) for the following reasons:

1. Although new dialysis drugs could improve patient outcomes, the proposal does not require that the new drugs be more effective than current treatment to qualify for the TDAPA. Under CMS’s proposal, the only proposed standard for paying the TDAPA is that a drug is new.
2. Paying the TDAPA for new dialysis drugs that fit into a functional category would be duplicative of the payment that is already made as part of the ESRD bundle. Beneficiaries and taxpayers already pay for drugs in each functional category because they are included in the ESRD PPS payment bundle. Essentially, the TDAPA policy proposes to make a second (duplicative) payment for new drugs that treat the same clinical condition as drugs already included in the payment bundle.
3. Applying the TDAPA to new dialysis drugs that fit into a functional category undermines competition with existing drugs included in the PPS payment bundle. By bundling drugs with similar function together, CMS encourages providers to make decisions about each drug’s clinical effectiveness for individual patients while also attempting to constrain costs. The Commission has documented the changes in drug use due to increased price competition with the vitamin D and ESA therapeutic classes.<sup>3</sup> The TDAPA proposal would unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices. Under the proposal, after the two-year TDAPA period concluded, the new, potentially high-priced dialysis drugs would be included in the PPS payment bundle and could thereby further increase dialysis spending through the periodic process of rebasing the market basket index.

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<sup>3</sup> Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

4. The proposed policy would increase spending for beneficiaries and taxpayers, as CMS acknowledges. However, the proposed rule did not include an estimate of expected spending changes in the “detailed economic analysis” section.

We strongly disagree with CMS’s proposal to pay separately for all new dialysis drugs (including composite rate drugs) that fit into a functional category under the TDAPA for two years and urge CMS to withdraw the proposal. However, if CMS decides to proceed with this proposed policy, we believe at a minimum several modifications to the proposal are necessary:

- CMS should require that the new product be an advance in medical technology that substantially improves beneficiaries’ outcomes relative to technologies in the PPS payment bundle. CMS could structure such a policy similar to the standard that the agency uses to pay for new technologies under the inpatient PPS and devices under the outpatient PPS.
- CMS should not make duplicative payments for a new product (assigned to a functional category) by paying under the TDAPA for two years and paying for its functional category under the ESRD PPS base rate. For example, the agency could reduce the TDAPA amount to reflect the amount already included in the base rate. In addition, CMS could consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices.
- CMS should publish in the final rule an estimate of the increase in beneficiaries’ and taxpayers’ spending due to the proposed policy change and the method used to develop the estimate.
- CMS should apply the proposed policy only to new dialysis drugs that have been assigned a HCPCS code. Applying the proposed policy to new drugs that have not been assigned a HCPCS code could undermine the HCPCS process and could result in overpayments by beneficiaries and taxpayers for a drug that the CMS HCPCS workgroup concludes fits into an existing HCPCS code. If CMS proceeds with this proposal, the agency should establish a policy for addressing situations in which an application does not lead directly to the assignment of a new HCPCS code.

Although the Commission does not support the proposal to pay separately for all new dialysis drugs that fit into a functional category, we believe there is good rationale for CMS’s proposal to change the basis for the TDAPA from ASP plus 6 percent to ASP with no percentage add-on. The ASP plus 6 percent policy was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. While the policy never stated what cost the “+6 percent” was intended to cover, we note that applying the policy to dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians’ purchasing power, whether they practice solo, as part of a group, or in a health system, is likely

to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the “+6 percent” was to address acquisition price variation, we believe that rationale is diminished for dialysis facilities. Second, we note that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, if the intent of the “+6 percent” was to address storage and administration costs, we believe these costs are already addressed through the ESRD bundle and do not contribute to the rationale for paying ASP plus 6 percent for the TDAPA. Overall, the proposal to change the basis of the TDAPA to ASP with no percentage add-on appears to be well founded.

### **The ESRD PPS’s comorbidity adjusters**

The agency is proposing to eliminate the requirement that ESRD facilities obtain results from specific diagnostic tests in order to qualify for the four comorbidity payment adjustments. According to the proposed rule, this change is motivated by:

- Stakeholders’ challenges in obtaining the required documentation to report specific diagnosis codes (in order to obtain the comorbidity payment adjustments), and
- The documentation requirements of the ESRD PPS are more rigorous than the documentation requirements used for other CMS payment systems, which generally rely on the ICD Official Guidelines for Coding and Reporting.

CMS is proposing to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. The agency is not proposing to remove the four comorbidity adjustment factors from the ESRD PPS.

### *Comment*

In our 2015 comments on the ESRD PPS proposed rule for calendar year (CY) 2016, we supported the agency’s proposal to remove two comorbidity adjusters, 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.<sup>4</sup>

The Commission supports the principle that case-mix adjustment should be implemented when identifiable exogenous factors affect the cost of treatment. However, we continue to believe that CMS should consider removing all comorbidity payment adjustments that are used in the current ESRD PPS because these adjustment factors may not be estimated accurately. A MedPAC analysis showed that the comorbid conditions are poorly identified on dialysis claims and reflect only differences in the cost of dialysis services that used to be separately billable.<sup>4</sup> To the extent

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<sup>4</sup> Medicare Payment Advisory Commission. 2015. Comment letter on CMS’s proposed notice entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program, Proposed Rules.” August 6.

that unreported comorbid conditions increase the cost of treatment above the ESRD PPS base rate, those costs are currently borne by the facility and the outlier payment pool.

Our chief concern is that the ESRD PPS's patient- and facility-level adjustment factors may not be estimated accurately because CMS used a two-equation model to derive them. The agency's model is comprised of (1) a facility-level regression analysis of ESRD cost reports to determine average cost per treatment for composite rate services; and (2) a patient-level regression model of dialysis facility claims to determine average payment per patient for ESRD-related drugs and laboratory services that were separately billable prior to 2011. Multiplying factors from each regression model with different bases may diminish the accuracy of the final (combined) factors. We believe that the two-equation approach may have contributed to shifting the lowest-cost reference population for the age category over various revisions of the ESRD PPS. We also have raised concerns that the two-equation approach generates factors that were found to be significant in only one of the regressions, based on either the facility-level or patient-level regression. For example, the comorbidity adjusters are found to be significant only in the patient-level regression, yet the final factor combines the results from both regressions. In addition, the current adjustment factors for body surface area and body mass index do not accurately account for the inherent correlation between these two factors, as one is based solely on the patient-level regression and the other is based solely on the facility-level regression.

Consequently, the Commission continues to believe that CMS should develop patient- and facility-level payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle. Medicare has paid ESRD facilities based on a single bundled rate since 2011.<sup>4</sup> 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.

### **The ESRD PPS's outlier policy**

CMS is seeking comments on expanding the ESRD PPS's outlier policy to include composite rate drugs and supplies (i.e., drugs and supplies that were covered under the ESRD payment system's bundle prior to 2011). The current policy provides outlier payments only for dialysis-related drugs, biologics, laboratory tests, and medical/surgical supplies (used to administer dialysis drugs) that, prior to 2011, were or would have been separately billable under Part B and dialysis-related drugs that, prior to 2011, were or would have been covered under Part D. According to CMS, expanding the outlier policy to include composite rate drugs and supplies could promote: (1) appropriate payment for composite rate drugs after the conclusion of the proposed two-year TDAPA period and (2) the use of new innovative devices and items that would otherwise be considered in the bundled payment.

#### *Comment*

MIPPA mandated a payment adjustment for high-cost outliers "due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis

stimulating agents necessary for anemia management.” A high-cost outlier policy should be designed to help ensure access to care for high-cost patients while protecting providers that treat them from high losses. That is, an outlier policy should act as a stop-loss insurance for medically necessary care.

Outlier payments are needed when the PPS’s payment adjustments do not capture all of the factors that may affect providers’ costs of delivering care. For example, higher costs may be triggered by the occurrence of random events, such as patients who suffer serious complications, and would appropriately trigger an outlier payment. Consequently, to develop an effective outlier policy, the agency must first develop accurate patient- and facility-level payment adjustments (as discussed in the prior section).

CMS should develop an outlier policy that accounts for variation in the cost of providing the full PPS payment bundle; the outlier policy should not apply solely to exceedingly high costs of ESRD drugs and supplies. Considering the full ESRD PPS payment bundle would be more patient-centric and would align the ESRD PPS outlier policy with the policies that Medicare uses for other PPSs.

If CMS elects to expand the outlier pool only for composite rate drugs and supplies, then the agency should explicitly define which supplies would be eligible for an outlier payment. In addition, the agency should develop clinical criteria for the use of all drugs and supplies that are eligible for outlier payments to ensure their appropriate (medically necessary) use.<sup>5</sup>

Expanding the outlier policy may require the agency to impose additional reporting requirements on facilities in order to determine patient-level costs. If the agency elects to expand the outlier policy, then it should minimize the administrative burden on providers and include a mechanism for validating the additional data that are collected.

### **The ESRD PPS’s wage index**

To account for wage-level differences in areas in which ESRD facilities are located, CMS adjusts the labor-related share of the ESRD PPS base payment rate using the most current hospital wage data.<sup>6</sup> Beginning in CY 2019, CMS is proposing to increase the ESRD wage index floor from 0.400 to 0.500 to address stakeholder comments about ensuring continued access to care in areas at the lowest end of the current wage index distribution. This proposed change will affect only ESRD facilities in Puerto Rico (rural Puerto Rico and four urban areas in Puerto Rico).

CMS’s proposal to increase the ESRD wage index floor to 0.500 is derived from analyses that found the following:

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<sup>5</sup> Medicare Payment Advisory Commission. 2009. Comment letter on CMS’s proposed notice entitled “Medicare Program; End-stage renal disease prospective payment system.” December 16.

<sup>6</sup> The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Social Security Act and utilize pre-floor hospital data that are unadjusted for occupational mix.

- Puerto Rico's wage index likely lies between 0.510 and 0.550. CMS derived these values by combining labor data from ESRD facilities' cost reports with wage information from the Bureau of Labor Statistics (BLS).
- Any ESRD wage index values less than 0.5936 are considered outlier values. CMS derived this value from the distribution of CY 2018 wage index values.<sup>7</sup>

### *Comment*

The Commission's standing position (stated in our June 2007 report to the Congress) is that creating rural floors and implementing other changes (e.g., exceptions and reclassifications) to a wage index system distorts area wage indexes.<sup>8</sup> In addition, the Commission believes that the current wage index is flawed in that it is based only on data from hospitals, rather than data for all of the health care providers in a given market.

In place of using the hospital wage index for ESRD facilities, CMS should establish an ESRD wage index for all ESRD facilities (not just those located in Puerto Rico) that:

- Uses wage data representing all employers and industry-specific occupational weights,
- Is adjusted for geographic differences in the ratio of benefits to wages,
- Is adjusted at the county level and smooths large differences between counties, and
- Is implemented so that large changes in wage index values are phased in over a transition period.<sup>8</sup>

MedPAC's alternative approach to the wage index is based on wage data from BLS and the Census Bureau, and benefits data from provider cost reports submitted to CMS. The agency's analysis of alternative wage indices (ranging between 0.510 and 0.550) for Puerto Rico also combined labor data from provider (ESRD facilities) cost reports with BLS wage information. CMS should provide additional documentation of its analysis to determine the two alternative wage indices for Puerto Rico.

### **Auditing dialysis facilities' cost reports**

PAMA required that the Secretary of Health and Human Services conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services, consistent with a prior MedPAC recommendation.<sup>9</sup> To support this effort, the law authorized the Secretary to transfer \$18 million (in fiscal year 2014)

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<sup>7</sup> To calculate the lower boundary, CMS subtracted from the wage index value at the 25<sup>th</sup> quartile the product of 1.5 multiplied by the difference between the wage index values at the 25<sup>th</sup> and 75<sup>th</sup> quartiles (i.e., the interquartile range).

<sup>8</sup> Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.

<sup>9</sup> Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. In September 2015, CMS awarded a contract to conduct the audit.

*Comment*

The Commission strongly encourages the agency to accelerate the audit's completion and release its final results. The Commission has repeatedly discussed the importance of auditing the cost reports that dialysis facilities submit to CMS to ensure that the data are accurate. First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Fourth, historically, facilities' cost reports have included costs that Medicare does not allow.

**The ESRD QIP**

In October 2017, CMS launched the Meaningful Measures Initiative aimed at improving patient outcomes and reducing burden by using a reduced set of the measures for patients, clinicians, and providers in quality programs. As a part of the initiative, CMS identified 19 high-priority areas for quality measurement with a focus on improving patient outcomes (e.g., admissions and readmissions to hospitals, patient's experience of care, transfer of health information, preventive care).

As a part of the Meaningful Measures Initiative, CMS proposes to remove four process measures from the ESRD Quality Incentive Program (QIP) in performance year (PY) 2021. The remaining QIP measures in PY 2021 would include 11 measures, 8 of which are "clinical" measures that assess the outcomes of care and the remainder are "reporting" measures intended to ensure certain processes of care. For PY 2022, CMS proposes to add one additional "clinical" (i.e., outcome) measure and one additional "reporting" (i.e., process) measure. CMS is proposing to introduce the following two facility-level measures in PY 2022:

- Percent of prevalent patients waitlisted for a kidney transplant
- Medication reconciliation for patients that assesses the percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional

In PYs 2021 and 2022, CMS is proposing to adjust the measure weights that are used to calculate a facility's total performance score to reflect the proposed removal and addition of the various process and outcome measures.

The following table summarizes the measures proposed for PYs 2021 and 2022:

Measure	Measure type	Payment year measure used
Dialysis adequacy <sup>1</sup>	Outcome	PYs 2021 and 2022 measure
Standardized transfusion ratio	Outcome	PYs 2021 and 2022 measure
Vascular access measure topic <sup>2</sup>	Outcome	PYs 2021 and 2022 measure
Hypercalcemia <sup>1</sup>	Outcome	PYs 2021 and 2022 measure
Standardized hospitalization ratio	Outcome	PYs 2021 and 2022 measure
ICH CAHPS survey	Outcome (patient experience)	PYs 2021 and 2022 measure
Standardized readmission ratio	Outcome	PYs 2021 and 2022 measure
<u>NHSN measurement</u>		
Standardized infection ratio of blood stream infections	Outcome	PYs 2021 and 2022 measure
NHSN dialysis event data <sup>3</sup>	Process	PYs 2021 and 2022 measure
Clinical depression screening and follow-up <sup>3</sup>	Process	PYs 2021 and 2022 measure
Percentage of patient-months that ultrafiltration rate is reported <sup>3</sup>	Process	PYs 2021 and 2022 measure
Percent of prevalent dialysis patients waitlisted for a kidney transplant	Outcome	PY 2022 measure
Medication reconciliation for dialysis patients <sup>3</sup>	Process	PY 2022 measure

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

<sup>1</sup> Percentage of patient-months for which patients achieved an outcome (delivered dose of dialysis, total uncorrected serum or plasma calcium) that is greater than a specified threshold.

<sup>2</sup> Comprised of two measures assessing use of AV fistulas and catheters for hemodialysis patients.

<sup>3</sup> Measure assesses whether facilities reported required data.

Source: Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare program; End-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, end-stage renal disease quality incentive program, durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (CBP) and fee schedule amounts, and technical amendments to correct existing regulations related to the CBP for certain DMEPOS. Proposed rule. *Federal Register* 83, no. 139 (July 19): 20370-34415.

### Comment

The goals of CMS’s Meaningful Measures Initiative—to improve patient outcomes and reduce burden—align with the Commission’s principles for quality measurement.<sup>10</sup> As CMS continues to revise Medicare quality programs with a focus on meaningful measures, we encourage CMS to use a uniform set of population-based outcome measures across settings and populations.

<sup>10</sup> Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington DC: MedPAC.

Accordingly, we commend CMS for removing from the PY 2021 QIP the following four process measures that report on:

- Anemia management
- Pain assessment and follow-up
- NHSN healthcare personnel influenza vaccination
- Serum phosphorus

The agency is removing these four process measures because they are either “topped out” (i.e., measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made) or because of their reporting burden and limited benefit.

With respect to the NHSN health care personnel influenza vaccination measure, the Commission has previously stated that all health care personnel, especially those dealing with immunologically vulnerable patients, should be immunized against influenza, unless the worker has a medical contraindication to the vaccine.<sup>11</sup> To ensure patient safety, CMS should consider addressing this topic as a requirement in Medicare’s conditions for coverage for ESRD facilities.

CMS should provide additional justification about the significant changes to the PY 2021 measure weights used to calculate each dialysis facility’s total performance score. For example, the agency is proposing to decrease by more than half the weights for dialysis adequacy and vascular access measures (from 13.5 percent to 6.0 percent for each measure) and more than double the weight assigned to the standardized transfusion measure.

For PY 2022, CMS is proposing to adopt a “medication therapy management” process measure, which assesses whether facilities have evaluated a patient’s medications. However, this measure only assesses attestation that medical reconciliation occurred.<sup>12</sup> Medication reconciliation—the identification of all medications that a patient is taking—is a critical safety issue for all patients, but particularly dialysis patients, who frequently require 10 or more medications and take an average of between 17 and 25 doses per day.<sup>12</sup> But we are also concerned about the continued reliance on process measures and the future proliferation of measures and that the use of such process measures is burdensome for providers (e.g., too many measures, measures that require medical records abstraction).

Instead of adopting a “medication therapy management” process measure, CMS should consider addressing this topic in Medicare’s conditions for coverage for ESRD facilities. In the final rule for the conditions for coverage for ESRD facilities, some commenters suggested adding medication therapy management as an additional plan of care component; in response, the agency said that: “Medication therapy management may be included within the action plan for

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<sup>11</sup> Medicare Payment Advisory Commission. 2015. Comment letter to CMS’s proposed notice entitled “Medicare Program; End-stage renal disease prospective payment system, and quality incentive program.” August 6.

<sup>12</sup> National Quality Forum. 2016. *Patient safety 2016*. September 7.

various components of the plan of care.”<sup>13</sup> CMS should consider strengthening provisions concerning this topic in Medicare’s conditions for coverage for ESRD facilities.

The Commission supports the kidney transplant measure that CMS is proposing to include in the PY 2022 ESRD QIP. Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients’ clinical and quality of life outcomes.

For PY 2023 QIP, CMS should consider including outcome measures that can replace one or more existing process measures. One such outcome measure is the standardized mortality measure, which captures patients’ health outcomes and could be assessed using existing administrative data sources and is included in the Dialysis Facility Compare star ratings.

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

CMS measures quality for each dialysis facility using two measurement systems, the ESRD QIP, which was mandated by Medicare Improvements for Patients and Providers Act of 2008 and implemented in 2012, and the Dialysis Star Ratings System, which CMS established through a subregulatory process in 2015.

#### *Comment*

The Commission continues to question why it is necessary to use two quality systems for dialysis facilities.<sup>14</sup> We have raised concerns that beneficiaries and their families might be confused if a facility’s star and QIP scores diverge, which could occur because the measurement systems use different methods and measures to calculate a facility’s performance score. The Commission believes the ESRD quality measurement process needs greater simplicity and clarity. Moving to one quality measurement system that is based on a reasonable number of outcomes-based performance measures would be easier to understand for beneficiaries and their families and would reduce administrative costs for providers and CMS.

### **Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

Medicare’s method of setting payment rates for DMEPOS products varies by whether an item is included in the Competitive Bidding Program (CBP) and where a beneficiary resides. Medicare pays for items not included in the CBP using a fee schedule that is largely based on supplier charges from 1986 to 1987 (updated for inflation) and undiscounted list prices. Medicare pays for items included in the CBP based on competitively determined payment rates, referred to as

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<sup>13</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Medicare and Medicaid programs; Conditions for coverage for end-stage renal disease facilities. Final rule. *Federal Register* 73, no. 73 (April 15): 20370–20484.

<sup>14</sup> Medicare Payment Advisory Commission. 2014. 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 15.

single payment amounts (SPAs), if a beneficiary lives in a competitive bidding area (CBA).<sup>15</sup> For those same items furnished to beneficiaries residing in non-CBAs, Medicare's method of setting payment rates has varied over time. Through 2015, Medicare paid historical fee schedule rates. In 2016, CMS began paying for such products using information from the CBP; specifically, Medicare paid a 50/50 blend of historical fee schedule rates and rates derived from the CBP. From January 2017 through May 2018, Medicare paid rates that were 100 percent derived from the CBP. Beginning June 2018, Medicare reverted to a 50/50 blend for rural and non-contiguous non-CBAs, while continuing to pay rates that are 100 percent derived from the CBP in urban, contiguous non-CBAs.

This rule proposes, among other policies, a new payment methodology for products and areas included in the CBP in the event that CMS is unable to recompetitively bid CBP contracts in a timely fashion, structural changes to the CBP, extending the use of 50/50 blended rates in certain non-CBAs, and other changes to the DMEPOS fee schedule.

### **Proposed fee schedule adjustments for items and services furnished in former competitive bidding areas during a gap in the DMEPOS CBP**

All current CBP rounds are set to expire on December 31, 2018. CMS does not expect that new CBP contracts will be in place on January 1, 2019, and thus anticipates CBP will lapse beginning January 1, 2019. In the event of such a lapse, CMS proposes to establish fee schedule payment rates for the products and areas formerly covered by the CBP based on the SPAs in effect on the last day before CBP contracts end, inflated by the projected percentage change in the CPI-U. If the temporary lapse in the CBP lasts for more than a year, payment rates would be increased by CPI-U annually.

#### *Comment*

The CBP has successfully driven down the cost of DMEPOS products for the Medicare program and beneficiaries and has been an important tool to combat fraud and abuse. The Commission therefore does not support allowing the CBP to lapse. Instead, the Commission encourages CMS to continue implementing the CBP, as required by statute. While we appreciate the fact that CMS is proposing some significant changes to the CBP (and provide specific comments on some of those changes below), we believe that reforms can be implemented while the program continues to operate. If additional time is needed to properly implement any finalized changes, we believe the agency has better alternatives than letting the program lapse. For example, the agency could seek to extend current contracts for six months or a year.

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<sup>15</sup>Currently, CBAs consist of 99 large metropolitan statistical areas.

### **Lead item pricing for all product categories under the DMEPOS CBP**

Under current CBP rules, suppliers bid on each individual item within a product category. CMS then creates composite bids based on the price that each supplier provided in its bid, multiplied by a utilization weight for each product in a category.

In this rule, CMS proposes to require suppliers to only bid on the lead item within a product category. CMS proposes to define the lead item as the product with the highest national allowed charges within a product category. To set SPAs for other items within a category, CMS would use the relative price differences (based on 2015 fee schedule prices) between the lead item and the rest of the items in a category. As part of instituting lead item pricing, CMS also proposes to split large product categories into smaller, more homogenous groups of products.

#### *Comment*

The Commission supports the use of lead item pricing. As detailed by CMS, lead item pricing has the potential to simplify the bidding process and eliminate a technical issue, referred to as “price inversions,” that undermine the efficacy of CBP.<sup>16</sup>

The rule does not propose the exact product categories that would be used for future CBP rounds. If CMS implements this provision, the agency should monitor the impacts of narrower product categories on the number of bids engendered and on beneficiaries (e.g., being forced to acquire needed DMEPOS from multiple suppliers instead of one).

### **Calculation of SPAs using maximum winning bids for lead items**

Under current CBP rules, CMS uses the median of all winning suppliers’ bids for specific items to determine the SPAs. In this rule, CMS proposes using maximum winning bids to set SPAs instead of median winning bids. CMS believes that using the median winning bid could potentially lead to beneficiary access problems because some suppliers are paid less than the amount they bid for an item. Alternatively, by using maximum winning bids to set SPAs, all suppliers would be paid at least what they bid for the item. CMS therefore suggests that setting SPAs using maximum rather than median winning bids will better ensure the long-term sustainability of the CBP. CMS estimates that setting SPAs using maximum winning bids (in conjunction with lead item pricing) will increase Medicare program spending by \$10 million over five years, an increase of roughly 0.2 percent in the affected areas.

#### *Comment*

The Commission does not object to using maximum winning bids to set SPAs, when used in conjunction with lead item pricing. However, the Commission believes that reliance on

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<sup>16</sup> CMS considers a “price inversion” to occur when the price of a more complicated item is lower than that of a similar, simpler product. For instance, a “price inversion” occurs when a walker without wheels costs more than a walker with wheels.

maximum winning bids to set SPAs could result in excessive payment rates if beneficiary demand is overestimated or supplier capacity is underestimated. Therefore, the Commission suggests CMS re-examine the methodologies it uses to measure beneficiary demand and supplier capacity and to disclose those methodologies publicly.

CMS estimates beneficiary demand using historic utilization, trended forward to the contract period based on the projected growth in beneficiary population in the CBA and utilization of items. When estimating demand, the Commission believes CMS should use the most recent claims data possible. In addition, when estimating demand expectations, CMS should account for growing (or shrinking) Medicare Advantage penetration rates, increases in the number of Part A-only beneficiaries, and the role of grandfathered suppliers. Specifically, demand estimations should only include FFS beneficiaries, should account for Part A-only beneficiaries (as such beneficiaries likely access DMEPOS products through other sources of coverage), and should only reflect the demand that contract suppliers, not grandfathered suppliers, need to meet. Especially if there is a prolonged lapse in the CBP, grandfathered suppliers could supply a substantial share of DMEPOS products in some CBAs. Given that these factors could substantially lower CMS's demand estimations, CMS should allow for negative demand trends if conditions warrant. For example, if the number of FFS beneficiaries in a CBA falls substantially because of an increasing Medicare Advantage penetration rate, a negative demand trend could be appropriate.

In the rule, CMS also proposes to continue its policy of limiting the market share a given supplier is assumed to be able to furnish to 20 percent, even if suppliers could meet far more than 20 percent of beneficiary demand. The Commission recognizes CMS's legitimate desire to include a sufficient number of suppliers in a market to adequately meet beneficiary demand and ensure a competitive marketplace. However, artificially capping assumed supplier capacity could lead to higher-than-necessary payment rates, especially if maximum winning bids are used to set SPAs. Therefore, the Commission suggests CMS consider capping assumed supplier capacity at a somewhat higher market share, such as 25 percent or 33 percent. While this might result in setting SPAs based on fewer bids, the agency would still retain the ability to offer additional contracts to small suppliers or other suppliers after SPAs are established if beneficiary demand is not being met.

In addition to these technical considerations, the Commission also suggests CMS provide more details regarding how the agency determined that setting SPAs using maximum winning bids (in conjunction with lead item pricing) will increase spending in former CBAs by only 0.2 percent. While estimating future expenditures is inherently difficult, understanding the likely costs of policy changes is important so that CMS can take steps to mitigate the effects of any increased costs on the Medicare program and beneficiaries.

### **Bid surety bonds**

For future CBP rounds, bidding suppliers are required to obtain a bid surety bond for each CBA in which they bid. CMS proposes that suppliers would forfeit their bid surety bond if their bid for

the lead item is at or below the median bid for the lead item for all suppliers included in the calculation of SPAs and the supplier does not accept the contract offer.

*Comment*

The Commission supports the use of bid surety bonds in the CBP and encourages CMS to strengthen the bond requirement to better align with CMS's proposals to revise CBP bidding rules. Under CMS's proposals to set SPAs based on lead items and maximum winning bids, all winning suppliers would be paid at least as much as they bid, so the justification for letting any winning supplier reject a contract offer without forfeiting their bid surety bond appears limited. Therefore, CMS should consider requiring suppliers to forfeit their bid surety bond if their bid is at or below the maximum winning bid (not the median) and the supplier does not accept the contract offer. A stronger bid surety bond requirement will help ensure the integrity of bids by increasing the cost of "low ball" bids.

**Splitting large CBAs**

CMS is soliciting feedback regarding whether or not certain large CBAs should be split into smaller CBAs. The stated goal would be to create more manageable service areas for suppliers.

*Comment*

The Commission suggests CMS proceed cautiously with regard to splitting large CBAs. While we understand some CBAs represent geographically large areas, splitting up CBAs or carving out a greater number of ZIP codes from CBAs could lead to beneficiaries in close proximity to one another paying substantially different amounts for similar products.

**Proposed fee schedule adjustments for items and services furnished in non-CBAs**

CMS proposes to continue the 50/50 blended payment rates for rural and non-contiguous non-CBAs from January 1, 2019, through December 31, 2020. CMS states the higher rates are needed based on stakeholder comments, higher costs in non-contiguous areas, increased travel distance in certain rural areas, and the lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas.

CMS also proposes that fee schedule rates in urban, contiguous non-CBAs continue to be 100 percent derived from CBP rates from January 1, 2019, through December 31, 2020.

*Comment*

The Commission does not support CMS's proposal to continue the 50/50 blended payment rates for rural and non-contiguous non-CBAs. As we stated in our July 2, 2018, comment letter on CMS's interim final rule that instituted 50/50 blended payment rates for the last seven months of 2018, the Commission believes any adjustment for rural and non-contiguous areas should be

limited to only the amount needed to ensure access, targeted at areas and products for which an adjustment is needed, and that CMS should consider taking steps to offset the cost of any adjustments.

- *Limited*—Using 50/50 blended payment rates results in large payment increases, often of 50 percent or more. While CMS presents data indicating that some supplier costs are higher in rural and non-contiguous areas, the agency also found that other costs are lower in those areas, and the agency does not present data to justify the large magnitude of the proposed adjustment.
- *Targeted*—Using 50/50 blended payment rates in all rural and non-contiguous areas for all DMEPOS products included in the CBP is not well targeted. For example, micropolitan areas (which are considered rural for the purposes of fee schedule adjustments) likely face different challenges than remote, non-contiguous areas.
- *Costly*—Using 50/50 blend rates creates a financial burden for the Medicare program and beneficiaries. Over two years, CMS estimates that its proposed fee schedule adjustments will cost more than \$1.3 billion dollars—\$1.05 billion for the Medicare program and \$260 million in beneficiary cost sharing.<sup>17</sup> This is in addition to the \$360 million in additional costs incurred by the Medicare program and beneficiaries associated with using 50/50 blended rates in rural and non-contiguous areas for the last seven months of 2018. The Commission continues to believe that CMS should use its current statutory authority (and seek additional legislative authority where necessary) to expand the CBP to offset these increased burdens. Expanding CBP into new product categories, such as orthotics, would produce substantial savings and help prevent fraud and abuse.

The Commission supports CMS's proposal to continue setting fee schedule rates in urban, contiguous non-CBAs based 100 percent on information from the CBP. We believe CMS's analyses, which suggest that the travel distance and costs are lower in urban non-CBAs relative to CBAs, support basing rates fully on information from the CBP instead of using a 50/50 blend. In the long term, CMS should use its current authority to expand the CBP to urban, non-CBAs to the extent any future concerns arise about the appropriateness of using CBP rates from large urban areas to set payment rates in smaller urban areas.

### **Applying budget neutrality offset to all oxygen and oxygen equipment classes**

CMS proposes to change the manner in which the oxygen budget neutrality provision is applied, which has historically decreased fee schedule payment rates for stationary oxygen equipment and contents to offset the cost of CMS adding a new payment class for oxygen generating portable equipment. Specifically, rather than applying the budget neutrality offset to the payment rate for stationary oxygen equipment and contents only, CMS proposes to apply the budget neutrality offset to all oxygen products beginning January 1, 2019.

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<sup>17</sup>In the proposed rule, CMS estimates the combined projected cost of a lapse in the CBP, 50/50 blended payment rates in rural and non-contiguous non-CBAs, and payment rates 100 percent based on CBP information in urban, contiguous non-CBAs. While CMS does not break down the cost for each of these three proposals, we believe that nearly all of the cost is associated with using 50/50 blended rates in rural and non-contiguous non-CBAs.

*Comment*

The Commission supports CMS's efforts to ensure that the addition of any new class of oxygen product is done in a budget neutral manner. Doing so financially protects both the Medicare program and beneficiaries. However, the Commission suggests CMS apply the budget neutral provision differently. Specifically, instead of applying payment reductions only to oxygen products, CMS should consider applying it to all DMEPOS products that have not been included in the CBP. Applying the budget neutrality provision in this manner ensures that the payment rates for oxygen products in non-CBAs are at least equal, on average, to CBP rates. (Previously, fee schedule rates in non-CBAs have been adjusted based on information from the CBP and then further reduced based on the budget neutrality provision.) In addition, products not included in the CBP continue to largely be paid on the basis of the historical fee schedule, and the Commission has found many of these rates are likely excessive. Therefore, reducing the payment rates for these products is unlikely to affect beneficiary access to these products.

**Conclusion**

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC 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 James E. Mathews, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." with a stylized flourish at the end.

Francis J. Crosson, M.D.  
Chairman