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Medicare Program: End-Stage Renal Disease (ESRD) Prospective Payment System; Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury; ESRD Quality Incentive Program; Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding and Fee Schedule Amounts and Technical Amendments Summary of Proposed Rule

On July 11, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule addressing the Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS), its Quality Incentive Program (QIP), other ESRD-related provisions and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. The proposed rule is expected to be published in the *Federal Register* on July 19, 2018. **The public comment period closes on September 10, 2018.**

Along with routine updates for 2018 payment under the ESRD PPS, the proposed rule would change the drug designation process for purposes of the transitional drug add-on payment adjustment; revise the low-volume payment adjustment; update the acute kidney injury (AKI) payment rate; and make changes to the QIP measures, scoring methodology, reporting periods and validation.

Bidding and pricing methodologies under the DMEPOS competitive bidding program would be changed by implementing lead item pricing and using maximum winning bids to establish single payment amounts. Three different temporary fee schedule adjustment methodologies would be established, depending on the area in which the items and services are furnished. CMS also proposes to create new payment classes for oxygen and oxygen equipment including a proposal to ensure budget neutrality; special payment rules for multi-function ventilators; and a proposal to include the Northern Mariana Islands in the national mail order competitive bidding program.

Supplemental information and Addenda provided by CMS on the ESRD PPS include a facility-level impact file and wage index files, and are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1691-P.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending.

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I. Background on the ESRD PPS

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all defined renal dialysis services furnished in the treatment of ESRD in the ESRD facility or in the patient's home. Payment consists of a base rate adjusted for characteristics of both adult and pediatric patients. The adult case-mix adjusters are age, body surface area (BSA), low body mass index (BMI), onset of dialysis, and four co-morbidity categories, while the pediatric patient-level adjusters consist of two age categories and dialysis modalities. In addition, the ESRD PPS provides for three facility-level adjustments: one for differences in area wage levels, another for facilities furnishing a low volume of dialysis treatments, and a third for facilities in rural areas. A training add-on payment adjustment is allowed for home dialysis modalities. Finally, additional payment is made for high-cost outliers.

II. ESRD PPS Policy Changes and Updates for 2019

The proposed rule includes policy changes to the ESRD PPS involving the transitional drug add-on payment adjustment, the low-volume payment adjustment, rebasing of the market basket, and annual updates to the ESRD PPS rates. In addition, CMS seeks comments on ways to increase kidney transplant referrals and improve the tracking process.

A. Drug Designation Process

CMS reviews the history of its policies for treating new drugs and biologicals under the ESRD PPS. These policies are promulgated at 42 CFR 413.234. Effective January 1, 2016 if a new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the product is considered included in the ESRD PPS bundled payment and qualifies as an outlier service. No separate payment is available. If, however, a new injectable or intravenous product treats a condition for which there is no ESRD PPS functional category, it is not included in the ESRD PPS and it is evaluated. An existing functional category is revised or a new category added; the product is then paid under the transitional drug add-on payment adjustment (TDAPA) until it is added to the ESRD PPS base rate. During the time it is paid under the TDAPA, the product is not eligible as an outlier service. Table 1 of the proposed rule shows the current ESRD PPS functional categories.

In this proposed rule, CMS would expand the TDAPA to apply to all new drugs and biologicals, not just those in a new functional category. In addition, payment for drugs under the TDAPA would be reduced from 106 percent of the average sales price (ASP + 6) to ASP + 0.

Expansion of TDAPA policy. In this rule, CMS proposes that the regulations at §413.234 be expanded to apply to all new renal dialysis drugs and biologicals regardless of how they are administered, with the exception of oral-only drugs. In that case, the statute requires they remain outside the ESRD PPS until 2025 and CMS therefore proposes they be excluded from the definition until that date. Specifically, the definition of "new injectable or intravenous products" would be replaced with a definition of "new renal dialysis drug or biological" as "an injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019…" The definition further specifies that the drug or biological be commercially available, have a healthcare common procedure coding system (HCPCS) application submitted, and be designated by CMS as a renal dialysis service. Oral-only drugs and biologicals are excluded until January 1, 2025.

CMS notes that the proposed requirement that a HCPCS code application be submitted is a change from the current requirement, under which a HCPCS code must be assigned before the TDAPA can apply. CMS says that this would allow faster application of the TDAPA to the ESRD base rate.

TDAPA Eligibility Criteria. CMS reviews the comments it received on the TDAPA eligibility process when it was adopted during 2016 ESRD PPS rulemaking; at the time it anticipated addressing the issues in future rulemaking. Some commenters said that the TDAPA should apply to all new drugs and biologicals and not just for those that do not fall into a functional category. These commenters believe that the functional categories are so broad that no additional payment would be made for drugs with novel mechanisms or other features and this could discourage innovation in treatments for the ESRD population. Some comments suggested that drugs and biologicals be paid under the TDAPA unless CMS determines through notice and comment rulemaking that they are substantially the same as those currently paid under the ESRD PPS and that the PPS rate is adequate to cover the cost. Yet others suggested a transition period during which all new drugs and biologicals would be paid under the TDAPA.

After considering these comments, CMS says it shares concerns about the potential to inhibit high-value innovation and proposes that, beginning January 1, 2019, the TDAPA would apply to all new renal dialysis drugs and biologicals, regardless of whether they fall into an existing functional category. For those that do not fall into an existing functional category, the current policy would continue, with TDAPA paid until sufficient claims data for rate setting are available, but not for less than 2 years. Once the data are available and the TDAPA is ended, CMS would modify the ESRD PPS base rate if appropriate for these drugs and biologicals.

For those new drugs and biologicals that do fall into an existing functional category, the TDAPA would apply for only 2 years. CMS believes that 2 years is a sufficient transition period for facilities to make changes to systems and care plans and would also recognize concerns about the cost of innovative drugs that might not be captured in the ESRD PPS base rate. CMS believes that this transition period would allow new drugs and biologicals a "foothold in the market" that

would enable them to compete once the transition ends and they are paid under the ESRD PPS outlier policy.

At the end of the 2 years, CMS proposes that it would not modify the ESRD PPS base rate, but the drug or biological would be eligible for outlier payment, unless it is a composite rate drug as discussed below. CMS believes it would be inappropriate to add dollars to the ESRD PPS base rate for new drugs and biologicals that fall within existing functional categories, and that doing so would be in conflict with the fundamental principles of prospective payment. The proposal to expand the application of the TDAPA to all new renal dialysis drugs and biologicals but not adjust the ESRD PPS payment rate for new renal dialysis drugs and biologicals that fall in existing functional categories is seen as maintaining the goals of a bundled PPS. This policy would be operationalized no later than January 1, 2020; CMS says this deadline would provide it sufficient time to prepare changes to its claims processing systems.

CMS notes that this proposal would increase Medicare program spending and would result in higher beneficiary cost sharing. It understands that there are new renal dialysis drugs and biologicals in the pipeline, and it intends to monitor the use of the TDAPA and carefully evaluate those that qualify.

TDAPA payment calculation. Beginning January 1, 2019, the TDAPA payment calculation would be changed under the proposal from 106 percent of Average Sales Price (ASP + 6) to 100 percent of ASP (ASP + 0). CMS believes that this is a reasonable basis for payment for new renal dialysis drugs and biologicals that fall into an existing functional category because there are already dollars for the category in the per treatment base rate. For drugs and biologicals that do not fall into an existing category, CMS says that the ESRD PPS base rate has overhead costs built into it. The proposal would not apply to calcimimetics, which would continue to be eligible for the TDAPA payment based on ASP + 6. Payment for both the injectable and oral versions are based on pricing methodologies under section 1847A of the Social Security Act.

In discussing the proposal to reduce the TDAPA payment, CMS cites concerns about the ASP + 6 policy identified by the Assistant Secretary for Planning and Evaluation,[1] the lack of consensus among stakeholders as to the rationale for ASP + 6 as described by the Medicare Payment Advisory Commission,[2] and a CMS contractor report on the difficulties of obtaining ASP data[3]. CMS says "We note there is no clear statement from Congress as to why the payment allowance

[1] ASPE. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. March 2016. (https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf).
[2] MedPAC. Report to Congress: Medicare and the Health Care Delivery System. June 2015. http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.
[3] HHS. Report to Congress: Sales of Drugs and Biologicals to Large Volume Producers. 2006. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/LVP_RTC_2_09_06.pdf.

is required to be 106 percent of ASP as opposed to any other value from 101 to 105 percent, and, as MedPAC discussed in their June 2015 report, there is no consensus among stakeholders."

CMS believes that this proposal strikes a balance between addressing stakeholder concerns about stifling renal dialysis drug innovation by expanding the TDAPA policy to apply to more new drugs and biologicals with the increase in Medicare expenditures and beneficiary cost sharing that would result from the expansion. **Commenters are specifically offered the opportunity to explain why it may be appropriate to apply add-on percentages between ASP+0 and ASP+6.**

When ASP data are not available, CMS proposes that the TDAPA payment would be based on 100 percent of Wholesale Acquisition Cost (WAC) and if WAC is not available, on the drug manufacturer's invoice. This would modify the policy adopted in the 2018 ESRD PPS final rule, under which section 1847A payment is used for separately billable Part B drugs when calculating outlier payments and for the TDAPA. That involves ASP + 6, substitution of WAC when ASP data are not available, and use of invoice pricing when neither are available. The proposal would be codified in regulations at 42 CFR 413.234(c).

Composite Rate Drugs and Biologicals. Prior to implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and biologicals and not billed separately.[4] These payments were used in calculating the ESRD PPS base rate and were grouped into the ESRD PPS functional categories. However, composite rate items that are routinely given during the time of dialysis but not specific for the treatment of ESRD were excluded (e.g., antihypertensives).

CMS proposes that composite rate drugs and biologicals that are furnished for the treatment of ESRD be eligible for the TDAPA. Specifically, beginning January 1, 2019, if a new renal dialysis drug or biological is considered to be a composite rate drug or biological and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. Composite rate drugs and biologicals that are not considered to be furnished for the treatment of ESRD and not included in the ESRD PPS, would not be eligible for the TDAPA.

As noted above, under the proposal new composite rate drugs would not be subject to outlier payments following the period that the TDAPA applies. CMS says that this is because it is not proposing to change the current outlier policy, which does not apply to composite rate drugs. **CMS solicits comments on whether it should consider applying the outlier policy to composite rate drugs in the future.** This is further discussed in section II.F below.

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[4] Readers are referred to Chapter 11, section 20.3F of the Medicare Benefit Policy Manual for a list of composite rate drugs and biologicals.
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf.

B. Low-Volume Payment Adjustment (LVPA) Revision

CMS proposes several changes to the LVPA, under which qualifying facilities receive a 23.9 percent payment adjustment. The proposals, which are made in response to stakeholder concerns, follow.

- The definition of a low-volume facility (§413.232(b)(2)) would be expanded to include facilities experiencing a change of ownership (CHOW) that results in a change in facility type (e.g., from hospital-based to freestanding) and the new owner accepts the existing Medicare provider agreement and a new provider transaction access number (PTAN) is issued. The proposal would not include facilities with a CHOW where a new PTAN is issued for any other reason; the current exclusion from the LVPA of facilities that have opened, closed, or received a new provider number due to a CHOW in the previous 3 cost reporting years would continue in these other cases. Conforming changes in regulatory text also would be made.
- An extraordinary circumstances exception would be provided for the annual November 1st deadline by which a facility must attest to meeting the LVPA eligibility criteria. CMS expects that these circumstances, such as natural disasters, would be rare and would be considered on a case-by-case basis. Under the proposal a facility would provide a narrative rationale for the exception to their MAC. No appeal of the decision would be allowed.
- ESRD facilities that change when their cost reporting year ends for purposes other than a CHOW could qualify for the LVPA if they otherwise meet the eligibility criteria. The current eligibility criteria reference consecutive 12-month cost reports; CMS does not intend that this requirement would result in a facility losing eligibility. Proposed regulatory text at new §413.232(g) would direct the MACs on how to handle situations in which a change in cost reporting period is approved.
- The reference in §413.232(b) to facilities under common ownership that are five miles from the ESRD facility applying for the LVPA would be clarified to be five road miles. A technical correction to a cross reference in regulatory text is also proposed.

C. ESRD PPS Update for 2019

The proposed 2019 ESRD PPS base rate is $235.82, compared with the final 2017 rate of $232.37. As shown in the table below, this increase of 1.48 percent reflects application of an update factor of 1.5 percent (reflecting an estimated increase of 2.2 percent in the ESRD bundled input price index (“market basket”) and an estimated multifactor productivity (MFP) adjustment of -0.7 percent) and a wage index budget neutrality adjustment of 0.999833. The rate is calculated as $232.37 X 1.015 X 0.999833 = $235.82. These calculations will be updated for the final rule with more recent data. (Note that 2018 was the final year for the legislated update reductions included in the Protecting Access to Medicare Act of 2014 (P.L. 113-93).)

Proposed 2019 ESRD PPS Base Rate Update	
Base Rate Update Components	**% effect on base rate**
Market basket	+2.2
Multifactor productivity adjustment	-0.7
Subtotal: update factor	+1.5
Wage index budget neutrality adjustment (0.999833)	-0.0167
Total change in base rate	+1.48
Note: The market basket and productivity adjustments are based on IHS Global Insight's Q1 2018 forecast for 2019 with historical data through Q4 of 2017.	

D. Rebasing the ESRD Bundled (ESRDB) Market Basket and Labor-Related Share

CMS proposes to rebase the ESRDB market basket for 2019 to reflect the 2016 cost structure of ESRD facilities. Currently, the market basket category weights are based on data from 2012; the proposal would make updates using 2016 Medicare cost reports and other supplemental data. The methodology is detailed in the proposed rule. CMS notes that it is not *revising* the market basket, meaning that it is not changing data sources, cost categories or price proxies that are used. Nonetheless, the proposed rule details the current price proxies, which would be continued. These are summarized in Table 8 in the proposed rule.

Table 5 in the proposed rule reproduced with minor changes below compares the current (2012) and proposed (2016) cost weights.

TABLE 5: Comparison of the Proposed 2016-based and the 2012-based ESRDB Market Basket Cost Categories and Weights

Cost Category	Proposed 2016 Cost Weights (percent)	2012 Cost Weights (percent)
Total	**100.0**	**100.0**
Compensation	**43.6**	**42.5**
Wages and Salaries	34.5	33.7
Employee Benefits	9.1	8.8
Utilities	**2.0**	**1.8**
Electricity	1.1	1.0
Natural Gas	0.1	0.1
Water and Sewerage	0.8	0.8
Medical Materials and Supplies	**24.9**	**28.1**
Pharmaceuticals	12.4	16.5
ESAs	10.0	12.9
Other Drugs (except ESAs)	2.4	3.6
Supplies	10.4	10.1

Cost Category	Proposed 2016 Cost Weights (percent)	2012 Cost Weights (percent)
Lab Services	2.2	1.5
All Other Goods and Services	**16.4**	**15.3**
Telephone & Internet Services	0.5	0.5
Housekeeping and Operations	3.9	3.8
Professional Fees	0.7	0.6
All Other Goods and Services	11.3	10.4
Capital Costs	**13.0**	**12.2**
Capital Related-Building and Fixtures	9.2	8.4
Capital Related-Machinery	3.8	3.9
Note: Cost weights are calculated using three decimal places but for display purposes are rounded to one decimal place. Totals may not sum as a result.		

CMS notes that the estimated 2.2 percent market basket increase for 2019 would be the same if the 2012-based ESRDB market basket were used. Table 9 in the proposed rule compares market basket increases going back to 2015 using the 2012- and 2016-based ESRDB market baskets. The largest difference is shown for 2015, where the proposed 2016 market basket would have resulted in an increase that is 0.2 percentage points lower (2.0 percent compared with 2.2 percent using the 2012-based ESRDB market basket).

Using the proposed 2016-based ESRDB market basket, the proposed labor-related share is 52.3 percent; slightly higher than the current 50.673 percent reflecting the 2012-based ESRDB market basket. CMS proposes to use a one decimal point level of precision for the labor-related share; it says it is making this change for all payment systems. No change is proposed to the previously applied estimates that 87 percent of professional fees and 46 percent of capital-related expenses vary by local labor market.

E. Wage Index

In addition to the proposed change in the labor-related share resulting from the rebasing of the ESRDB market basket, CMS proposes to employ the previously adopted methodology for determining the wage indices for ESRD facilities updated for 2019 to reflect more recent data. The wage indices are listed in Addendums A (urban areas) and B (rural areas) available on the CMS web page for this proposed rule at the link provided on page 1 of this summary.

CMS proposes to increase the wage index floor from 0.4000 to 0.5000 for 2019; wage areas in Puerto Rico are currently the only ones to benefit from the floor. The proposal is made in response to comments regarding the impact of the low floor on facilities and access to care, and the effects of natural disasters on the labor market and in accelerating kidney failure and need for renal dialysis facility services.

CMS undertook calculation of alternative wage indices for Puerto Rico using cost report data from facilities in Puerto Rico for 2013 through 2015 and concluded that the wage index likely lies between 0.5100 and 0.5500. In addition, it says an outlier analysis also supported a floor higher than 0.400. CMS says it considered floor values between 0.400 and 0.5500 and is proposing 0.500 to balance additional payments to affected areas while minimizing the effect on the base rate.

Finally, CMS notes that OMB Bulletin 17-01 issued in August 2017 announced Twin Falls, Idaho, as a new urban core based statistical area (CBSA 46300). It was previously classified as a micropolitan statistical area. The wage indexes in the Addenda to the proposed rule do not yet reflect this change. CMS estimates that this area will have a wage index of 0.8335.

F. Outlier Policy

An ESRD facility is eligible for outlier payments if its actual or imputed Medicare Allowable Payment (MAP) per treatment for ESRD outlier services exceeds a threshold, which is equal to the facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus a fixed-dollar loss amount. ESRD outlier services are defined as specified items and services included in the ESRD PPS bundle. The final rule reviews the history of regulations and guidance on outlier policy.

For 2019, CMS proposes no changes to the methodology used to compute the MAP amount per treatment or fixed-dollar loss amounts used to calculate ESRD PPS outlier payments. However, these amounts would be updated using 2017 claims data. The 2019 proposed outlier policy amounts and those for 2018 are shown in Table 11 of the proposed rule, reproduced below. As shown in the table, CMS estimates that based on 2017 data, the percentage of patient months qualifying for outlier payments in 2019 will be 8.0 percent for adult patients and 9.2 percent for pediatric patients. MAP and fixed-dollar loss amounts continue to be lower for pediatric patients than for adults due to continued lower use of outlier services (particularly ESAs and other injectable drugs).

Based on 2017 claims, outlier payments represented about 0.80 percent of total payments, in line with the 0.78 percent for 2016 but below the 1 percent target. CMS says that recalibration of the thresholds using 2017 data is expected to result in aggregate outlier payments close to the 1 percent target in 2019. While no change in payments would result for those beneficiaries who are ineligible for outlier payments, CMS notes that the higher coinsurance obligations result for those beneficiaries for whom outlier payments are made.

CMS seeks comment on whether it should expand outlier services to include composite rate drugs and supplies. Currently, formerly separately payable Part B drugs, laboratory services and supplies are eligible for the outlier payment. The exclusion of composite rate drugs and supplies from the outlier policy is discussed above in regard to the proposed changes in the drug designation process and the TDAPA. CMS says that including composite rate drugs and supplies as outlier services could be appropriate payment for them once the TDAPA period has ended, and could also promote use of innovative devices and items that would otherwise be considered

part of the bundled payment. CMS is interested in hearing from commenters who support this change and how it might be effectuated. In particular, these services have not previously been reported on ESRD claims, and CMS is interested in feedback on whether adding these items under the existing outlier framework is possible or whether specific policy changes would be needed to accommodate them.

TABLE 11: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY				
	Final outlier policy for 2018 (based on 2016 data inflated to 2018)		**Proposed outlier policy for 2019 (based on 2017 data inflated to 2019)**	
	Age < 18	**Age≥ 18**	**Age < 18**	**Age ≥ 18**
Average outlier services MAP amount per treatment	$37.41	$44.27	$34.33	$41.97
Adjustments:1.0588				
Standardization for outlier services	1.0177	0.9774	1.0588	0.9786
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$37.31	$42.41	$35.62	$40.25
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$47.79	$77.54	$47.88	$69.73
Patient-months qualifying for outlier payment	9.0%	7.4%	9.2%	8.0%

G. Solicitation for Information on Transplant and Modality Requirements

CMS notes that despite the benefits of timely kidney transplantation and requirements that Medicare-certified dialysis facilities evaluate all patients for transplant suitability and make appropriate referrals, the percentage of dialysis patients wait-listed for a kidney has recently declined. Readers are given this link https://www.usrds.org/2017/view/v2_06.aspx and gaps in facility performance are discussed.[5]

Elsewhere in this rule, CMS proposes a reporting measure under the ESRD QIP to track the percentage of patients who are on the kidney or kidney-pancreas transplant waiting lists. **CMS seeks additional input on ways to increase kidney transplant referrals and improve the tracking process.** Specifically, CMS asks:

[5] The proposed rule cites R. E. Patzer, L. Plantinga, J. Krisher, S. O. Pastan, "Dialysis facility and network factors associated with low kidney transplantation rates among U.S. dialysis facilities," American Journal of Transplantation, 2014 Jul;14(7):1562-72; and Sudeshna Paul, Laura C. Plantinga, Stephen O. Pastan, Jennifer C. Gander, Sumit Mohan, and Rachel E. Patzer, "Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities," Clinical Journal of the American Society of Nephrology, January 2018.

- Are there ways to ensure facilities are meeting the Conditions for Coverage (CfC) requirements, in addition to the survey process?
- Are the current dialysis facility CfC requirements addressing transplantation support services adequately, or should additional requirements be considered?

CMS is also concerned about disparities in access to dialysis modality options. Minority individuals are far less likely to be treated with home dialysis than white patients,[6] and CMS is concerned that not all dialysis patients have the opportunity to learn about the benefits of home modalities regarding greater independence and flexibility.

Therefore, dialysis facilities are reminded of their responsibilities regarding modality education and options. While not all dialysis facilities support home modalities, all facilities are required to make appropriate referrals if a patient elects to pursue home treatments. CMS reiterates the regulatory requirements at §490.70 for facilities which address informing patients about treatment modalities, ensuring patient access to resource information, assessing patient abilities and preferences, identifying a plan of care, and providing education and training. It believes that practitioners and professionals who care for dialysis patients are best suited to provide information to support shared decision-making. **CMS welcomes suggestions on ways to ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities.**

III. 2019 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

In the 2017 ESRD PPS final rule, CMS adopted policies to implement payment for renal dialysis services furnished to individuals with AKI, as required under section 808 of the Trade Preferences Extension Act (TPEA) of 2015 (Pub. Law 114-27). TPEA defines an individual with AKI to mean "…an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) [ESRD PPS]." In the 2017 final rule, CMS established payment for AKI to equal the ESRD PPS base rate updated by the ESRD bundled market basket, minus a productivity factor, and adjusted for wages and any other amount deemed appropriate by the Secretary. For 2018 the updated AKI dialysis payment rate is set to equal the 2018 ESRD PPS base rate of $232.37, adjusted by the facility's wage index.

In this rule, CMS similarly proposes that for 2019, the AKI dialysis payment rate be set to equal the 2019 ESRD PPS base rate (proposed to be $235.82), adjusted by the facility's wage index.

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[6] 4 Mehrotra, R., Soohoo, M., Rivara, M.B., Himmelfarb, J., Cheung, A.K., Arah, O.A., Nissenson, A.R., Ravel, V., Streja, E., Kuttykrishnan, S., Katz, R., Molnar, M., Kalantar-Zadeh, K., "Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States," Journal of the American Society of Nephrology December 10, 2015.

IV. ESRD Quality Incentive Program (QIP)

A. Background

Under the ESRD QIP, ESRD facilities' performance on a set of quality measures is assessed and scored, and a payment reduction of up to 2 percent is applied to those facilities that do not achieve a minimum total performance score (TPS). Facilities' QIP performance is publicly reported on the Dialysis Facility Compare website: https://www.medicare.gov/dialysisfacilitycompare/. ESRD networks and dialysis facilities use the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) to enter and submit patient and clinical quality of care data to CMS.

In previous rulemaking, CMS adopted QIP measures for payment years (PYs) through 2021. QIP measure specifications by PY are available on the CMS website at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html.

A summary table of previously adopted and proposed ESRD QIP measures appears below at the end of section IV of this summary.

CMS discusses its Meaningful Measures Initiative, which is aimed at prioritizing high impact measure areas while minimizing provider burden. Table 12 of the proposed rule shows how CMS has mapped 19 meaningful measure areas into six quality priorities.

B. Accounting for Social Risk Factors in the ESRD QIP

CMS reviews its past discussion of accounting for social risk factors in the ESRD QIP and other quality reporting and value-based purchasing programs. It cites the July 2017 final report of the National Quality Forum (NQF) on its 2-year trial period of risk adjustment for social risk factors, and notes that NQF has launched a follow-up 3-year initiative that will continue to include social risk factors in outcome measures submitted for endorsement and will also explore unresolved issues that surfaced in the initial trial. In addition, CMS notes that the Assistant Secretary for Planning and Evaluation (ASPE) is working on a second report to Congress on this topic required by the IMPACT Act, which is due in the fall of 2019.

As a next step, CMS is considering options to increase the transparency of quality measure disparities shown among patient groups within and across hospitals, such as stratification of Inpatient Quality Reporting Program outcome measures. It plans to continue to work with ASPE, the public, and other stakeholders to identify policy solutions that improve health equity while minimizing unintended consequences.

C. Updates to Regulation Text

CMS proposes to codify into regulation text previously adopted requirements for the ESRD QIP. Proposed §413.178 would codify definitions, applicability of the ESRD QIP (including new

facilities), measure selection, performance scoring, public availability of ESRD QIP performance information, and limitations on administrative and judicial review. Revisions to §413.177 set forth the ESRD QIP payment adjustment. The current regulatory text refers only to Secretarial discretion in how to calculate the adjustment, while the proposed regulatory text codifies the formula by which a reduction is made to facilities with a TPS below the minimum.

D. Requirements for the PY 2021 ESRD QIP

1. Changes to measure removal criteria. CMS proposes to modify the criteria it considers for removing a measure from the ESRD QIP to align with the removal "factors" identified for other CMS quality reporting and pay-for-performance programs. The proposal would combine two current criteria (previously 4 and 5) into one factor and add two new factors (7 and 8). The proposed seven factors consider whether 1) performance on the measure is so high and unvarying that meaningful distinctions among ESRD facilities can no longer be made; 2) performance or improvement on the measure does not result in better patient outcomes; 3) the measure no longer aligns with current clinical guidelines or practice; 4) another more broadly applicable measure is available; 5) another available measure is more strongly associated with the desired patient outcomes; 6) collection or public reporting of the measure leads to negative unintended consequences other than patient harm; 7) it is not feasible to implement the measure specifications; and 8) measure costs outweigh the benefit of its continued use in the program.

In proposing new factor 8, CMS notes that there are different types of costs associated with measures. These include the direct cost of information collection and submission of quality measures to CMS; the provider and clinician cost associated with complying with quality program requirements; the provider and clinical cost associated with participating in multiple quality programs and tracking similar or duplicative measures across programs; the CMS cost associated with program oversight of the measure; and the provider/clinician cost associated with compliance with other federal or state regulations (if applicable).

In considering the case-by-case application of the proposed factor 8, CMS says it might remove a measure that is of limited use because publicly reported data cannot be easily interpreted by beneficiaries. In contrast, it might retain a measure that is burdensome for providers to report if the benefit to beneficiaries justifies the reporting burden. CMS notes that none of the factors results in automatic removal; these are considerations that are taken into account on a case-by-case basis. Factor 8 would be effective beginning with PY 2021.

2. Removal of four measures. Four measures would be removed from the ESRD QIP beginning with PY 2021. The measures and the rationale for removal are summarized in the following table:

Measure proposed for removal	**Rationale for removal**
Healthcare Personnel Influenza Vaccination	*Factor 1, performance is high and unvarying*. All facilities reporting the measure received maximum points in 2016.
Pain Assessment and Follow-Up	*Factor 1, performance is high and unvarying*. 90% of facilities received maximum points in 2016.

Measure proposed for removal	Rationale for removal
Anemia Management	*Factor 1, performance is high and unvarying* 96% of facilities received maximum points in 2016.
Serum Phosphorus	*Factor 5, another measure available.* CMS considers Hypercalcemia a superior measure of bone mineral metabolism because it is more focused on outcomes and on clinical factors more directly under the facility's control.

3. Performance Standards, Achievement Thresholds and Benchmarks for PY 2021

Using preliminary data for 2017, Table 14 in the proposed rule sets forth estimated numerical values for the achievement threshold (15th percentile), benchmark (90th percentile), and performance standards (50th percentile) for each of the remaining measures for PY 2021. The final rule will include updated values based on more complete data. CMS notes that it previously adopted a policy to maintain the previous year's numerical levels if newer data would result in worse levels.

4. Scoring Methodology Changes

Beginning with 2021 payment, CMS proposes to remove the reporting measures domain from the ESRD QIP and restructure and reweight the remaining domains. The following table shows the current and proposed measures and weights from Table 15 of the proposed rule and from the 2018 ESRD PPS final rule. CMS says that the proposed weightings are higher for measures that directly impact clinical outcomes and where a facility has greater influence on the measure rate.

Proposed Domain and Measure Weighting for the PY 2021 ESRD QIP	
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	**% of TPS**
ICH CAHPS measure	15%
Domain Subtotal	**15%**
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14%
SHR measure	14%
Clinical Depression and Follow-Up reporting measure	2%
Domain Subtotal	**30%**
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	6%
Vascular Access Type measure topic*	6%
Hypercalcemia measure	3%
STrR measure	22%
Ultrafiltration Rate reporting measure	3%
Domain Subtotal	**40%**
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9%
NHSN Dialysis Event reporting measure	6%
Domain Subtotal	**15%**

Previously Finalized PY 2021 Measure and Domain Weights as Share of TPS	
Clinical Measure Domain	**75%**
Patient and Family Engagement/Care Coordination Subdomain	30%
ICH CAHPS Measure	18.75%
Standardized Readmission Ratio (SRR) Measure	11.25%
Clinical Care Subdomain	**45%**
Standardized Transfusion Ratio (STrR) Measure	8.25%
Dialysis Adequacy Measure	13.5%
Vascular Access Type (VAT) Measure Topic	13.5%
Hypercalcemia Measure	1.5%
Standardized Hospitalization Rate (SHR) Measure	8.25%
Safety Measure Domain	**15%**
NHSN Bloodstream Infection (BSI) Clinical Measure	9%
NHSN Dialysis Event Reporting Measure	6%
Reporting Measure Domain*	**10%**
*Each of the six reporting measures weighted as 1.66% of the total performance score.	

In addition, CMS proposes that to receive a TPS under the ESRD QIP, a facility must be eligible to be scored on at least one measure in any two of the four proposed domains. Currently, the requirement is that a facility be eligible to be scored on at least one measure in the clinical measure domain and at least one measure in the reporting domain. The proposal reflects the proposed removal of the reporting domain and retains the ability of a facility to receive a score based on as few as two measures. CMS says the proposal would also maximize the number of participating facilities in the ESRD QIP.

In the case of a facility that is scored on enough measures to qualify for a TPS but does not have a score on all measures, CMS proposes that the weights of any measures for which the facility does not receive a score would be distributed to the remaining measures proportionately based on the measures' weight as a percentage of the TPS. The redistribution would occur across all measures, regardless of domain. CMS considered an alternative under which the weights for the missing measures would be redistributed evenly across the remaining measures but concluded that the proposed approach would better reflect the Meaningful Measure Initiative's priorities.

5. Reporting Requirements. CMS proposes that for PY 2021 and beyond, facilities would be required to collect data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CMS Certification Number (CCN) becomes effective. For example, a facility with a CCN effective on January 15, 2019 would begin data collection with services furnished on May 1, 2019. This would give new facilities more time to become familiar with the program before data are used for scoring.

6. Payment Reductions. Based on updated performance standards, CMS estimates that a facility must meet or exceed a TPS of 57 for PY 2021 to avoid a payment reduction. Reductions would be applied using the scale in Table 16 of the proposed rule, reproduced here. The numeric values will be updated in the 2019 ESRD PPS final rule.

TABLE 16 –ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2021 BASED ON THE MOST RECENTLY AVAILABLE DATA	
Total Performance Score	**Reduction**
100 – 57	0.0%
56 – 47	0.5%
46 – 37	1.0%
36 – 27	1.5%
26 or lower	2.0%

7. Data Validation. In the 2018 ESRD PPS final rule, CMS continued for PY 2020 (2018 reporting period) the data validation study it began with 2016 and said that for future years it will consider whether to continue it as a pilot or make it a permanent feature of the program. Under the study, CMS samples approximately 10 records per facility from 300 facilities. A facility selected for the study that does not provide the required medical records within 60 days will lose 10 points from its TPS.

In this rule, CMS proposes to continue the validation approach for 2019 data submitted for 2021 payment as a feature of the program rather than a study. It has found an overall match rate of 92.2 percent among the participating facilities, which it considers reliable results that can be used to ensure that accurate data are reported to CROWNWeb.

For PY 2020, CMS also continued the dialysis event validation study regarding data reported to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for the bloodstream infection measure. Under this study 35 facilities will be selected to submit 10 records covering 2 quarters of data during 2018. The sampling method targets facilities at risk for under-reporting.

In this rule, CMS proposes to expand the sample from 35 to 150 for PY 2021, and then to 300 for PY 2022. After working with CDC, it has concluded that to achieve reliable results for a payment year it would need to review 6,072 charts submitted by 303 facilities. Each facility would be required to submit, within 60 days of receiving a request, 20 records per quarter for each of the first 2 quarters of the calendar for which it was selected for validation.

CMS seeks comment on these proposals and others that would encourage accurate, comprehensive reporting to NHSN. This might include introducing a penalty for facilities that do not meet a reporting or data accuracy threshold; providing a bonus to facilities that perform above a threshold; developing targeted education on NHSN reporting; or requiring that a facility failing to meet established thresholds be selected for validation again in the following year.

E. Requirements for the PY 2022 ESRD QIP

In addition to continuing the 12 measures that would remain if its proposed measure removals for PY 2021 are finalized, CMS proposes to add two new measures to the ESRD QIP beginning

in PY 2022. Readers are referred for more information on the measure to the ESRD QIP technical specifications web page; the link is provided at the beginning of section IV of this summary, although at the time this summary was prepared the 2019 ESRD PPS proposed rule measure information was not yet available.

Proposed Percentage of Patients Waitlisted (PPPW) is a clinical measure that tracks the percentage of patients attributed to each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas transplant waiting list. Patients would be assigned to one facility only for a month and patient counts would occur on the last day of the month. Patients age 75 or older and those admitted to a skilled nursing facility or hospice would be excluded from the measure. The measure would be risk adjusted. CROWNWeb data would be used for the measure denominator; the number of patients who are waitlisted would come from the Organ Procurement and Transplant Network.

The Measure Applications Partnership (MAP) provided conditional support for adding this measure to the ESRD QIP. In response to its review, CMS has submitted the measure to the National Quality Forum for endorsement. CMS reiterates concern about variability in waitlist rates among dialysis facilities. Because it believes the measure fills an important quality gap, CMS is proposing now to adopt the measure for PY 2022.

Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Reporting Measure (NQF #2988) assesses whether a facility has appropriately evaluated a patient's medications. CMS discusses the importance of medication management as a critical patient safety issue. It is proposed for addition to the Patient Safety domain of the ESRD QIP. The measure applies to all patients attributed to a renal dialysis center for a month except those who receive fewer than 7 treatments during the month; it calculates the percentage of patient-months during the reporting period for which medication reconciliation was performed and documented by an eligible professional. The MAP supported inclusion of this measure in the ESRD QIP.

CMS proposes that for PY 2022 it would continue to set the performance standards, achievement thresholds, and benchmarks for clinical measures, including the proposed new PPPW measure, at the 50^{th}, 15^{th}, and 90^{th} percentiles of national performance in 2018. CMS anticipates publishing numerical values for these performance standards in the 2019 ESRD PPS final rule. The minimum TPS would be published in the 2020 ESRD PPS proposed rule. The current scoring methodologies for clinical, CAHPS and reporting measures would continue. For the proposed MedRec measure, the performance standard would be successfully reporting to CROWNWeb for each patient for each month the date of completion of the medication reconciliation, and the name and type of clinician completing the reconciliation.

CMS proposes to adjust measure weights in order to accommodate the two proposed new measures for PY 2022 without changing the overall domain weights from the proposed levels for PY 2021. Specifically, the PPPW measure is proposed to have a measure weight of 4 percent, and the other two continuing clinical measures in the Care Coordination domain would have weights of 12 percent each (from 14 percent) and the clinical depression reporting measure would continue to receive a weight of 2 percent. Overall, the domain weight would remain at 30

percent. For the MedRec measure, CMS proposes a weight of 4 percent, with the weight of the continuing clinical BSI measure reduced to 8 percent from 9 percent and the weight of the continuing NHSN dialysis event reporting measure reduced from 6 percent to 3 percent. The Patient Safety domain weight would remain at 15 percent.

F. Requirements for the PY 2024 ESRD QIP

CMS proposes to add one new measure to the ESRD QIP beginning in PY 2024. Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) is a clinical measure that assesses the number of patients who are placed on the transplant waitlist or receive a living donor kidney within one year of the date when dialysis is initiated. CMS believes this measure would encourage facilities to more rapidly evaluate patients for transplant and coordinate their wait-listing. Although similar, this measure is narrower than the proposed PPPW measure because the latter includes patients who have been on dialysis for longer than one year. The reason this measure is proposed for addition in PY 2024 is that it would be based on data for a 3-year performance period (2019-2021). Performance standards for achievement would be based on data for 2017 through 2019 and for improvement on a performance period from 2018 through 2020. The MAP conditionally supported addition of this measure; CMS has submitted the measure to NQF for endorsement. The measure would be added to the Care Coordination domain and would be scored with the PPPW measure as a measure topic.

Summary Table: ESRD QIP Measure Sets *Proposals in Italics*			
	PY2020	**PY2021**	**PY2022**
Clinical Care Measure Domain*			
Kt/V Dialysis Adequacy Comprehensive measure	X	X	X
Vascular Access Type Measure Topic:			
Maximizing Placement of AV Fistula	X**	X	X
Minimizing Use of Catheters as Chronic Dialysis Access	X**	X	X
Hypercalcemia	X	X	X
Standardized Transfusion Ratio (STrR)	X	X	X
Ultrafiltration Rate reporting measure		*Moved from reporting domain*	X
Patient & Family Engagement Measure Domain			
ICH CAHPS measure	X	X	X
Care Coordination Measure Domain			
Standardized Readmission Ratio (SRR)	X	X	X
Standardized Hospitalization Ratio (SHR)	X	X	X
Clinical Depression Screening and Follow-up		*Moved from reporting domain*	X
Safety Domain			
NHSN Bloodstream Infection (BSI)	X	X	X
NHSN Dialysis Event reporting measure	X	X	X
Percentage of Patients Waitlisted			*Proposed*
Medication Reconciliation reporting measure			*Proposed*

Summary Table: ESRD QIP Measure Sets *Proposals in Italics*			
	PY2020	**PY2021**	**PY2022**
Standardized First Kidney Transplant Waitlist Ratio			*Proposed for 2024*
Reporting Measure Domain		*Remove*	
Serum Phosphorus	X	*Remove*	
Anemia Management	X	*Remove*	
Clinical Depression Screening and Follow-up	X	*Move to care coordination*	
Pain Assessment and Follow-up	X	*Remove*	
NHSN Healthcare Personnel Influenza Vaccination	X	*Remove*	
Ultrafiltration Rate	X	*Move to clinical care*	
*This table is organized around the ESRD QIP domains as restructured in the proposed rule. The three current domains are the clinical measure domain (with two subdomains: patient and family engagement/ care coordination and clinical care), the safety measure domain, and the reporting measure domain. ** In PY 2020, the measures in this topic were AV Fistula and Catheter ≥ 90 days.			

V. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

A. Background

As way of background, section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), requires the Secretary to establish and implement the Competitive Bidding Program (CBP) in Competitive Bidding Areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The CBP, phased in over several years, utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.[7] These items include, for example, hospital beds and related accessories, oxygen supplies and equipment, and wheelchairs, scooters, and related accessories. The programs are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program."

CMS discusses the current status of the CBP. The CBP is currently operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the CBP has not yet been phased in, including approximately 275 MSAs. In addition, CMS phased in a national mail order program for diabetic testing supplies in 2013. In the Round 1 2017 and

[7] The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the April 10, 2007 Federal Register (72 FR 17992)) established CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States.

Round 2 Recompete competitions, the product categories currently include: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies; Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive airway pressure devices, and respiratory assist devices); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies. The Round 2 Recompete, National Mail-Order Recompete, and Round 1 2017 contract periods of performance will end on December 31, 2018.

Section 522(a) of Medicare Access and Children's Health Insurance Program Reauthorization (MACRA) also added certain requirements for the DMEPOS Competitive Bidding Program, including requiring a bid surety bond for each CBA in which the entity submits its bid and requiring the bidding entity to meet applicable state licensure requirements. CMS notes that it has interpreted section 522(a) of MACRA as applying to the next round of competitive bidding even through the next round will begin after the time period specified in the statute (i.e., after January 1, 2019).

CMS discusses other provisions that are particularly relevant for its proposals. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. In the 2016 ESRD final rule, CMS finalized its proposal to revise §414.412(b) to specify that the bids submitted for each individual item of DMEPOS other than drugs cannot exceed the fee schedule amounts established in accordance with sections 1834(a), 1834(h), or 1842(s) of the Act for DME, off the-shelf (OTS) orthotics, and enteral nutrition, respectively, as if adjustments to these amounts based on information from CBPs had not been made. The bid limits for DME will be based on the 2015 fee schedule amounts (before adjustments made based on the CBP program), but updated each year based on the covered item update – the percentage increase in the consumer price index for all urban consumers reduced by the productivity adjustment.[8] CMS will apply similar provisions for the bid limits for OTS orthotics and enteral nutrients, equipment, and supplies (enteral nutrition).

To receive payment under Medicare Part B for items and services furnished under the CBP, a supplier had to have submitted a bid to furnish those items and been awarded a contract. In past rounds of competition, CMS has allowed a 60-day bidding window for suppliers to prepare and submit their bids. CMS' regulations at §414.412 specify the rules for submission of bids under

[8] With respect to the statute, the bid limits for DME would be based on the 2015 fee schedule amounts established in accordance with section 1834(a)(1)(B)(ii) of the Act, prior to application of section 1834(a)(1)(F)(ii) and (iii), but updated for subsequent years based on the factors provided at section 1834(a)(14) of the Act.

the DMEPOS CBP. CMS notes that before awarding a contract, a supplier must meet the financial standards established for the program and must be able to provide the product to the beneficiary for the bid amount. CMS notes that about 94 percent of bids screened as part of Round 2 and Round 1 recompete competitions were determined to be bona fide.

As required by statute, CMS has taken steps to ensure small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS CBP. CMS has established a 30 percent target for small supplier participation in regulation (at §414.414(g)(1)(i)). A small supplier is defined by CMS in this section as one that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue.

B. Current Method for Submitting Bids and Selecting Winners

CMS explains in this section its current method for how it evaluates bids. CMS explains that because multiple bids for individual items are submitted when competing to become a contract supplier for the product category of items and services as a whole, it is necessary to calculate a composite bid for each bidding supplier to determine the lowest bids for the category as a whole. In accordance with §414.402, a composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Tables 18 and 19 in the proposed rule illustrate how this calculation currently works.

After a composite bid is computed for each supplier, CMS establishes the "pivotal bid" for each product category. In accordance with §414.402, pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for items in that category. Table 20 of the proposed rule contains an example of how the pivotal bid is determined.

C. Current Method for Establishing SPAs

Section 1847(b)(5) of the Act mandates a single payment amount (SPA) for each item based on winning bids from multiple suppliers but does not specify the approach for calculating this amount. CMS discussed various options for determining the SPA for individual items under the DMEPOS CBP during the notice and comment rulemaking conducted in 2006 and 2007 (71 FR 25653 and 72 FR 17992, respectively), including using the minimum winning bid, using the highest winning bid, using the median of winning bids, and using an average adjusted price methodology.

CMS finalized using the median of bids submitted for each item by winning bidders in each CBA as the methodology for establishing the SPA for each item in each CBA. At the time, CMS stated that it believed this methodology results in a single payment amount for an item under a competitive bidding program that is representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item. The median is also not influenced by outliers at the extremes of the data.

CMS rejected the average adjusted price methodology – the same methodology that was used in competitive bidding demonstrations mandated by section 4319 of the Balanced Budget Act of 1997 (BBA). This methodology involved using the average of the winning bids adjusted up to the point where the adjusted bids for each supplier in the winning range equaled the level of the pivotal bid. Ultimately, CMS chose not to use this approach because it was not reflective of all of the winning bids accepted, and CMS was concerned that this methodology may be confusing and overly complicated. Also, at that time, CMS did not support determining the SPA for individual items using a minimum bid methodology or a maximum bid methodology. CMS stated that these approaches only reflect the bid of a single supplier and may be an outlier in the overall bid for an item.

D. Provisions of the Proposed Rule

1. Lead item pricing for all product categories under the DMEPOS CBP

As way of background, in the 2016 ESRD PPS final rule, CMS established alternative rules for submitting bids and determining SPAs for certain groupings of similar items with different features under the DMEPOS CBP. CMS was particularly concerned about avoiding price inversions. Price inversion occurs when a higher weighted and higher priced item (with more features) at the time of the competition becomes the lower priced item in the CBP following the competition.[9] To avoid issues of price inversion, CMS finalized an alternative bidding methodology, referred as the lead item bidding method. Under the lead item bidding method, CMS designated one item as the lead item for the grouping for bidding purposes. The item in the grouping with the highest allowed services during a specified base period would be considered the lead item of the grouping. The lead item bidding method applies to a subset of similar items with different features as opposed to an entire product category.

Under the approach finalized in the 2016 ESRD PPS final rule, the supplier's bid for the lead item would be used as the basis for calculating the SPAs for similar items within that grouping. That is, CMS would automatically calculate the SPAs for any similar item in the grouping based on the ratio of the average of the similar item's fee schedule amounts for all areas nationwide in 2015, to the average of the lead item's fee schedule amounts for all areas nationwide in 2015. CMS would use the fee schedule amounts for 2015 for the purpose of determining the relative difference in fee schedule payments for similar items because it believed they reflected the relative difference in cost for the items under the fee schedule prior to any adjustments being made to the amounts based on information from the CBPs. CMS found price inversions for groupings of similar items within the following categories: standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, TENS devices, support surface mattresses and overlays,

[9] This situation can occur because of unbalanced bidding where a bidder has a higher incentive to submit a lower bid for one item than another due to the fact that the item has a higher weight and therefore greater effect on the supplier's composite bid for the product category than the other item.

and seat lift mechanisms. These groupings of similar items were a subset of similar items with different features, as opposed to entire product categories.

CMS' proposal in this rule builds upon its approach finalized in the 2016 ESRD PPS final rule but is much more comprehensive and has some important distinctions. CMS proposes the following:

- To establish a similar lead item pricing methodology for all items and all product categories under the DMEPOS CBP.
- The methodology would now apply to all items in the product category rather than groupings of items within a product category.
- The lead item would be identified based on total national allowed charges rather than total national allowed services.

CMS believes that the lead item pricing would address all price inversions it has already identified as well as potential future price inversions for other items. CMS states that this approach would no longer be an alternative bidding method, but it would replace the current bidding method (where bids are submitted for each item in the product category) for all items. Since the bid for the lead item would be used to establish the SPAs for both the lead item and all other items in the product category, CMS refers to this proposed policy as "lead item pricing" rather than "lead item bidding." CMS notes that using allowed charges rather than allowed services is a better way to identify the lead item in the product category as it is the item that generates the most revenue for the supplier of the item in the product category, and in many cases, it is also the item with the most allowed services.

CMS states that it is proposing to implement lead item pricing and to change the methodology for establishing SPAs under the CBP for a number of reasons. CMS notes that for some product categories there are hundreds of items, and many suppliers submit bids for multiple product categories and in multiple CBAs. This has caused errors in some suppliers' bids, resulting in their bids being disqualified. CMS states that lead item pricing would also eliminate the need for item weights and for the calculation of composite bids based on item weights. CMS states that this would reduce supplier burden since they would no longer have to submit bids for each individual item in a product category.

CMS raises a couple of issues related to lead item pricing that warrant discussion. First, CMS emphasizes that lead item pricing would apply to all items in each product category (for example, power wheelchairs) and all codes for accessories for base equipment (for example, wheelchair batteries). Thus, bids used to establish the SPA for the code for the lead item would then be used to establishing pricing for all items in that product category. Second, CMS acknowledges that some of the larger, conglomerate product categories would need to be split into multiple product categories so that lead item pricing is not implemented for certain categories that include different types of base equipment. For example, the general home equipment category includes a variety of items such as hospital beds, commode chairs, and walkers. CMS believes it would be overly complex and confusing to establish prices for one

type of equipment, such as power wheelchairs, based on bids submitted for another type of equipment, such as walkers. Although CMS acknowledges this as an issue, it does not make any proposals on how these conglomerate product categories should be reclassified for purposes of lead item pricing.

CMS proposes the following changes to its regulation with respect to lead item pricing (see table below).

Proposed change	**New regulatory language**
New definition under §414.402 for lead item	Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. Note: In the preamble, CMS states that the lead item definition would also include "Total nationwide Medicare allowed charges means the total sum of charges allowed for an item furnished in all states, territories, and D.C. where Medicare beneficiaries reside and can receive covered DMEPOS items and services". This language, however, is not included in the proposed regulatory text. CMS also notes in the preamble that it proposes to delete the lead item bidding provision that refers to "allowed services" in §414.412(d)(2) and replace it with the language in §414.402 for lead item,
Revises current definition for "bid" and "composite bid" The revised definition of "bid" includes the words "or items" to indicate the bid is the suppliers' bid for furnishing all of the items.	Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items. Composite bid means the bid submitted by the supplier for the lead item in the product category.
Revises language to incorporate "lead item" into §414.412(b)(2)	The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under subpart C of this part, without the application of §414.210(g), or subpart D of this part, without the application of §414.105. In other words, the supplier's bid for each lead item and product category in a CBA cannot exceed the fee schedule amount that would otherwise apply to the lead item without any adjustments based on information from CBP.

With respect to the composite bid, CMS explains that under lead item pricing, the suppliers' bid amount for the lead item is the composite bid. CMS further states that it will educate suppliers regarding how pricing for all of the items in the product category would be established based on the bids submitted for the lead item, and that suppliers should consider their costs for furnishing these various items when submitting their bid for the lead item.

CMS would continue to calculate the median of the winning bids for the lead item in the product category for use in implementing the bid surety bond requirement at section 1847(a)(1)(H)(i) of the Act and §414.412(h). CMS explains that under the lead item pricing method, suppliers would forfeit their bid surety bond for a product category in a CBA if (i) their composite bid (their bid for the lead item) is at or below the median composite bid rate for all bidding suppliers included in the calculation of SPAs for the product category and CBA, and (ii) they do not accept a contract offer for the product category and CBA.

CMS also proposes to amend the conditions for awarding contracts under the CBP in §414.414(e) related to the evaluation of the bids under the CBP. Currently, CMS evaluates bids submitted for items within a product category, and the expected beneficiary demand in a CBA is calculated for items in the product category. Under the lead item pricing methodology, CMS proposes to calculate expected beneficiary demand and total supplier capacity based on the lead item in the product category when evaluating bids. CMS also proposes that the projected demand and supplier capacity would only be calculated for the lead item for the purpose of determining or establishing the pivotal bid. The pivotal bid is where total supplier capacity for furnishing the items within a product category meets projected beneficiary demand for the items. The winning range of suppliers would be set based on where the cumulative capacity of suppliers for furnishing the lead item equals or exceeds the projected beneficiary demand for the lead item. CMS states it believes that the suppliers with the capacity to furnish the lead item in the product category would also have the capacity to furnish the remaining items in the product category as well.

In summary, CMS proposes to amend §414.402, §414.412, and §414.414 to change the definitions, the methodology for the calculation of SPAs, and the evaluation of bids under the CBP to reflect and establish the lead item pricing methodology.

2. Calculation of single payment amounts (SPAs) using maximum winning bids for lead items

CMS proposes to revise §414.416 to change the methodology from calculating SPAs under the CBP using the median of winning bids to using the maximum winning bid. The SPA for the lead item in each product category and CBA would be based on the maximum or highest amount bid for the item by suppliers in the winning range as shown in Table 23 of the proposed rule (reproduced below). The bid amount of $3.00 from supplier 7 is the maximum winning bid, the pivotal bid, and the SPA.

Table 23: Proposed Maximum Winning Bids Methodology

Supplier Bids	Bid Amounts for the Lead Item
Supplier 1 bid	$1.00
Supplier 4 bid	$2.00
Supplier 6 bid	$2.00
Supplier 9 bid	$2.00
Supplier 5 bid	$2.00

Table 23: Proposed Maximum Winning Bids Methodology	
Supplier Bids	**Bid Amounts for the Lead Item**
Supplier 11 bid	$3.00
Supplier 7 bid (pivotal bid)	$3.00
Maximum bid/SPA	$3.00

CMS notes that the SPAs for all other items in the product category would be based on a percentage of the maximum winning bid for the lead item. Specifically, the SPA for a non-lead item in the product category would be equal to the SPA for the lead item multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, D.C., Puerto Rico, and the U.S. Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item. Thus, the SPAs for a non-lead item would be based on the relative difference in the fee schedule amounts for the lead and non-lead item before the fee schedule amounts were adjusted based on information from the CBP.

CMS provides an example using power wheelchairs as the lead item and wheelchair battery as a nonlead item within the product category. For example, if the average 2015 fee schedule amount for a non-lead item such as a wheelchair battery is $107.25, and the average 2015 fee schedule amount for the lead item (Group 2, captain's chair power wheelchair) is $578.51, the ratio for these two items would be computed by dividing $107.25 by $578.51 to get 0.18539. If under the lead pricing methodology, the maximum winning bid for the power wheelchair was $433.88, then the SPA for the non-lead item (wheelchair battery) would be computed by multiplying $433.88 by 0.18539 to generate an SPA of $80.44 for the non-lead item (wheelchair battery).

CMS believes that establishing the SPA for the lead item based on the maximum winning bid rather than the median of winning bids could simplify the bidding process and better ensure the long-term sustainability of the CBP. CMS believes that the lead item pricing based on the maximum bid ensures that the supplier can furnish the quantity of items and services it indicates because all suppliers in the winning range would be paid at least what they bid for the lead item or more. CMS states that as median bid levels continue to decline over time, it is possible that many of the suppliers with bids above the median would not be willing or able to accept contract offers and meet beneficiary demand. CMS also notes that applying this approach would eliminate price inversions associated with suppliers bidding high for low weight items, since items weights and bids for low weight items would no longer be used to establish SPAs for items under the CBP.

CMS also explains that bids from small suppliers awarded contracts in order to help meet the small supplier target (target is 30 percent) would not be used to determine the maximum winning bid because those contracts are awarded after the SPAs are determined. CMS notes that while SPAs based on the proposed maximum winning bids would still be below what these suppliers bid, they are going to be closer to the amount they bid than the SPA based on a median of the winning bids.

CMS acknowledges that the maximum winning bid methodology has some risks. The methodology could skew the data set of bids if there is an outlier. CMS gives the example that if one supplier bids $20 and the majority of suppliers bid between $1 and $3, this would cause the entire item price to be inaccurately skewed in one direction and would increase the cost of the item significantly.

CMS seeks comment on its proposal to use the maximum winning bid and ways to minimize the potential risk of skewed bids.

CMS also seeks feedback on whether or not certain large CBAs should be split into smaller size CBAs to create more manageable service areas for suppliers, as has been done for the New York, Los Angeles, and Chicago CBAs. In addition, CMS seeks approaches on how best to adjust the size and boundaries of CBAs for future competitions.

As part of its discussion, CMS specifically mentions the nine largest CBAs. The three largest are Phoenix-Mesa-Scottsdale, Arizona CBA, the largest CBA with approximately 12,000 square miles, Boise City, Idaho CBA (11,800 square miles), and the Dallas-Fort Worth-Arlington, Texas CBA (9,100 square miles). The other six CBAs with more than 7,000 square miles are Riverside-San Bernardino-Ontario, California, Houston-The Woodlands-Sugar Land, Texas, Bakersfield, California, Salt Lake City, Utah, San Antonio-New Braunfels, Texas, and Atlanta-Sandy Springs-Roswell, Georgia.

CMS notes that one result of subdividing the CBAs and creating more CBAs is that suppliers who wish to bid for furnishing items and services in all of the areas that formerly would have been one area would have to incur the cost and effort of obtaining multiple bid surety bonds for the new areas rather than one bid surety bond.

VI. Adjustments to DMEPOS Fee Schedule Amount Based on Information from the DMEPOS CBP

A. Background

Section 16008 of the Cures Act mandates that CMS solicit and take into account stakeholder input in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. CMS hosted a national provider call in 2017 to solicit stakeholder input and also requested written comments. The overall conclusion by stakeholders was that an increase in adjusted payment amounts for rural areas was warranted. Stakeholders believed that the adjusted fee schedule amounts are not sufficient to cover the costs of furnishing items and services in non-CBAs and that this is having an impact on access to items and services in these areas. CMS summarizes the oral and written comments (pages 196-198 in the display copy) into the following categories: inadequacy of adjusted fee schedule amounts, travel distance, volume of services, beneficiary access, adverse beneficiary health outcomes, delivery expenses, and costs in rural areas.

Section 16008 of the Cures Act also mandated that CMS take into account the highest amount bid by a winning supplier in a CBA in making adjustments to fee schedule amounts for item furnished on or after January 1, 2019, based on information from the CBP. CMS performed an analysis that considered the highest amounts bid by a winning supplier for a specific item (maximum bid) in the various CBAs in Round 1 2017 and Round 2 Recompete to see if maximum bids varied in different types of areas (that is, low volume versus high volume areas, large versus small delivery service areas, areas with few suppliers versus many suppliers). CMS also analyzed maximum bids for the lead items in each product category (those with the highest allowed charges) and for other lower volume items. The details of its analysis are shown in Tables 25-52 on pages 199 through 244 of the display copy.

CMS presents a brief summary of its general findings developed in accordance with section 16008 of the Cures Act. CMS makes the following conclusions:

Highest Winning Bid

Highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others).

Stakeholder Input

Stakeholders, mostly suppliers, stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in non-CBAs. Stakeholders expressed concerns about the average travel distance, higher costs, and lower average volumes, in rural areas. They believe that this could cause or has caused beneficiary access issues and could potentially cause adverse health outcomes if beneficiaries go without items. Several stakeholders also suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs.

Distance

From its analysis presented, CMS notes that the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as far and remote areas (FAR), Outside Core Based Statistical Area (OCBSAs), and super rural areas, suppliers generally must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs.

Costs

Costs, on average, are higher in CBAs than they are in the non-CBAs, for most of the cost data that CMS examined and presented in this proposed rule.

Volume

Overall, suppliers in CBAs have significantly more volume than suppliers in non-CBA MSAs, micro areas, or OCBSAs, based on claims data CMS examined and its analysis.

Number of Suppliers

The number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, while volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. CMS notes that instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. CMS also did not find any correlation between number of suppliers and SPA or maximum winning bid amount.

CMS solicits comments on its findings.

B. Current Issues

1. Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas During a Gap in the DMEPOS CBP

With respect to section 16008 of the Cures Act, CMS states that it has taken information mandated by this section into account when developing the proposed fee schedule adjustments for items and services furnished on or after January 1, 2019 through December 31, 2020, in areas that are currently non-CBAs. In particular, CMS states that it took into account stakeholder input on the higher costs for suppliers in non-contiguous areas, the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of non-CBA supplier locations.

Rural and Non-Contiguous non-CBAs

CMS proposes to revise §414.210(g)(9) and to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous[10] non-CBAs by extending through December 31, 2020, the current methodology which bases the fee schedule amounts on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amount in accordance with the current methodologies under paragraphs (1) through (8) of §414.210(g).

[10] Alaska, Hawaii, and the U.S. territories.

Non-rural and contiguous non-CBAs

CMS proposes to revise the fee schedule adjustment methodology at §414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount. **CMS requests specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well.**

CMS states that it plans to continue monitoring health outcomes, assignment rates, and other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after January 1, 2021, in future rulemaking. It also notes that in the event the proposed method for calculating SPAs under the CBP is finalized, this may warrant further changes to the fee schedule adjustment methodologies under §414.210(g)(1) through (8). CMS states that it would address further changes to the fee schedule adjustment methodologies in future rulemaking.

2. Proposed Fee Schedule Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During a Gap in the DMEPOS CBP

CMS also proposes a methodology for adjusting the fee schedule amounts for items and services that are currently subject to competitive bidding furnished in former CBAs in the event of a lapse in the DMEPOS CBP. This lapse is likely, and CMS states elsewhere in the proposed rule that the next round of DMEPOS CBP could potentially be delayed until January 1, 2021.

CMS plans to update the SPAs by an inflationary factor using the Consumer Price Index for all Urban Consumers (CPI–U) in the interim period before the next round of competitive bidding. Specifically, CMS proposes to create a new paragraph (10) under §414.210(g) titled "Payment Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During Temporary Gaps in the DMEPOS CBP" that has the following text underneath: "During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date."

Finally, with regard to payment for non-mail order diabetic testing supplies in the event of a gap in the CBP, CMS states that payment would continue at the SPA rates for mail order diabetic testing supplies as mandated by section 1834(a)(1)(H) of the Act. CMS would pay for non-mail order diabetic supplies at the current SPA rates until new rates are established under the national mail order program. CMS does not believe the statutory provision provides the agency the discretion to adjust these SPA rates by inflation adjustment factors.

VII. New Payment Classes for Oxygen and Oxygen Equipment and Methodology to Ensure Budget Neutrality

A. Background

CMS provides a review of its Medicare payment rules for oxygen and oxygen equipment. Of particular note, CMS as part of the calendar year 2007 Home Health Prospective Payment System final rule, amended §414.226 by adding a new paragraph (c) and separate payment classes for: oxygen generating portable equipment (OGPE) consisting of portable oxygen concentrators and transfilling equipment that met the patient's portable oxygen needs without relying on the delivery of oxygen contents; stationary oxygen contents after the 36-month rental period; and portable oxygen contents after the 36-month rental period. With the addition of the new class for OGPE, rather than receiving the standard monthly add-on payment of $31.79 for portable oxygen equipment, CMS established a higher amount of $51.63 per month for this new technology as opposed to furnishing portable gaseous or liquid oxygen.

CMS notes that new, separate classes of oxygen and oxygen equipment must be budget neutral, and that requirement applies regardless of whether fee schedule amounts are adjusted based on information from the DMEPOS CBP.[11] CMS has ensured budget neutrality each year by determining how much expenditures increased as a result of the higher paying OGPE class and reducing the monthly payment amount for stationary oxygen equipment and oxygen contents by a certain percentage to offset the increase in payments attributed to the higher amount paid for OGPE.

As of January 1, 2018, the average adjusted fee schedule monthly add-on amount for OGPE was $40.08 and for portable gaseous and liquid oxygen equipment was $18.20. Either of these monthly add-on amounts is added to the average adjusted fee schedule monthly payment for stationary oxygen equipment and oxygen contents which was $72.95.

B. Provisions of the Proposed Rule

1. Adding a portable liquid oxygen equipment class

As discussed above, the add-on payment for OGPE is higher than the add-on payment for portable gaseous and liquid equipment. CMS states that the higher payments and incentive for furnishing OGPE may have created a disincentive to furnish portable liquid equipment.

CMS proposes to amend its regulations at §414.226 by using the authority at section 1834(a)(9)(D) to add separate payment classes for portable gaseous oxygen equipment only and portable liquid oxygen equipment only. Instead of having one class for portable oxygen

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[11]Section 1834(a)(9)(D) of the Act provides the authority to create separate classes of oxygen and oxygen equipment, and section 1834(a)(9)(D)(ii) of the Act mandates budget neutrality.

equipment (gaseous and liquid tanks), CMS proposes splitting this class into two classes and increasing the add-on amount for portable liquid oxygen equipment.

CMS also proposes establishing the initial add-on amounts for portable liquid oxygen equipment so that they are equal to the add-on amounts for OGPE, thus reducing the incentive to furnish OGPE over portable liquid oxygen equipment. The add-on payment amounts would be adjusted in the future based on pricing information from the DMEPOS CBP. These new classes are required to be annually budget neutral, but CMS does not expect this change to result in a dramatic increase in the use of portable liquid oxygen equipment, and so it does not believe the budget neutrality offset would be significant.

CMS believes this will eliminate any disincentives for providing portable liquid oxygen equipment as its rate will be the same as the OGPE.

2. Adding a liquid high-flow oxygen contents class

CMS notes that in a limited number of cases where a patient is ambulatory and is prescribed a very high flow rate of oxygen (generally greater than 6 liters per minute), a portable liquid oxygen system is the only modality that would meet their high flow, portable oxygen needs. CMS proposes to add a new separate class for "portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute" to ensure that these beneficiaries have access to these items.

CMS proposes to establish the initial fee schedule amounts for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute by multiplying the fee schedule amounts for portable oxygen contents by 1.5 to increase the payment amount by 50 percent above the payment amount for portable oxygen contents. CMS notes that like the other classes of oxygen and oxygen equipment, the fee schedule amounts for this class would be adjusted in the future based on pricing information from the DMEPOS CBP. CMS notes that the requirement for budget neutrality should have a very minimal impact on expenditures due to the limited number of beneficiaries who require a high flow rate for oxygen and are ambulatory.

Table 53 (reproduced from the proposed rule) compares the current classes of oxygen and oxygen equipment and the proposed classes of oxygen and oxygen equipment.

Table 53: Current and Proposed Oxygen and Oxygen Equipment Classes

Current Oxygen and Oxygen Equipment: 5 Classes Described in 414.226	**Proposed Oxygen and Oxygen Equipment: 7 Classes**
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)

Current Oxygen and Oxygen Equipment: 5 Classes Described in 414.226	Proposed Oxygen and Oxygen Equipment: 7 Classes
Portable equipment only (gaseous or liquid tanks)	Portable gaseous equipment only
	Portable liquid equipment only
Oxygen generating portable equipment only	Oxygen generating portable equipment only
Stationary oxygen contents only	Stationary oxygen contents only
Portable oxygen contents only	Portable gaseous and liquid oxygen contents only except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute
	Portable liquid oxygen contents only for prescribed flow rates greater than four liters per minute

3. Applying a Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

CMS proposes to change §414.226(c)(6) and the methodology for applying the budget neutrality offset, in addition to adding the two new oxygen and oxygen equipment classes proposed above. Rather than applying the budget neutrality offset to the payment for stationary equipment and oxygen contents only, CMS proposes to apply the budget neutrality offset to all oxygen and oxygen equipment classes and HCPCS codes beginning January 1, 2019. CMS states that this approach spreads the budget neutrality offset more equitably across all classes and codes for oxygen and oxygen equipment. Table 54 in the proposed rule (reproduced below) shows an example of the fee schedule amounts when the budget neutrality offset is applied only to the stationary oxygen equipment rate versus applying the budget neutrality offset to all oxygen classes.

Table 54: January 1, 2018 Fees for Current and Proposed Budget Neutrality Methods

Current Method	2018 Rate	Proposed Method	2018 Rate
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	$70.23	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable)	$72.59
Portable equipment only (gaseous or liquid tanks)	$17.29	Portable gaseous equipment only	$16.04
		Portable liquid equipment only	$34.73
Oxygen generating portable equipment only	$37.44	Oxygen generating portable equipment only	$34.73
Stationary oxygen contents only	$53.32	Stationary oxygen contents only	$49.46

Current Method	2018 Rate	Proposed Method	2018 Rate
Portable oxygen contents only	$53.32	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute	$49.46
		Portable liquid contents only greater than four liters per minute	$74.19

Note: This example depicts fully adjusted fee schedule amounts, including budget neutrality adjustments, for oxygen and oxygen equipment furnished in non-rural areas in the Southeast U.S.

VIII. Payment for Multi-Function Ventilators

A. Background

CMS provides background on the separate payment categories of DME and how the fee schedule amounts for items under each of the categories are established in sections 1834(a)(2) through (a)(7) of the Act. Table 55 in the proposed rule provides a summary of the payment categories, corresponding payment methodology, and statutory and regulatory sections. The main payment categories are inexpensive or other routinely purchased items, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, and other items of DME (capped rental). Differences exists in the payment rules for certain payment categories.

Section 1834(a)(3) of the Act, for example, mandates that payment for covered items such as ventilators and intermittent positive pressure breathing machines be made on a monthly basis for the rental of the item, whereas ventilators that are either continuous positive airway pressure devices or intermittent assist devices with continuous positive airway pressure devices are excluded from section 1834(a)(3) of the Act. Respiratory assist devices, suction pumps (aspirators), and nebulizers fall under section 1834(a)(7) of the Act.

B. Current Issues

Concerns have been raised by the manufacturer of a multi-function ventilator about how the separate payment categories set forth at sections 1834(a)(2) through (a)(7) of the Act would apply to a new type of ventilator, which consists of a ventilator base item classified under section 1834(a)(3) of the Act, but can also perform the function of portable oxygen equipment classified under the payment categories in section 1834(a)(5), and the functions of a nebulizer, a suction pump, and a cough stimulator classified under section 1834(a)(7) of the Act. For example, a new product was recently cleared by the Food and Drug Administration (FDA) as a ventilator, but can also function as a portable oxygen concentrator, nebulizer, suction pump (aspirator), and cough stimulator. The multi-function ventilator assists with serving multiple, different medical needs of beneficiaries with diagnoses such as chronic lung disease, cystic fibrosis, ALS, and muscular dystrophy.

As shown in Table 56 of the proposed rule (reproduced below), separate DME items perform each of these functions, and the DME items that perform these functions have already been assigned separate HCPCS codes and payment amounts under the DMEPOS fee schedule.

Table 56: Functions, Payment Category, and HCPCS for Functions of a Multi-function Ventilator		
HCPCS Code	**Function**	**Payment Category**
E0465 or E0466	Ventilator	Items requiring frequent and substantial servicing
E1390 and E1392	Portable Oxygen Concentrator	Oxygen and oxygen equipment
E0570	Nebulizer	Capped rental items
E0600	Suction Pump	Capped rental items
E0482	Cough Stimulator	Capped rental items

CMS noted other concerns while considering how to categorize and pay for the multi-function ventilator. These concerns include that there are different Medicare medical necessity coverage criteria for each of the five different functions typically performed by five different pieces of equipment. There are also issues associated with this product and inclusion in the CBP.

Based on its review of this issue, CMS believes that it should classify multi-function ventilators in the frequent and substantial servicing payment category under section 1834(a)(3) of the Act and address payment for these ventilators that can perform multiple functions. Multi-function ventilators are classified by the FDA as ventilators, instead of oxygen concentrators, nebulizers, suction pumps, or cough stimulators. CMS believes that section 1834(a)(1)(C) of the Act requires that DME be classified into one of the payment categories in section 1834(a)(2) through (a)(7) of the Act.

CMS believe this is appropriate to establish fee schedule amounts for multifunction ventilators based on the current Medicare fee schedule amounts for ventilators plus an additional amount for the average cost of the various additional functions or features the equipment offers (oxygen concentration, drug nebulization, respiratory airway suction, and cough stimulation). This is similar to how fee schedule amounts have been established for other DME items in the past, such as using the average of allowed charges for underarm crutches with shock absorbers and allowed charges for underarm crutches without shock absorbers to establish the fee schedule amounts for underarm crutches with or without shock absorbers (HCPCS code E0116).

C. Provisions of the Proposed Rule

Based on its review, CMS proposes to add a provision to the regulation at §414.222(f) to establish a payment methodology for multi-function ventilators effective for dates of service on or after January 1, 2019. CMS believes these devices can enhance patient care and promote ambulation by eliminating the need for the patient to be tethered to several pieces of equipment.

CMS proposes that multi-function ventilators be classified under section 1834(a)(3) of the Act which are paid on a continuous monthly rental basis.

CMS proposes to establish the monthly rental fee schedule amounts for a multi-function ventilator based on the existing monthly rental fee schedule amounts for ventilators plus payment for the average cost of the additional functions. Under this proposal, a single monthly rental fee schedule amount shall be paid to encompass the base ventilator item and its additional functional components. Table 57 in the proposed rule (reproduced below) provides an example of how this payment would work.

Table 57: Proposed Payment Method for Multi-function Ventilators (example)		
Step	**Method**	**HCPCS Codes**
(1)	Base amount = ventilator monthly rental fee schedule amount	E0465 or E0466
(2)	Determine monthly rental fee schedule amount for each additional function:	
(a)	(Portable Oxygen Concentrator monthly fee schedule amount x 36 months) / 60 months*	E1392 + E1390
(b)	CY 1993 Nebulizer monthly rental fee schedule amount x covered item update factor for DME to CY 2019**	E0570
(c)	CY 1993 Suction Pump monthly rental fee schedule amount x covered item update factor for DME to CY 2019**	E0600
(d)	(Cough Stimulator newly purchased fee schedule amount) / 60 months*	E0482
(3)	Base amount from Step 1 + lowest cost function amount from Step 2	
(4)	Base amount from Step 1 + all function amounts from Step 2	
(5)	Determine Payment for Multi-function ventilator (average of step 3 and 4)	

*5 years (60 months) is the reasonable useful lifetime of the equipment.
**The monthly rental amounts paid prior to 1994 included payment for the equipment and all related accessories.

CMS states that Medicare coverage and payment can be available for multi-function ventilators furnished to beneficiaries who are prescribed a multi-function ventilator and meet the Medicare medical necessity coverage criteria for a ventilator and at least one of the four additional functions of the device. The fee schedule amount for the multi-function ventilator would be determined in advance for each calendar year and would not vary based on additional functions. CMS proposes that the payment amount would be established for calendar year 2019 and then updated each year after 2019 using the covered item update factors mandated by section 1834(a)(14) of the Act. In the event that a patient is furnished a multi-function ventilator and only meets the Medicare medical necessity coverage criteria for a ventilator, Medicare coverage and monthly rental payments would be for the ventilator only, and payment could not be made for the other functions of the device.

CMS further states that if a beneficiary is furnished a multi-function ventilator, payment would be denied for any separate claims for oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories, and cough stimulators and any related accessories. CMS believes that this proposed payment method lessens confusion for the supplier which could occur if the supplier were to receive varying monthly rental amounts for a multi-function item; instead the proposal would permit a supplier to receive predictable monthly payments over the 60-month reasonable useful lifetime of the multi-function ventilator. CMS is not proposing to apply §414.222(f) to other DME items. Subsequent rulemaking would be necessary to address other multi-function items.

CMS solicits comments on this proposal and is interested in comments on alternatives to the approach it is taking regarding the proposed classification and payment of multi-function ventilators.

IX. Including the Northern Mariana Islands in Future National Mail Order CBPs

CMS explains that the national mail order program for diabetic testing supplies is currently in effect in all areas of the U.S., except for the Northern Mariana Islands. The Northern Mariana Islands are currently the only non-CBA for mail order diabetic testing supplies. CMS states, however, that even though the Northern Mariana Islands are currently not included in the national mail order program, per §414.210(g)(7), CMS pays for mail order items furnished in the Northern Mariana Islands at 100 percent of the SPAs established under the national mail order CBP. After further examining this issue, CMS now holds the view that the Northern Mariana Islands are an area eligible for inclusion under a national mail order CBP.

CMS proposes to amend §414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order CBP, the fee schedule adjustment methodology under this paragraph would no longer apply. Under this proposed rule, the Northern Mariana Islands would be included in the CBA for all competitions under the national mail order CBP beginning on or after January 1, 2019.

CMS solicits comments on this proposal.

X. Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS Items

CMS explains that it is required to establish fee schedule amounts based on the amounts and levels established under the reasonable charge payment periods set forth in the statute (that is, July 1, 1986 through June 30, 1987, for prosthetic devices, prosthetics and orthotics, therapeutic shoes, and most DME items). CMS uses a "gap-filling" process to establish the fee schedule amounts for newly covered items – DMEPOS items that came on the market that were not paid for by Medicare during the reasonable charge payment period.

CMS defines its gap-filling process in subregulatory guidance, as described in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100-04). CMS "fills the gap" in the

data due to the lack of historic reasonable charge payments from 1986 and 1987 by estimating what the historic reasonable charge payments would have been for the items. CMS gap-fills by using fees for comparable equipment or prices from supplier price lists, such as mail order catalogs. The gap-filling process only applies to items not assigned existing HCPCS codes that are also not items that previously were paid for under a HCPCS code that was either deleted or revised, in other words truly new items or technology as opposed to recoded/reclassified or technologically refined items or technology. CMS notes that this gap-filling process can result in fee schedule amounts that greatly exceed the cost to suppliers of the new technology items (if inflated prices were given from a manufacturer as a proxy) or do not cover the costs of furnishing the technology if the comparable items used for gap-filling purposes are less expensive than the new item.

CMS is considering whether changes should be made to the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. **CMS seeks information on how the gap-filling process could be revised in terms of data sources or methods that could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services.**

XI. DMEPOS CBP Technical Amendments

CMS proposes to make minor technical amendments as follows:

- In §414.422, CMS proposes to correct the numbering in section (d)(4), which contains subsections (i) through (vi) but omits subsection (ii) in the numbering sequence. This error was made when the regulation was promulgated. The proposed new numbering in section (d)(4) contains subsections (i) through (v), including (ii). The content of (d)(4) would remain the same.
- In §414.423(i)(8), CMS proposes removing the reference to "42 U.S.C." before Title 18. This statutory citation was inadvertently included when the regulation was promulgated.

CMS solicits public comments on these technical amendments and requests that when commenting on this section, commenters reference "DMEPOS CBP Proposed Technical Amendments."

XII. Burden Reduction on Comorbidities (ESRD)

CMS proposes to reduce the documentation requirements necessary to demonstrate eligibility for the comorbidity payment adjustment under the ESRD PPS. This change is proposed in response to ongoing stakeholder concerns about the burden of the current documentation requirements. Most recently, CMS received comments on this issue in response to the request for information published in the 2018 ESRD PPS proposed rule regarding reducing unnecessary provider burdens. CMS says that in addition to the issues raised by facilities regarding the difficulties they face in obtaining the required documentation, it has determined that the ESRD PPS

documentation requirements are more rigorous than those under other CMS payment systems that rely on the ICD codes.

Under the proposal, CMS would no longer require that ESRD facilities obtain results from specific diagnostic tests in order to qualify for the comorbidity adjustment. Instead, CMS would rely on the Official ICD Guidelines for Coding and Reporting. ESRD facilities would still have to maintain clear documentation in the beneficiary's medical record to justify the reporting of diagnostic codes, as required by ICD Guidelines.

XIII. RFIs on Promoting Interoperability and Price Transparency

CMS makes two requests for information (RFIs) as part of this proposed rule; these requests have appeared in other Medicare provider payment proposed rules issued this year. The usual procedures and disclaimers associated with RFIs are included (e.g., proprietary or confidential information should not be included; CMS may post the comments received or a summary of them.)

A. Request for Information on Promoting Electronic Interoperability

CMS discusses the status of adoption of health IT among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA)[12] is highlighted.

CMS is interested in feedback from stakeholders on how it should use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, it might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

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[12]The draft is available at https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

Relevant provisions of proposed CoP regulations are discussed including the November 3, 2015 proposed rule to implement provisions of the IMPACT Act (80 FR 68126), June 16, 2016 proposed changes to CoPs for hospitals and CAHs (81 FR 39448), and an October 4, 2016 final rule on requirements for LTC facilities (81 FR 68688).

In this rule, CMS requests stakeholder feedback on the following questions:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact th,e effectiveness of these requirements?

In addition, CMS discusses the MyHealthEData initiative to promote patient access to their medical records and the Blue Button 2.0 initiative for beneficiary access to Medicare claims information through API technology.

CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData initiative for patients. In particular, it would like to identify fundamental barriers to interoperability and patient access and how they might be reduced through revisions to the CoPs, CfCs, and RfPs for hospitals and other Medicare providers and suppliers. CMS has a particular interest in hearing about issues for providers and suppliers who are ineligible for the Medicare and Medicaid EHR Incentives program, such as long-term care and post-acute care providers, behavioral health providers, clinical laboratories and social service providers.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The Affordable Care Act established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States to make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2015 IPPS/LTCH rule (79 FR 50146), CMS reminded hospitals of their obligation to comply with this provision by making public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH proposed rule, CMS updated its guidelines effective January 1, 2019 to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually. All providers are encouraged to engage in consumer-friendly communication of their charges to help patients understand their potential financial liability for services and to enable comparison of charges across providers, and to update this information at least annually.

The proposed rule describes CMS' concern that challenges continue to exist for patients due to insufficient price transparency. Such challenges include surprise billing for out-of-network physicians and chargemaster data that are not helpful in estimating what a patient is likely to pay for a service.

CMS is considering ways to improve the accessibility and usability of current charge information, and seeks comments from providers and suppliers on the following:

- How should "standard charges" be defined in various provider and supplier settings? Should it be defined as average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should "standard charges" be defined and reported

for both some measure of the average contracted rate and the chargemaster? Or is the best measure of a provider or supplier's standard charges its chargemaster?

- What types of information would be most beneficial to patients, how can providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?

- Should providers and suppliers be required to inform patients of how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients' choice and decision making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Can CMS require providers and suppliers to provide patients with information on what Medicare pays for services? If so, what changes would providers and suppliers have to make? What burden would such a requirement add?

In addition, CMS seeks comment on the following questions involving how to improve a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care?
- What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap?
- What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage?
- Who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care?
- What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

XIV. Collection of Information Requirements and Regulatory Impact Analysis

A. Impact of Changes in ERSD PPS Payments

Table 64 of the proposed rule provides the accounting statement showing estimated transfers of costs and savings that would result if the rule were finalized. Medicare payments to ESRD facilities for both the ESRD PPS and the payments for AKI would increase by $190 million in

2019; beneficiary coinsurance payments would increase by $30 million. In the text of the executive summary and the regulatory impact analysis section of the proposed rule, however, different figures are presented. There CMS says that payments to ESRD facilities would increase by $220 million ($190 million due to payment updates and $30 million due to changes in the outlier thresholds) and beneficiary copayments would increase by $60 million as a result of the overall payment increase. Medicare program payments for ESRD facilities in 2019 are estimated to total $10.6 billion, reflecting an expected 1.2 percent increase in fee-for-service Medicare dialysis beneficiary enrollment.

Table 58 in the proposed rule shows the impact on ESRD payments by various types of ESRD facilities. The estimates are based on 2017 data from the Part A and B Common Working Files as of February 16, 2018. A portion of that table is reproduced below. Omitted rows display facility impact by region, urban/rural location, and percentage of pediatric patients.

Impact of Final Rule Changes in 2019 Payment to ESRD Facilities (from Table 58)						
Facility Type	**Number of Facilities**	**Number of Treatments (millions)**	**Effect of Proposed 2019 Changes in Outlier Policy**	**Effect of Proposed 2019 Wage Index, Wage Floor, and Labor Share Changes**	**Effect of Proposed 2019 Rate Update**	**Total Effect of Proposed 2019 changes**
All Facilities	7,042	44.5	0.2%	0.0%	1.5%	1.7%
Type						
Freestanding	6,626	42.4	0.2%	0.0%	1.5%	1.7%
Hospital-based	416	2.1	0.4%	-0.1%	1.5%	1.8%
Ownership						
Large dialysis organization	5,355	34.4	0.2%	0.0%	1.5%	1.7%
Regional chain	871	5.7	0.3%	0.1%	1.5%	1.9%
Independent	479	2.9	0.2%	0.2%	1.5%	2.0%
Hospital-based	325	1.6	0.4%	0.0%	1.5%	1.9%
Facility Size (Treatments)						
Less than 4,000	1,689	5.9	0.2%	0.0%	1.5%	1.8%
4,000 to 9,999	2,502	11.8	0.2%	-0.2%	1.5%	1.6%
10,000 or more	2,776	26.7	0.2%	0.1%	1.5%	1.8%
Unknown	75	0.2	0.4%	0.3%	1.5%	2.2%

Table 59 in the proposed rule shows the impact of the proposed changes in payments for dialysis services furnished to AKI patients by type of facility. That table shows a total of 157,000 treatments would be provided to beneficiaries across 3,861 facilities.

B. Estimated Impact of ESRD QIP in PY 2021

For PY 2021, CMS estimates that the payment reductions under the final rule would total $38 million across the 2,896 facilities (about 44 percent) estimated to receive a reduction. A similar total is estimated for PY 2022. The tables below, reproduced from the proposed rule, show the

estimated distribution of payment reductions for PY 2021 and the impact by facility type. (With respect to the latter, only a portion of the table is shown here.) For a majority of the facilities receiving a payment reduction, the estimated reduction is 0.5 percentage points. Overall, CMS estimates the payment reductions would represent 0.4 percent of payments in PY 2021; reductions would be largest for independent facilities. Costs to facilities associated with collection of information requirements for the ESRD QIP are estimated to total $181 million for PY 2021 and $202 million in PY 2022. The PY 2021 figure of $181 million represents a reduction of $12 million from current policies.

Table 60: Estimated Distribution of PY 2021 ESRD QIP Payment Reductions		
Payment Reduction	**Number of Facilities**	**Percent of Facilities**
0.0%	3,639	56.68%
0.5%	1,351	20.68%
1.0%	923	14.12%
1.5%	437	6.69%
2.0%	185	2.83%
Note: Excludes 279 facilities for which CMS estimates no reduction will apply because of insufficient data to calculate a TPS.		

Impact of QIP Payment Reductions to ESRD Facilities for PY 2021 (from Final Rule Table 62)			
Facility Type	**Number of Facilities With QIP Score**	**Number of Facilities Expected to Receive a Payment Reduction**	**Payment Reduction as Percent of Total ESRD Payments**
All Facilities	6,535	2,896	-0.40%
Type			
Freestanding	6,149	2,740	-0.40%
Hospital-based	386	156	-0.39%
Ownership			
Large dialysis	4,945	2131	-0.37%
Regional chain	841	341	-0.36%
Independent	448	291	-0.69%
Hospital based (non-chain)	301	133	-0.44%
Facility Size (Treatments)			
Less than 4,000	900	301	-0.33%
4,000 to 9,999	2,502	978	-0.35%
10,000 or more	3,007	1,558	-0.45%
Unknown	126	59	-0.50%

C. Estimated Impact of DMEPOS Provisions

CMS estimates that its proposal to base single payment amounts on the maximum bid and to implement lead item pricing in the Medicare DMEPOS CBP is expected to cost $10 million in Medicare benefit payments and about $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. CMS implies that its cost estimate assumes that the next round of CBP would be delayed until January 1, 2021. In alternatives considered, CMS estimates that if it maintained the current SPA determination methodology (using the median of winning bids), this would save $1.14 billion in Medicare benefit payments and $280 million in Medicare beneficiary cost sharing beginning in January 1, 2019.

This rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) inflationary adjustment (based on the CPI-U) for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) 100 percent of the adjusted payment amount for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S); and (3) a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

CMS estimates that these policies combined are expected to cost $1.05 billion in Medicare benefit payments and $260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020. In addition, CMS estimates that the Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $45 million and $30 million, respectively. CMS also considered using a different blended rate for super rural and non-contiguous areas (75 unadjusted/25 adjusted) and the opposite blend (25 unadjusted/75 adjusted) in all other non-CBAs. CMS estimates that this alternative would have cost $30 million in Medicare benefit payments and $5 million in Medicare beneficiary cost sharing.

This proposal to establish new payment classes for oxygen and oxygen equipment is budget neutral.

CMS estimates that its proposal to establish payment rules for multi-function ventilators is expected to cost $15 million in Medicare benefit payments and $0 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023.

As required by OMB Circular A-4, CMS prepared an accounting statement (Table 64 in the proposed rule) showing the classification of the transfers and costs associated with the various provisions of the proposed rule.