2021 Medicare ESRD PPS
Proposed Rule Summary
CMS-1732-P

On July 6, 2020, the Centers for Medicare & Medicaid Services (CMS) posted for public inspection a proposed rule addressing the Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), and the ESRD Quality Incentive Program. It will be published in the *Federal Register* on July 13, 2020. **The public comment period ends on September 4, 2020.**

Along with proposing routine updates for 2021 payments under the ESRD PPS and for acute kidney injury, the proposed rule would add to the ESRD base amount to reflect the cost of calcimimetics and end the payments for these drugs under the transitional drug add-on payment adjustment. Outlier thresholds would change, and a transition to new wage index areas would be implemented for 2021. Eligibility criteria for the transitional add-on payment for new and innovative equipment and supplies (TPNIES) would be modified and further expanded to include eligibility for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient. ESRD facilities that would otherwise qualify for the Low Volume Payment Adjustment (LVPA) would be held harmless for an increase in dialysis treatment counts in 2020 due to the COVID-19 pandemic that would prevent them from qualifying for the LVPA. Two applications for 2021 payment of the TPNIES are reviewed. Scoring of the Ultrafiltration Rate reporting measure would be modified; other features of the ESRD Quality Incentive Program would remain unchanged.

Addenda provided by CMS on the ESRD PPS provide a facility-level impact file and wage index files. These are available at: https://www.cms.gov/medicaremedicare-fee-service-paymentesrdpaymentend-stage-renal-disease-esrd-payment-regulations-and/cms-1732-p.

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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 two 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. Additional payment is made for high-cost outliers. A Transitional Drug Add-On Payment (TDAPA) is available for qualifying new injectable or intravenous renal dialysis drugs and biologicals, and effective January 1, 2020 a similar transitional payment adjustment (the TPNIES) is available for qualifying, new and innovative renal dialysis equipment and supplies.

II. ESRD PPS Policy Changes and Updates for 2021

Policy changes are proposed involving the inclusion of calcimimetics into the ESRD PPS bundled payment, the eligibility criteria for the transitional add-on payment adjustment to support new and innovative renal dialysis equipment and supplies, expansion of the TPNIES to include new and innovative capital assets that are home dialysis machines when used for a single patient in the home, annual updates to the ESRD PPS rates, and the low-volume payment adjustment. Two applications under the TPNIES for 2021 are reviewed.

A. Inclusion of Calcimimetics into the ESRD PPS Bundled Payment

1. Background

CMS reviews the legislative and regulatory history of policies for treating new drugs and biologicals under the ESRD PPS. These policies are promulgated at 42 CFR 413.234. Particularly relevant to the proposals in this rule, 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[1], 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 for how payment should be made. In that case 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. Under statute, CMS is prohibited from paying for oral-only ESRD-related drugs (i.e., drugs with no injectable or intravenous administration) under the ESRD PPS prior to January 1, 2025. These drugs are covered under Medicare Part D. CMS has noted that the only oral-only

[1] The ESRD PPS functional categories are Access Management; Anemia Management; Bone and Mineral Metabolism; Cellular Management; Antiemetic; Anti-infective; Antipruritic; Anxiolytic; Excess Fluid Management; Fluid and Electrolyte Management Including Volume Expanders; and Pain Management. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.

ESRD-related drugs it has identified are calcimimetics and phosphate binders, which fall into the bone and mineral metabolism functional category. A number of changes to the new drug designation requirements were subsequently made and are detailed in the proposed rule. For example, the 2020 ESRD PPS final rule limited drugs and biologicals eligible for the TDAPA (85 FR 60565).

An exception to the policy for new injectable or intravenous drugs was made for calcimimetics and phosphate binders because payment for the oral form of these drugs was delayed and dollars were never included in the ESRD PPS base rate to account for them. For these drugs, CMS policy is to pay for the injectable form through the TDAPA for at least 2 years, during which time CMS will collect data that would allow it to add these drugs to the ESRD PPS bundled payment. This policy was used following FDA approval of an injectable calcimimetic in 2017; payment for this drug under the TDAPA began January 1, 2018 and was continued through 2020. Initially, payment under the TDAPA was based on 106 percent of the average sales price (ASP+6), but it was reduced to 100 percent of ASP (ASP+0) effective January 1, 2020.

2. Methodology for Modifying the ESRD PPS Base Rate to Account for Calcimimetics

Beginning in 2021, CMS proposes that the ESRD PPS base rate be modified to include the cost of calcimimetics, and that these drugs would no longer be paid under the TDAPA for dates of service on or after January 1, 2021. It believes that the claims data it has collected for 2018 and 2019 are sufficient for it to make this change. CMS has analyzed available ASP data and the utilization of every generic and brand name oral calcimimetic as well as the injectable calcimimetic. It notes an increase in use of oral generic calcimimetics (which entered the market in late 2018) and a decline in the brand-name oral drug, resulting in an overall decrease in the ASP for these drugs.

In order to modify the ESRD PPS base rate to include calcimimetics, CMS proposes to use a methodology similar to the one it used in initially establishing the ESRD PPS rates and to add new regulatory text at §413.234(f) to reflect this policy. It would calculate a per-treatment amount to add to the base rate by first taking the most recent calendar quarter ASP available to the public for calcimimetics and applying this price to the utilization data for calcimimetics from 2018 and 2019 claims data to calculate an expenditure amount. The resulting expenditure amount would be divided by the total number of hemodialysis-equivalent dialysis treatments paid in 2018 and 2019 under the ESRD PPS. The resulting average per-treatment amount would be reduced by 1 percent to account for outlier policy, and this is the amount that would be added to the ESRD PPS base rate, which would then be subject to the annual ESRD PPS rate updates. CMS notes that this proposed methodology applies only to calcimimetics. As for this drug, its policy states that for any eligible new renal dialysis drug it will consider whether the PPS base rate should be adjusted based on the utilization data it collects while the drug is paid under TDAPA. The proposed rule further details the calculations:

- Data on utilization of calcimimetics for the proposed rule were drawn from adjudicated 2018 claims submitted by ESRD facilities and available from the National Claims History (NCH) File as of June 30, 2019 and from 2019 claims available from the NCH File as of January 31, 2020. For the final rule, CMS will update the calculations to use 2019 claims available from the NCH File as of June 30, 2020. CMS proposes not to use

data from claims submitted in 2020 because practice patterns have been affected by the COVID-19 pandemic. **Comments are solicited on the proposed use of data for both 2018 and 2019 and whether CMS should use data for a single year instead.**

- For price, the most recent calendar quarter of ASP[2] calculations available to the public for the proposed rule are those for the second quarter of 2020, which reflect manufacturer sales data submitted into CMS for the fourth quarter of 2019 due to a two-quarter data lag. For the final rule, CMS would update the calculations using data for the fourth quarter of 2020 (reflecting manufacturer sales data submitted into CMS for the second quarter of 2020). CMS believes that using ASP data for oral and injectable calcimimetics reflects the prices to ESRD facilities for these drugs because ASP reflects manufacturer sales information including discounts specified in section 1847 of the Social Security Act (i.e., rebates, volume discounts, prompt payment, cash payment). CMS reiterates its rationale for use of ASP+0 instead of ASP+6 as described in the 2020 ESRD PPS final rule.

The specific proposed rule calculations using these data are summarized in the following table, resulting in a per treatment payment amount of $12.06 when the outlier reduction is applied. This is the amount that CMS proposes to add to the ESRD PPS base amount.

	Utilization	**Price**	**Expenditures**
Oral (unit = mg)	1,824,370,957	$0.231	$421,429,691
Injectable (unit = 0.1 mg)	306,714,207	$2.20	$674,771,255
Total calcimimetic expenditures*			**$1,096,200,947**
Paid hemodialysis-equivalent dialysis treatments	**90,014,098**		
Per treatment amount (total expenditures / total treatments)			$12.18
Per treatment amount with outlier adjustment (per treatment amount x 0.99)			**$12.06**
*Total shown is taken directly from proposed rule; likely differs from sum of earlier rows due to rounding.			

In the Executive Summary of the proposed rule, CMS states that payments under the ESRD PPS would be reduced by $80 million in 2021 as a result of the proposed addition to the ESRD PPS base rate for calcimimetics and the elimination of the TDAPA for these drugs.

[2] The ASP-based value is a CMS-derived weighted average of all the National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the two existing HCPCS codes for calcimimetics. The oral calcimimetic is reported as HCPCS J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) and the injectable calcimimetic is reported as HCPCS J0606 (Injection, etelcalcetide, 0.1 mg). For each billing code, CMS calculates a weighted ASP using manufacturer data, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold and the ASP for those units. Next, the number of billing units in an NDC is determined by the amount of drug in the package. CMS uses the following weighting methodology to determine the payment limit: (1) Sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code; (2) Divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code, and (3) Weights the ASP for an NDC by the number of billing units sold for that NDC. This calculation methodology is discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752). The general methodology for determining ASP-based payments for the PFS is authorized in section 1847A of the Act.

Comments are sought on an alternative methodology that CMS considered. Under the alternative instead of calculating total expenditures using the most recent ASP data, CMS would take actual expenditures for calcimimetics in 2018 and 2019 ($2.3 billion) and divide it by the total number of paid hemodialysis-equivalent dialysis treatments furnished during those years. This approach would not reflect the impact of generic oral calcimimetics which entered the market from late December 2018 through early January 2019. In addition, the alternative methodology would not reflect the change to ASP+0, as the TDAPA paid for calcimimetics at ASP+6 in 2018 and 2019. CMS believes that the proposed approach is more appropriate because it better aligns with how ESRD facilities would be purchasing and furnishing the oral calcimimetics than using expenditure data from previous periods. It believes that ESRD facilities would want to support CMS's goal of lower drug and biological products prices for its beneficiaries. The alternative methodology would increase beneficiary cost sharing more than the proposed approach.

B. Changes to the TPNIES Eligibility Criteria

In the 2020 ESRD PPS final rule, CMS established a new transitional add-on payment adjustment for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS and codified it at §413.236. To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item must meet all the following requirements:

1. Has been designated by CMS as a renal dialysis service under §413.171;
2. Is new, meaning it is granted marketing authorization by the FDA on or after January 1, 2020;
3. Is commercially available by January 1 of the year in which the payment adjustment would take effect;
4. Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;
5. Is innovative, meaning it meets the substantial clinical improvement criteria used by CMS for the IPPS new technology add-on payment (NTAP), as specified in §412.87(b)(1) and related guidance; and
6. Is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

In addition, CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. Decisions about whether an applicant meets the eligibility criteria are announced as part of the ESRD PPS rulemaking cycle. More information on the TPNIES is available at https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies.

In this rule, CMS proposes several modifications to these criteria, including changes involving the definition of new, and the timing of HCPCS application requirements and FDA marketing authorization described below. Another proposed change would specify in the regulatory text the TPNIES effective date of January 1, 2020, and other technical changes to the regulatory text

would be made. CMS notes that by referencing §412.87(b)(1) with respect to the requirement for substantial clinical improvement, it has adopted the codification included in the FY 2020 IPPS final rule of additional substantial clinical improvement criteria that had previously been included in manuals and other sub-regulatory guidance. Therefore, it proposes to remove the phrase "and related guidance" in the regulatory text with respect to the substantial clinical improvement requirement for TPNIES eligibility.

1. Definition of "New"

CMS proposes to modify the criteria with respect to defining new renal dialysis equipment and supplies. Under the proposal, a new equipment or supply item would be one within 3 years beginning from the date of the Food and Drug Administration (FDA) marketing authorization. CMS notes that the effective date of the TPNIES remains January 1, 2020 and therefore no equipment or supply receiving FDA marketing authorization before January 1, 2020 would be eligible for the TPNIES.

The change is proposed because under the current requirement CMS could receive an application for the TPNIES for equipment and supplies many years after FDA marketing authorization, when the equipment is no longer new. The proposed 3-year newness window is consistent with the timeframes under the IPPS NTAP requirements in § 412.87(b)(2). Under the NTAP, new technologies are considered to be new for 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. In addition, CMS notes that under the hospital outpatient PPS, the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

CMS seeks comment on this proposed definition of new for purposes of the TPNIES eligibility, and also on the number of years for an item to be considered new, or if newness should be based on different criteria, such as the later date of marketing availability or FDA marketing authorization. CMS understands that there may be situations in which a manufacturer has FDA marketing authorization for an item, but the process of manufacturing the item has been delayed, for example, by a public health emergency, such as the current COVID-19 pandemic.

2. Timing of HCPCS Application and FDA Marketing Authorization

As shown above, another TPNIES eligibility criterion requires applicants to have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year. Further, applicants must have the FDA marketing authorization for the equipment or supply by September 1 prior to the particular calendar year.

CMS proposes to change this requirement to reflect changes in the HCPCS Level II coding procedures made after publication of the 2020 ESRD PPS final rule.[3] Under those procedures, beginning in January 2020, CMS implemented quarterly HCPCS code application opportunities for drugs and biological products, and biannual application opportunities for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other non-drug, non-biological items and services. For 2020, the deadline for HCPCS Level II code applications for biannual Coding Cycle 1 for DMEPOS items and services was January 6, 2020 with issuance of final code decisions occurring July 2020. These final code decisions are effective October 1, 2020. For biannual Coding Cycle 2, the code application deadline for DMEPOS items and services is June 29, 2020 with issuance of final code decisions occurring January 2021 or earlier. These final code decisions are effective April 1, 2021. All the dates are specific for 2020 and may change annually. Specific dates for biannual Coding Cycles 1 and 2 for future years will be published on the HCPCS website annually.

The new biannual coding cycles conflict with the TPNIES deadlines regarding HCPCS coding and FDA marketing authorization, and CMS therefore proposes to align the TPNIES regulations with the HCPCS guidelines. Specifically, instead of the September 1st deadline currently specified in regulation, the applicant would need to have a complete HCPCS Level II code application submitted by the code application deadline for biannual Coding Cycle 2 for DMEPOS items and in accordance with the procedures for these applications on the CMS website. CMS notes that use of this deadline may result in a final HCPCS code determination by January 1, when the TPNIES payment would begin. The HCPCS code application would have to be completed and submitted as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. Because final decisions on HCPCS Level II codes for the 2020 biannual Coding Cycle 2 will be issued by January 1, 2021 but will not be effective until April 1, 2021, CMS proposes to use a miscellaneous HCPCS code to provide the TPNIES payment in the interim.

The same deadline is proposed with respect to the requirement for FDA marketing authorization and would replace the current deadline of September 1 of the prior year for this authorization. That is, the FDA marketing authorization for the new and innovative equipment or supply would have to accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year. Although applicants for TPNIES may submit a TPNIES application while the equipment or supply is undergoing the FDA marketing authorization process, FDA marketing authorization would have to be granted prior to the HCPCS Level II code application deadline. If it is not granted in time, the TPNIES application would be denied and the applicant would need to reapply and submit an updated application by February 1 of the following year or within 3 years beginning on the date of FDA marketing authorization as discussed above.

[3] See the HCPCS Level II coding procedures at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf, and the application instructions at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf.

C. Expansion of the TPNIES for New and Innovative Capital-Related Assets that are Home Dialysis Machines When Used in the Home for a Single Patient

Currently, the TPNIES is not available for a new and innovative renal dialysis equipment or supply item that is a capital-related asset, regardless of whether the item meets the other eligibility criteria. In making that exclusion CMS cited that the cost of capital items is captured in cost reports, the items depreciate over time, and they are generally used for multiple patients. In addition, CMS noted the complexity of establishing a cost per treatment for these items. Responding to comments from the device industry and others, CMS also observed that accounting for renal dialysis service equipment can vary depending on whether the asset is owned or leased. However, in light of industry concerns that the potential benefits to ESRD patients of innovations in medical equipment would essentially be excluded from the TPNIES with this policy, CMS committed to close examination of how capital-related assets are treated with respect to inpatient hospitals to see if similar policies would be appropriate for the ESRD PPS.

Since the 2020 ESRD PPS final rule was issued, CMS has consulted with industry stakeholders and a technical expert panel to investigate the issue of capital-related assets used for renal dialysis services, including analysis of business and financial arrangements (e.g., ownership versus leasing) and single versus multiple use of capital-related assets. It also cites the President's July 19, 2019 Executive Order on Advancing American Kidney Health, which included a focus on encouraging in-home dialysis, and CMS' proposed ESRD Treatment Choices (ETC) Model (84 FR 34478), a mandatory payment model for selected geographic areas which would focus on encouraging greater use of home dialysis and kidney transplants. Finally, CMS notes the benefits of home dialysis to ESRD patients during the COVID-19 pandemic.

1. Expansion of Eligibility

CMS now proposes to expand TPNIES eligibility to include eligible new and innovative capital-related assets that are home dialysis machines when used in the home. CMS intends to target the TPNIES to equipment that supports HHS goals and initiatives regarding home dialysis. Further, after studying business arrangements, CMS has concluded that eligibility should be limited to cases where the capital-related assets are purchased in their entirety and owned as capital-related assets, whether purchased or attained through a capital lease. Under the proposal CMS would not pay the TPNIES for equipment that is leased because in that case the ESRD facility has no ownership rights. CMS continues to analyze other business arrangements, but concludes ownership is the most straightforward because who owns the asset is clear, the asset is retained at the end of the TPNIES period, and the asset is on the facility's balance sheet. The regulatory text at §413.436 would be further amended to reflect this expansion of the TPNIES.

Other capital-related assets, such as water purification systems and dialysis machines that are used in a facility would continue to be excluded from the TPNIES because they would not be advancing HHS's goal of increasing home dialysis. In addition, CMS continues to believe that additional payment for these capital-related assets is inappropriate because the cost of these items is captured in cost reports and reported in the aggregate, depreciate over time, and are generally used for multiple patients. It notes that capital-related assets that are home dialysis

machines when used in the home are intended for use by a single patient and can be reported on a per treatment basis on the ESRD facility's claim. This allows for a simple methodology for determining a per treatment TPNIES payment.

Under the proposal, the existing exclusion from TPNIES eligibility for capital-related assets would be modified to simply state that eligibility is not provided to a capital-related asset, except for capital-related assets that are home dialysis machines. Other requirements, procedures, and deadlines (with proposed changes as discussed above) would apply to capital-related assets as well as other renal dialysis related equipment and supplies, including the substantial clinical improvement provision. CMS notes that FDA provides a separate marketing authorization for equipment intended for home use, and for purposes of determining whether a home dialysis machine is new it would look at the date the machine is granted marketing authorization by FDA for home use. Further, CMS notes that applicants would be expected to submit information on the price of their home dialysis machine as part of the TPNIES application, along with the equipment or supply's projected utilization.

As part of this proposal, CMS would add several definitions to the regulatory text. It proposes to define a "capital-related asset" as an asset that an ESRD facility has an economic interest in through ownership (regardless of the way it was acquired) and is subject to depreciation. This proposed definition is based on the definition of "depreciable assets" in the Provider Reimbursement Manual.[4] "Home dialysis machines" would be defined as hemodialysis machines and peritoneal dialysis cyclers in their entirety (which CMS says means one new part of a machine would not make the entire capital-related asset new), that receive FDA marketing authorization for home use and when used in the home for a single patient. "Particular calendar year" would be defined as the year in which the TPNIES payment adjustment would take effect. Other proposed new definitions are discussed below with respect to the pricing of capital-related assets that are home dialysis machines used in the home.

2. Pricing of New and Innovative Capital-Related Assets that are Home Dialysis Machines When Used in the Home

Under current policy, the TPNIES payment amount equals 65 percent of a price for the item that is established by the Medicare Administrative Contractors (MACs) on behalf of CMS. The MACs establish the price using verifiable information from the following sources, if available:

1. The invoice amount, facility charges for the item, discounts, allowances, and rebates;
2. The price established for the item by other MACs and the sources of information used to establish that price;
3. Payment amounts determined by other payers and the information used to establish those payment amounts; and
4. Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

[4] See chapter 1, section 104.1 of the Provider Reimbursement Manual available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929

CMS believes the same invoice-based approach should be used for pricing capital-related assets that are home dialysis machines used in the home, but there needs to be recognition that these are depreciable assets. It proposes to apply a 5-year straight-line depreciation method to determine the basis of the TPNIES for these items, and cites the Provider Reimbursement Manual discussion of these issues at chapter 1, section 116.1 and section 104.17 as well as the American Hospital Association (AHA) guidelines for identifying the useful life for computing depreciation. The Provider Reimbursement manual provides that under the Medicare program, only the AHA guidelines may be used in selecting a proper useful life for computing depreciation.

Using the manual's definitions, CMS proposes to define "depreciation" as the amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation; "straight-line depreciation method" as a method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life; and "useful life" as the estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

In sum, the MACs would use a two-step process to establish a price for capital-related assets that are home dialysis machines used in the home. First, they would determine a price using the general method under the TPNIES, and then using the straight-line depreciation method, the MAC-determined price would be divided by equipment's useful life (i.e., 5 years), resulting in the annual allowance. In the second step the MACs would calculate a *pre-adjusted per treatment amount* by dividing the annual allowance by the number of treatments expected to be furnished in a year. The number of expected treatments would be provided to the MACs by CMS through the change request[5], and based on current payment policy this is 3 treatments per week, or 156 treatments per year (3 x 52 =156). CMS notes that the 5-year useful life and 3 treatments per week arise from Medicare policy and are fixed amounts for home dialysis machines.

No other potential elements (e.g., financing, sales tax, freight, installation and testing, excise taxes, legal or accounting fees, maintenance costs) would be used to determine the total cost basis for applying straight-line depreciation. CMS considered other depreciation methods (e.g., units of production, double declining balance, sum-of-the-years-digits) but determined these would be more complex to implement. Noting that the TPNIES does not reimburse the cost of the equipment, and at the end of the 2-year TPNIES add-on period the ESRD PPS base rate will not be revised, CMS believes that the proposed approach is appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies

CMS proposes that the TPNIES payment amount would be 65 percent of the pre-adjusted per treatment amount, consistent with current TPNIES policy and the inpatient hospital NTAP. The following table displays how the payment amount would be calculated using the proposed rule's hypothetical dialysis machine with a MAC-established price of $25,000.

[5] Once CMS has all of the required information for equipment and supplies eligible for the TPNIES, it will issue a change request with billing guidance that will provide notice to the dialysis community that the equipment or supply is eligible for the TPNIES as of January 1 and technical instructions on how ESRD facilities are to report the equipment or supply on the ESRD claim. This change request will initiate the TPNIES period for the equipment or supply and it will end 2 years from the change request's effective date. For any equipment or supply approved for the TPNIES for 2021, the TPNIES will begin on January 1, 2021 and end on December 31, 2022.

MAC-established price of home dialysis machine (hypothetical)	$25,000
Annual allowance (straight line depreciation over 5 years)	$5,000
Number of expected treatments (3 per week x 52 weeks)	156
Pre-adjusted per treatment amount (annual allowance/expected treatments)	$32.05
TPNIES adjustment (65% of pre adjusted per treatment amount)	$20.83

CMS notes that if in the future an innovative home dialysis machine is designed to require more or fewer treatments per week, MACs would use the same methodology except to use a different number of treatments in the denominator when calculating the pre-adjusted per treatment amount. The total TNPIES adjustment for the year (e.g., $5,000 x 0.65) would be the same regardless of the number of treatments.

Further, CMS proposes that like other renal dialysis related equipment and supplies, the TPNIES for home dialysis machines would be applied for 2 calendar years from the effective date of the change request, which would coincide with the effective date of a PPS ESRD final rule. It believes the duration of the application of the TPNIES should be the same for all equipment and supplies and that 2 years would allow ESRD facilities sufficient time to make adjustments to allow seamless access to the new and innovative home dialysis machines. CMS reiterates that the TPNIES is intended to give new and innovative equipment and supplies a foothold in the market to compete with other equipment and supplies accounted for in the ESRD PPS base rate.

As under current TPNIES policy, once the 2-year period is over, the ESRD PPS base rate would not be adjusted to reflect to the costs of capital-related assets that are home dialysis machines; unlike current TPNIES policy, these capital assets would be excluded from outlier policy. CMS notes that the TPNIES is meant to be transitional, and the base rate already reflects the cost of equipment and supplies needed to provide dialysis services. With respect to the proposed exclusion from outlier payments, CMS states that capital expenses are distinct from operating expenses, which are generally accounted for on a per patient basis. The per patient accounting of operating expenses allows for identification of higher-than-average utilization for purposes of outlier payments. It intends to monitor utilization during the TPNIES period.

Although the proposal would increase Medicare expenditures and beneficiary coinsurance, CMS believes that it is appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment to ESRD patients.

Comments are sought on an alternative methodology that CMS is considering for the final rule. Under the alternative, the pre-adjusted per treatment amount would be calculated as proposed and then offset to reflect the costs of dialysis equipment that are included in the ESRD PPS base rate. That is, the TPNIES payment would be intended to cover the estimated marginal costs of new and innovative home dialysis machines. CMS discusses how the ESRD PPS base rate was calculated in the 2011 ESRD PPS final rule (75 FR 49075).

Under the alternative, the MACs would take a third step in calculating the pre-adjusted per-treatment amount. This step would involve computing an offset by using annual dialysis machine and equipment cost and treatment counts from 2018 ESRD facility cost reports to derive an average home dialysis machine and equipment cost per home dialysis treatment across all ESRD

facilities. This figure would then be updated to 2021 using the ESRDB market basket less productivity updates for 2019, 2020, and 2021. The proposed rule details which cost report elements would be used and how figures for individual freestanding and hospital-based ESRD facilities would be aggregated for this purpose. **CMS particularly seeks comments on this methodology.** CMS believes the methodology it describes would provide an approximation of the cost of the home dialysis machine in the base rate, and that making this offset would be reasonable because a beneficiary would not be using two home dialysis machines at the same time, and at the end of the 2-year TPNIES period, the facility would retain ownership of the home dialysis machine.

CMS reports that using this methodology would result in an offset of $9.23. The table below shows how the alternative would be calculated based on the numerical example of the proposal described earlier. (As proposed, this hypothetical home dialysis machine would result in a TPNIES adjustment of $20.83.)

MAC-established price of home dialysis machine (hypothetical)	$25,000
Annual allowance (straight line depreciation over 5 years)	$5,000
Number of expected treatments (3 per week x 52 weeks)	156
Pre-adjusted per treatment amount (annual allowance/expected treatments)	$32.05
Offset to pre-adjusted per treatment amount under alternative	*$9.23*
Alternative per treatment amount (per treatment amount – offset)	*$22.82*
Alternative TPNIES adjustment (65% of per treatment amount)	*$14.83*

D. 2021 ESRD PPS Update

CMS proposes a 2021 ESRD PPS base rate of $255.59, compared with the final 2020 rate of $239.33. As shown in the table below, this increase is the result of several factors: Application of the proposed wage index budget neutrality adjustment of 0.998652; the proposed addition to the base rate for calcimimetics (discussed above) of $12.06; and application of the proposed update factor of 1.8 percent. The update factor reflects an estimated increase of 2.2 percent in the ESRD bundled input price index ("market basket") and an estimated multifactor productivity (MFP) adjustment of -0.4 percent. The figures will be updated for the final rule to reflect more recent information, if available.

Proposed 2021 ESRD PPS Base Rate	
Base Rate Update Components	**Amount**
Final 2020 ESRD PPS Base Rate	**$239.33**
Wage index budget neutrality adjustment	0.998652
Addition to the base rate for calcimimetics	+$12.06
Market basket increase	+2.2%
Multifactor productivity adjustment	-0.4%
Subtotal: update factor	+1.8%
Proposed FY 2021 ESRD PPS Base Rate	**$255.59**
Note: the proposed 2021 base rate is calculated as (($239.33*0.998652) +$12.06) x 1.018 = $255.59.	

1. Wage Index

The ESRD PPS adjusts the labor-related portion of the base rate to reflect geographic differences in wage levels using wage index values based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. That is, the ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Social Security Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2021, the updated wage data are from hospital cost reporting periods for FY 2017 and are listed in Addendum A available on the CMS web page for this proposed rule at the link provided on page 1 of this summary. The previously adopted wage index floor of 0.5000 is applied; wage areas in Puerto Rico are currently the only ones to benefit from the floor. The labor-related share (the portion of the base rate adjusted by the wage index) continues to be 52.3 percent, based on the 2016-based ESRD market basket.

For 2021, CMS also proposes to use wage index areas that reflect updates to the Office of Management and Budget (OMB) designations of Metropolitan and Micropolitan Statistical Areas. In particular, for 2021, the wage index would reflect changes included in OMB Bulletin No. 18-04, issued on September 14, 2018. Further, CMS notes that on March 6, 2020, OMB issued OMB Bulletin No. 20-01. While it was not issued in time for development of this proposed rule, CMS has reviewed the changes and determined they are minor. Any updates from this Bulletin will be proposed in the 2022 ESRD PPS proposed rule.

The changes included in OMB Bulletin No. 18-04 would result in new Core Based Statistical Areas (CBSAs), changing 34 urban counties to rural, 47 rural counties to urban, and splitting some existing CBSAs. Tables 1, 2, and 4 in the proposed rule detail these substantive changes; Table 3 identifies areas where only the CBSA name or number would change, without affecting assignment of a wage index.

To mitigate any negative impact of these changes in the wage index, CMS proposes to adopt the changes in OMB Bulletin No. 18-04 beginning with the 2021 ESRD PPS wage index, and to provide for a 5 percent cap on decreases in any facility's wage index for 2021 when compared to 2020. The cap would provide for a transition to the new wage index areas. No cap would be applied in 2022. Addendum A, cited above and available on the ESRD PPS proposed rule web page (link on page 1 of this summary), displays the current and revised wage areas for each county and the wage index using the new wage area delineations. However, Addendum B, which is the facility-specific ESRD PPS impact file, shows the proposed transition wage index values for 2021.

Table 10 in the proposed rule, reproduced in part in section V of this summary, shows the impact of the proposed adoption of the new wage area delineations by type and region of ESRD facility.

2. 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 (FDL). ESRD outlier services are defined as specified items and services included in the ESRD PPS bundle.

For 2021, CMS proposes no changes to the methodology used to compute the MAP amount per treatment or FDL amounts used to calculate ESRD PPS outlier payments. However, these amounts would be updated using 2019 claims data. The 2021 outlier policy amounts and those for 2020 are shown in Table 5 of the proposed rule, reproduced below. As shown in the table, the proposed MAP and FDL amounts are much higher than those for 2020. The MAP and FDL amounts continue to be lower for pediatric patients than for adults due to continued lower use of outlier services (particularly calcimimetics, ESAs and other injectable drugs) among the pediatric ESRD population.

Based on 2019 claims, outlier payments represented about 0.50 percent of total payments, below the 1 percent target. CMS observes that the use of ESAs and other outlier services has continued to decline under the ESRD PPS, and it has reduced the MAP amounts and FDLs each year as a result. CMS believes that recalibration of the thresholds using 2019 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2021 because the data it is using for computing the MAP and FDL are more current and in line with current outlier services utilization rates.

CMS notes that for 2021, the predicted outlier services MAP amounts and FDL amounts have increased as a result of the proposal to incorporate oral and injectable calcimimetics into the outlier policy. (This policy change is discussed in section II.A above.) CMS believes the inclusion of calcimimetics as ESRD outlier services in 2021 would fundamentally change the per-treatment distribution of outlier services relative to previous years. It notes that about 30 percent of ESRD beneficiaries receive calcimimetics and often have significantly higher utilization of ESRD outlier services relative to other beneficiaries.

TABLE 5: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)*		**Column II Proposed outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)**	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$30.95	$37.33	$32.12	$56.50
Adjustments				
Standardization for outlier services	1.0655	0.9781	1.0509	0.9801
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$32.32	$35.78	$33.08	$54.26
FDL amount that is added to the predicted MAP to determine the outlier threshold	$41.04	$48.33	$47.73	$133.52
Patient-months qualifying for outlier payment	11.35%	10.38%	8.65%	4.91%

*Note that Column I was obtained from Column II of Table 2 from the CY 2020 ESRD PPS final rule (84 FR 60705).

E. Changes to the Low-Volume Payment Adjustment

The ESRD PPS provides a low-volume payment adjustment (LVPA) of 23.9 percent to reflect the higher costs incurred by low-volume facilities, identified as those that furnished less than 4,000 treatments in each of the 3 preceding cost reporting years and has not opened, closed, or received a new provider number due to change in ownership during those years. In order to receive the LVPA an ESRD facility must submit a written attestation statement to its Medicare MAC confirming that it meets all the requirements specified in §413.232 and qualifies as a low-volume ESRD facility. The attestation is required because facility cost reporting periods vary and the lag in submission of cost reports may mean that the MAC does not have the facility's cost report for the third year to determine eligibility. The attestation is generally due by November 1st for the upcoming payment year.

As a result of the COVID-19 public health emergency (PHE), some low-volume facilities have been providing more treatments than usual. ESRD facilities have worked together to limit the risk of spreading COVID-19 by shifting patients among ESRD facilities in the same area, and in some parts of the country the number of patients with acute kidney injury has increased because some COVID-19 patients discharged from inpatient care require outpatient dialysis services for some time while their kidneys regain normal function. CMS is concerned that the unusual increase in treatments in 2020 may result in the loss of the LVPA in 2021, 2022 and 2023 for some facilities. In 2020, 368 facilities qualified for the LVPA; some 50-60 facilities typically lose LVPA status each year.

CMS proposes to hold ESRD facilities harmless if an increase in their treatment counts in 2020 is COVID-19 related and would prevent them from qualifying for the LVPA. Under the proposal, the ESRD facility would attest that the increase in treatments was temporary and related to the redistribution of patients in response to the COVID-19 PHE. For these facilities, for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, CMS would not use the total dialysis treatments furnished in cost reporting periods ending in 2020. Instead, it would only consider total dialysis treatments furnished for 6 months of a facility's cost-reporting period ending in 2020, and the ESRD facility would decide which 6 months to use (consecutive or non-consecutive).

An ESRD facility in this situation would attest that, while it furnished 4,000 or more treatments in its cost-reporting period ending in 2020, the number of treatments exceeding the LVPA threshold was due to temporary patient shifting as a result of the COVID-19 PHE, and that their total dialysis treatments for any 6 months of that period is less than 2,000. MACs would annualize the total dialysis treatments for those 6 months by multiplying the treatments by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request. The proposal would be codified in a proposed new §413.232(g)(4). Other technical changes are proposed in the regulatory text in §413.232.

Noting that it has changed cost reporting deadlines due to the COVID-19 PHE, CMS also proposes to extend the deadline for making the LVPA attestation for 2021 payment to December 31, 2020.

Finally, CMS clarifies that if an ESRD facility provides an attestation for the third eligibility year and is paid the LVPA and the MAC subsequently determines based on the cost report that the facility does not meet the definition of a low-volume facility, the MAC will reprocess claims and recoup the low volume adjustments paid during the payment year. CMS understands that in some instances, MACs may be discontinuing LVPA payments to a facility during the payment year for which the facility is eligible for the adjustment. However, the established policy is that if an ESRD facility meets the LVPA eligibility criteria it is entitled to the payment adjustment for the entire payment year.

F. Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies for 2021 Payment

1. TPNIES Eligibility Criteria

In the 2020 ESRD PPS final rule[6], CMS finalized the establishment of a transitional add-on payment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS. To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item must meet all the following requirements:

7. Has been designated by CMS as a renal dialysis service under §413.171;
8. Is new, meaning it is granted marketing authorization by the FDA on or after January 1, 2020;
9. Is commercially available by January 1 of the year in which the payment adjustment would take effect;
10. Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;
11. Is innovative, meaning it meets the substantial clinical improvement criteria used by CMS for the IPPS NTAP (described in the regulatory text as meeting the criteria specified in §412.87(b)(1) and related guidance); and
12. Is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

As discussed above in section II.B of this summary, CMS proposes to refine the newness criteria and establish that an equipment or supply is considered "new" within 3 years beginning on the date of FDA marketing authorization for that equipment or supply. For capital-related assets that are dialysis machines used in the home setting, the 3 years would begin from the date of FDA marketing authorization for home use. Additional proposed revisions to the TPNIES are also discussed in above in section II.B.

[6] 84 FR 60681 - 60698

2. Applications for the TPNIES

For 2021, CMS received two applications for the TPNIES:

- Theranova 400 Dialyzer and Theranova 500 Dialyzer and
- Tablo® Cartridge for the Tablo® Hemodialysis System.

The summary below provides a high-level discussion of each new technology assessment, including comments by members of the CMS TPNIES Work Group.[7] Readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether these technologies meet the newness and substantial clinical improvement criteria.**

a. Theranova 400 Dialyzer and Theranova 500 Dialyze

Baxter Healthcare Corporation submitted an application for the Theranova 400 Dialyzer and the Theranova 500 Dialyzer. The 400 and 500 denote differences in surface area; the application collectively refers to the products as "Theranova".

According to the applicant, Theranova is a new class of hollow-fiber, single-use dialyzers intended to treat renal failure by hemodialysis (HD). The Theranova dialyzer consists of an innovative 3-layer membrane structure that offers a higher permeability than high-flux dialyzers, with improved removal of large proteins up to 45 kilodaltons (kDA) while selectively maintaining essential proteins such as albumin. The applicant stated that Theranova has the potential to transform in-center HD by providing expanded hemodialysis HDx[8] to Medicare beneficiaries with renal failure. In addition, the design of the Theranova dialyzer allows use on any HD machine.

Newness. The Theranova received approval for an Investigational Device Exemption (IDE) protocol from the FDA in August 2017. The applicant is seeking FDA authorization through the FDA's DeNovo pathway and anticipated marketing authorization for the May 2020 cycle.[9] The applicant planned to submit a HCPCS application in June 2020. The applicant stated that it expects Theranova to be commercially available after receiving marketing authorization.

Substantial Clinical Improvement. The applicant stated Theranova effectively targets the removal of large middle molecules (LMM) uremic toxins (25 kDa to 60 kDa), which are linked to the development of inflammation, cardiovascular disease, and other comorbidities in dialysis patients. The applicant submitted evidence to support improved clinical outcomes in four categories: (1) decreased rate of subsequent therapeutic interventions including decreased infections, decreased hospitalizations, and reduced medication usage; (2) reduced patient

[7] The CMS TPNIES Work Group consists of CMS Medical Officers, senior staff, a senior technical adviser, a biomedical engineer, and contracted physicians, including nephrologists.
[8] HDx is defined as a process of blood purification that includes the clearance of small uremic toxins through large middle molecule (categorized as uremic solute whose molecular size is 25 kDa up to 60 kDa) toxins without the need for an external infusion of replacement fluid.
[9] According to the FDA database, the decision date has been moved to July 10, 2020 (FDA database is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm).

recovery time after HDx therapy; (3) reduced inflammation as demonstrated by reduction of inflammatory markers; and (4) enhanced quality of life.

CMS TPNIES Work Group Analysis. The Work Group acknowledged that patients with ESRD requiring dialysis are at high risk of mortality due to uremic toxins and highlighted the limitations of current HD technology. The Work Group discussed innovations in dialysis care including hemodiafiltration (HDF) technology that removes larger molecules by combining convection (based on pressure gradients across the dialyzer membrane) with diffusion; online HDF, which enables dialysis providers with ultrapure water systems to generate replacement fluid solutions; and new dialysis membranes aimed at improved middle molecule clearance.

Assessment of Substantial Similarity to Currently Available Equipment or Supplies. The Work Group believes that Theranova is a slight modification to existing HD technology and treats similar patients as existing technology.

Assessment of Substantial Clinical Improvement. The Work Group noted that Theranova is a treatment modality that would be available for patients who are also eligible for HD, HDF, or online HDF. The Work Group evaluated the information provided by the applicant and published articles identified by a literature search. Its review included 12 published peer-review journal articles, four review articles/editorials, 18 posters and abstracts, and three incomplete manuscripts provided by the applicant. The Work Group concluded that Theranova represents a unique technology but the current evidence supporting the substantial clinical improvement is lacking. The Work Group raised several concerns about the methodology used in the studies, including small sample size and open-label observational studies, and believed these limited evaluation of patient outcomes. The Work Group believes larger studies are needed focused on the U.S. dialysis population with patients blinded to their treatment. The Work Group were also concerned that the evidence does not support that HDx provides a substantial benefit as compared to conventional HD or that online HDF improves health outcomes relative to conventional HD with high-flux membranes. Finally, the Work Group raised concerns about the safety and efficacy studies and the possible impact of clearing large middle molecules in rigorously conducted, randomized clinical studies.

b. Tablo® Cartridge for the Tablo® Hemodialysis System

Outset Medical submitted an application for the Tablo® Cartridge for the Tablo® Hemodialysis System in the home setting. The cartridge is only compatible with the Tablo® Hemodialysis System. The cartridge consists of a rigid "Organizer" which mounts the necessary hemodialysis tubing to allow for greater ease in set-up. This single-use cartridge contains both the arterial and venous lines, an adaptor to connect the lines, a saline line and an infusion line. The cartridge also contains a pressure transducer protector, venous drip chamber with clot filter, and an arterial pressure pod. The applicant stated the Tablo® Hemodialysis System, including the Tablo® Cartridge, have been designed for patient-driven self-care using an iterative human factor process to facilitate learning and to minimize device training time. The applicant discussed four unique features of the Tablo® Hemodialysis System. The applicant stated the single-use Tablo® Cartridge has an integrated blood pressure monitor that interfaces with the console and enables

automated features such as air removal, priming, and blood return which reduces user errors and streamlines the user experience.

Newness. The TPNIES application is only for the Tablo® Cartridge and its components for home use with the Tablo® Hemodialysis System. On March 31, 2020, Outset Medical received FDA clearance to market the System for home use. Previous 510(k) authorizations for the Tablo® Hemodialysis System and Tablo® Cartridge were for hospital and outpatient use. CMS notes that the first patient to start training is scheduled for June 1, 2020. The applicant planned to submit a HCPCS application before the September 1, 2020 deadline.

According to the applicant, the Tablo® Hemodialysis System provides a treatment option for a patient population unresponsive to, or ineligible, for current available treatments. The Tablo® Hemodialysis System is designed to address many barriers that prevent HD in the home.

Significant Clinical Improvement. The applicant stated that the Tablo® Hemodialysis System and Tablo® Cartridge significantly improves clinical outcomes by reducing hospitalizations and increasing quality of life. According to the applicant, the Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians the ability to monitor patients in real time which allows for earlier identification and intervention by the health care team preventing hospitalizations for dialysis related events or missed treatments. The applicant also stated that the System can effectively deliver HD adequacy with 3 to 4 treatments per week which has the potential to reduce Medicare expenditures and also reduce vascular access complications.
The applicant submitted evidence to support improved quality of life in four areas: (1) improved sleep and reduction in fatigue; (2) reduced frequency of hypotensive events; (3) reduced feeling cold during HD; and (4) patient preference for the Tablo® Hemodialysis System because it was easier to use than other available home HD systems. The applicant concluded that the Tablo® Hemodialysis System is an innovative HD system that removes most of the device-related barriers, reduces dialysis-related symptoms, is mobile and easy to use.

CMS TPNIES Work Group Analysis. The Work Group acknowledged that home dialysis use in the U.S. remains low and that home HD may offer an alternative to peritoneal dialysis (PD). The Work Group discussed the challenges associated with home HD including patient's concerns about self-cannulation and performing all the necessary steps to safely connect the various components of a home HD system.

Assessment of Substantial Similarity to Currently Available Equipment or Supplies. The Work Group believes the Tablo® Hemodialysis System is most comparable to the NxStage® System One. The Tablo® Hemodialysis System differs from the NxStage® in that dialysate is produced on demand and the NxStage® requires patients batch dialysate or use pre-filled concentrate with the Pure Flow tap water source. The Tablo® Hemodialysis System also includes the Cartridge designed to facilitate the connection of tubing in the appropriate configuration. The product treats similar ESRD patients as other home HD systems.

Assessment of Substantial Clinical Improvement. The Work Group noted that the Tablo® Hemodialysis System is a treatment modality that would be available for patients who are also eligible for in-center HD, home HD with currently available treatments, and possibly PD. The

Work Group evaluated the information provided by the applicant and published articles; the focus of the review of the evidence was clinical improvement or patient reported outcomes. Its review included 2 published peer-review journal articles, 3 posters and abstracts, and one set of unpublished data provided by the applicant.

The Work Group noted that although there are changes to the Tablo® Hemodialysis System for home use, the Cartridge is unchanged from its original FDA approval and is not new. They also raised concerns that much of the evidence presented is really about the system itself including ease of training, its various features, and less about the incremental benefit of using the Cartridge. The Work Group thought it would be helpful to have studies focused on the Cartridge and suggested larger studies of patient-reported outcomes that looked at the benefits of using this home-based modality. The Work Group also raised concerns about the FDA approval and information in the current application and concluded that the stand-alone cartridge cannot be evaluated for meeting the substantial clinical improvement criteria.

III. 2021 Payment for Renal Dialysis Services Furnished to Individuals with 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]." 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. Therefore, for 2021 CMS proposes to set the AKI dialysis payment rate to equal the proposed 2021 ESRD PPS base rate of $255.59, adjusted by the facility's wage index.

In the regulatory impact analysis section of the proposed rule, CMS estimates that the proposed updates would increase payments to ESRD facilities by $5 million in CY 2021. Table 11 of the proposed rule shows the impact of individual provisions as a percentage change in payments, by type of ESRD facility. Across all facilities, CMS estimates an increase of 1.8 percent from payment updates, 5 percent from the addition of calcimimetics to the ESRD base rate, with a total increase of 6.9 percent.

CMS further estimates that approximately $56 million would be paid to ESRD facilities in 2021 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system. This shift in site of care to the ESRD facility setting also reduces beneficiary coinsurance obligations.

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IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The proposed rule would change the scoring methodology of one ESRD QIP reporting measure and modify some data validation requirements. No changes are proposed to the ESRD QIP

measure set. Numerical performance standards are estimated for payment year (PY) 2023 ESRD 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. 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. Facilities' QIP performance is publicly reported on the Dialysis Facility Compare website: https://www.medicare.gov/dialysisfacilitycompare/. In previous rulemaking, CMS adopted QIP measures for payment years (PYs) through 2023. General information on the ESRD QIP is available on the CMS website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP, and measure specifications at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html. A summary table of ESRD QIP measures for PYs 2021 to 2024 appears at the end of this section of the summary.

As discussed further in the Regulatory Impact Analysis (section V below), penalties associated with the ESRD QIP are estimated to total $16 million for each of PYs 2023 and 2024. CMS estimates that the reporting burden associated with the ESRD QIP totals $205 million annually.

B. Updates to Requirements Beginning with the PY 2023 ESRD QIP

No changes are proposed to the ESRD QIP measure set for PY 2023 (see summary table at the end of this section) or the eligibility requirements for ESRD QIP scoring, which are shown in Table 8 of the proposed rule. Estimated performance standards are shown in Table 7 in the proposed rule; these will be updated in the 2021 ESRD PPS final rule using data for 2019.

1. Update to the Scoring Methodology for the Ultrafiltration Rate Reporting Measure

CMS proposes to change the scoring methodology for the Ultrafiltration Rate reporting measure. The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. This measure is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hr) (NQF #2701). Beginning in PY 2020, the measure is scored using the following equation:

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ x } 12\right) \text{-2}$$

CMS proposes to replace the current Ultrafiltration Rate reporting measure scoring equation with the following equation, beginning with PY 2023:

$$\left(\frac{\text{number of patient-months successfully reporting data}}{\text{number of eligible patient-months}} \text{ x } 12\right) \text{-2}$$

The proposal to score facilities based on patient-months is intended to give them more flexibility to receive credit in reporting this measure. The current method requires that facilities report all the data required to calculate a UFR rate for 100 percent of its patients for a full month in order to get any credit for successful reporting in that month. Stakeholders have raised concerns that when a patient is hospitalized and the ESRD facility cannot obtain UFR data for that patient, the facility will receive zero credit for reporting on this measure for that month, even if reporting is complete for all other patients. The proposed change would instead score facilities based on the percentage of eligible patients for which they report all UFR data elements, which CMS believes is a more objective measure and will better support the goal of assessing performance on facility documentation of UFR, which will improve patient outcomes.

CMS further notes that this change makes the measure more consistent with the specifications for the NQF-endorsed measure on which it is based, and with the Medication Reconciliation reporting measure. CMS is not proposing to modify the equations used to score the current Anemia Management or Serum Phosphorus reporting measures because these have been finalized for removal beginning with PY 2021.

2. Clarification of Timeline for Facilities to Change to National Healthcare Safety Network Measures for the ESRD QIP

The ESRD QIP currently includes two measures that facilities report via the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). These are the NHSN Bloodstream Infection (BSI) clinical measure and the NHSN Dialysis Event reporting measure. Facilities report monthly data on a quarterly basis, with a deadline of 3 months after the end of the quarter. After each quarterly data submission deadline CDC takes a snapshot of each facility's data and creates a permanent data file; these quarterly files are aggregated into the CMS ESRD QIP Final Compliance File, which the CDC transmits to CMS.
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Facilities may make changes to their quarterly NHSN data for purposes of the ESRD QIP at any point up until the quarterly submission data deadline. CMS has learned that the NHSN system allows facilities to make changes to their data for CDC surveillance purposes after the ESRD QIP quarterly data submission deadline. CMS clarifies that any changes that a facility makes to its data on ESRD QIP measures after the ESRD QIP data submission deadline will not be included in the CMS ESRD QIP Final Compliance File. The data cannot be updated for purposes of the ESRD QIP because of operational and timing issues.

3. Payment Reductions

CMS estimates that based on the finalized performance standards for PY 2023, a facility would have to meet or exceed a total performance score of 57 to avoid a payment reduction. The estimates are based on data for 2018 and will be updated for the final rule. The estimated scale of reductions is shown in Table 9 of the proposed rule, reproduced here.

TABLE 9 –PROPOSED PAYMENT REDUCTION SCALE FOR PY 2023 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%

4. Data Validation

CMS previously adopted two data validation studies as permanent features of the ESRD QIP. One study involves validation of the CROWNWeb data, and in that case a facility has 10 points deducted from its ESRD QIP score if it is selected for validation and does not submit the requested records. The other is the NHSN validation study, which samples 300 facilities which submit 20 patient records for each of the first two quarters of the year (83 FR 57701).

In this rule CMS proposes to reduce the number of records that a facility selected for the NHSN validation study must submit to a total of 20 records submitted from any two quarters of the calendar year. For example, a facility could choose to submit 2 records from Q1 and 18 records from Q4, or 6 records from Q2 and 14 records from Q3, but it could not submit 4 records from Q1, 8 records from Q2, and 8 records from Q3. That is, the records must all come from two selected calendar quarters.

CMS believes that this proposed modification would reduce burden on facilities chosen for validation by reducing the number of records and increasing flexibility in the selection of calendar quarter while maintaining an adequate sample size for validation. CMS reports that a recent estimation analysis conducted by CDC supports its view that a review of 20 charts per facility across a specified validation timeline that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology. This would meet the CDC's recommended sample estimate to achieve 95 percent confidence level precision and a 1 percent margin of error, while also reducing facility burden.

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that the reduction in reporting burden for NHSN data validation in PY 2023 under the proposal would total approximately $65,460 a year across the facilities selected for validation.

C. The PY 2024 ESRD QIP

No changes are proposed to the ESRD QIP for PY 2024. Under previously adopted policy, the PY 2023 measure set will be continued, as will the measure weights. No changes are proposed for the performance period. Numerical values for the clinical measure performance standards, using 2020 data, will be published in the 2022 ESRD PPS final rule. Existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the

Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the Medication Reconciliation reporting measure (83 FR 57010) will be continued for PY 2024. No changes are proposed for scoring ESRD QIP measures, except that CMS notes the proposed change to scoring of the Ultrafiltration Rate reporting beginning in PY 2023 discussed above.

Summary Table: ESRD QIP Measure Sets for PYs 2021-2024			
National Quality Forum #	**Measure Domain, Domain Weight, and Measure**	**PY2021**	**PYs 2022-2024**
	Clinical Care Measure Domain (40%)		
	Kt/V Dialysis Adequacy (Comprehensive)	X	X
2979*	Standardized Transfusion Ratio (STrR) **	X	X
2977	Standardized AV Fistula Rate	X	X
2978	Long-term Catheter Rate	X	X
1454	Hypercalcemia	X	X
	Ultrafiltration Rate reporting measure	X	X
	Patient & Family Engagement Measure Domain (15%)		
0258	In-Center Hemodialysis CAHPS measure	X	X
	Care Coordination Measure Domain (30%)		
2496	Standardized Readmission Ratio (SRR)	X	X
1463	Standardized Hospitalization Ratio (SHR)	X	X
0148*	Clinical Depression Screening and Follow-up reporting measure	X	X
	Safety Domain (15%)		
1460*	NHSN Bloodstream Infection (BSI)	X	X
	NHSN Dialysis Event reporting measure	X	X
	Percentage of Prevalent Patients Waitlisted (PPPW)		X
2988	Medication Reconciliation (MedRec) reporting measure		X
*QIP measure is based on this NQF measure **STrR will be a reporting measure beginning with PY 2022			

V. Regulatory Impact Analysis

A. Impact of Changes in ERSD PPS Payments

CMS estimates that the proposed revisions to the ESRD PPS would increase payments to ESRD facilities by approximately $190 million in 2021; $150 million from increased Medicare program payments and $40 million from increased beneficiary coinsurance. The Executive Summary of the Proposed rule further breaks down the $190 million total as the net result of a $230 million increase from the payment rate update, a $40 million increase due to the updates to the outlier threshold amounts, and an $80 million decrease from the proposal to add $12.06 to the ESRD PPS base rate to include calcimimetics and no longer provide the TDAPA for these drugs. These figures do not reflect any change in expenditures associated with the proposal to expand eligibility for the TPNIES to certain new and innovative home dialysis machines when used in the home. CMS says the fiscal impact of this proposal cannot be determined due to the uniqueness of each new and innovative home dialysis machine and its cost.

Medicare program payments for ESRD facilities in 2021 are estimated to total $9.3 billion, reflecting an expected 8.6 percent decrease in fee-for-service Medicare dialysis beneficiary enrollment. (The proposed rule does not address the reasons for a projected enrollment decline, but it is notable that beginning in 2021, Medicare ESRD beneficiaries may elect to enroll in a Medicare Advantage plan, pursuant to section 17006 of the 21st Century Cures Act (P.L. 114-255)).

Table 10 in the proposed rule shows the estimated impact on ESRD payments in 2021 by various types of ESRD facilities. The estimates are based on 2019 data from the Part A and Part B Common Working Files as of April 3, 2020. A portion of that table is reproduced below, omitted rows display facility impact by region, urban/rural location, and percentage of pediatric patients.

Overall, CMS estimates the combined effects of all the policies in the proposed rule would be an increase of 1.6 percent across all ESRD facilities. With respect to calcimimetics the impact reflects the addition of $12.06 to the base rate, elimination of TDAPA payments for these drugs, and making calcimimetics outlier-eligible services.

Impact of Finalized Changes in 2020 Payment to ESRD Facilities (from Table 10)

Facility Type	Number of Facilities	Number of Treatments (millions)	Effect of 2021 Changes in Outlier Policy	Effect of Change in Wage Index Data	Effect of CBSA changes & 5% Cap Policy	Effect of Bundling Calcimi-metics into Base Rate	Effect of Payment Rate Update	Total Effect of 2021 Proposed Changes
All Facilities	7,610	44.8	0.3%	0.0%	0.0%	-0.6%	1.8%	1.6%
Type								
Freestanding	7,224	43.1	0.3%	0.0%	0.0%	-0.5%	1.8%	1.6%
Hospital-based	386	1.8	0.6%	0.1%	0.1%	-2.9%	1.8%	-0.4%
Ownership								
Large dialysis organization	5,809	34.8	0.3%	0.0%	0.0%	0.3%	1.8%	2.4%
Regional chain	944	5.7	0.2%	0.0%	-0.1%	-3.9%	1.8%	-2.0%
Independent	534	2.9	0.3%	0.1%	0.3%	-2.5%	1.8%	0.0%
Hospital-based[1]	299	1.3	0.6%	0.1%	0.2%	-2.5%	1.8%	0.1%
Facility Size (Treatments)								
Less than 4,000	1,315	2.6	0.3%	0.0%	0.0%	0.6%	1.8%	2.7%
4,000 to 9,999	2,803	12.2	0.3%	0.0%	-0.1%	-0.5%	1.8%	1.6%
10,000 or more	3,246	29.7	0.3%	0.0%	0.0%	-0.7%	1.8%	1.4%

[1]Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

B. Estimated Impact of ESRD QIP in PY 2023

For PY 2023, CMS estimates that the payment reductions from not receiving the full update under the ESRD QIP program under the proposed rule will total $15.6 million across the 1,657 facilities (about 23.2 percent of the 7,386 ESRD facilities) that it estimates would receive a reduction. Identical estimates are provided for PY 2024. The tables below, reproduced from the final rule, show the estimated distribution of payment reductions for PY 2023 and the impact by facility type. (With respect to the latter, only a portion of the table is shown here.) For about three-quarters of the facilities receiving a payment reduction, the estimated reduction is 0.5 percentage points. Only 41 facilities are estimated to receive the maximum 2 percent penalty. Because the performance period used for these calculations differs from the performance period for the PY 2023 ESRD QIP, CMS cautions that the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided in the tables.

Overall, CMS estimates the payment reductions will represent about 0.15 percent of payments in PY 2023; reductions are shown to be largest for hospital-based facilities. Costs to facilities associated with reporting of data for the ESRD QIP through CROWNWeb are estimated to total $205 million for PY 2023 under the proposed rule.
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Table 12: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions		
Payment Reduction	**Number of Facilities**	**Percent of Facilities**
0.0%	5,490	76.82%
0.5%	1,215	17.00%
1.0%	336	4.70%
1.5%	65	0.91%
2.0%	41	0.57%
Note: 239 facilities not scored due to insufficient data.		

Impact of QIP Payment Reductions to ESRD Facilities for PY 2023 (from Proposed Rule Table 14)			
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	7,386	1,657	-0.15%
Facility Type			
Freestanding	6,995	1,556	-0.15%
Hospital-based	391	101	-0.22%
Ownership Type			
Large Dialysis	5,603	1,115	-0.12%
Regional Chain	927	241	-0.19%
Independent	512	216	-0.34%
Hospital based (non-chain)	305	83	-0.24%

Impact of QIP Payment Reductions to ESRD Facilities for PY 2023 (from Proposed Rule Table 14)			
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**
Facility Size (Treatments)			
Less than 4,000	1,206	220	-0.15%
4,000 to 9,999	2,644	488	-0.11%
10,000 or more	3,159	882	-0.18%