2020 Medicare ESRD PPS and DMEPOS Competitive Bidding Program
Summary of the Proposed Rule
[CMS-1713-P]

On July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule addressing the Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS), the ESRD Quality Incentive Program (QIP), payment for renal dialysis services furnished to individuals with acute kidney injury, other ESRD PPS requirements and payment for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). It will be published in the *Federal Register* on August 6, 2019.

Along with routine updates for 2020 payments under the ESRD PPS and for acute kidney injury, the proposed rule would modify policies under the transitional drug add-on payment adjustment; add a new transitional add-on payment for new and innovative equipment and supplies; discontinue the erythropoiesis-stimulating agent (ESA) monitoring policy; and make changes to the ESRD QIP. For DMEPOS, the proposed rule would develop policies on how Medicare pricing is determined for DMEPOS new items; develop a single list of items potentially subject to a face-to-face encounter and written order prior to delivery, and/or prior authorization request; and revise the existing DMEPOS Competitive Bidding Program regulations to address change of ownership issues. Requests for information are included in the proposed rule addressing ESRD data collection, the ESRD PPS wage index, and sources of market-based data measuring sales of diabetic testing strips. **Public comment on the proposed rule ends on September 27, 2019.**

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-1713-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 2020

Policy changes are proposed to the ESRD PPS involving the transitional drug add-on payment adjustment, a new transitional add-on payment adjustment to support new and innovative renal dialysis equipment and supplies; discontinuation of the erythropoiesis-stimulating agent (ESA) monitoring policy; and annual updates to the ESRD PPS rates.

A. Changes to Transitional Drug Add-on Payment Adjustment Eligibility

1. Background

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[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.

In the 2019 ESRD PPS final rule, CMS expanded the TDAPA to apply to all new drugs and biologicals, not just those in a new functional category, effective for drugs or biological products approved by the Food and Drug Administration (FDA) on or after January 1, 2020 under section 505 of the Food, Drug and Cosmetic (FD&C) Act (drugs) or section 351 of the Public Health

[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.

Service Act (biological products). In addition, payment for drugs under the TDAPA was reduced from 106 percent of the average sales price (ASP + 6) to ASP + 0. The TDAPA applies 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 oral-only drugs to remain outside the ESRD PPS until 2025.

2. Development of Proposed Changes

In this proposed rule for 2020, CMS proposes to narrow the eligibility of new drugs for the TDAPA. A lengthy discussion is provided of the comments it received from stakeholders on TDAPA policies during the public comment period on the 2019 ESRD PPS rule as well as subsequent to publication of the final rule. These comments are described as generally supportive of expanding eligibility for TDAPA to more drugs and biologicals but divergent in the specific policy recommendations for the drug designation process. In particular, CMS notes comments expressing concern that the expansion of the TDAPA was too broad. For example, some recommended that CMS not apply the TDAPA to generic drugs or biosimilar biological products. Others expressed concern that the policy would promote development of "me too" drugs and higher launch prices and suggested that TDAPA eligibility should be limited to drugs that have clinical superiority over existing drugs in the bundled payment.

Regarding the recommendation from some commenters for using a clinical improvement standard for TDAPA eligibility, CMS states that ESRD beneficiaries are complex and have unique challenges for medical management of drugs and biologicals, so the determination of whether a new drug represents a clinical improvement can vary across patient characteristics.

The implications for the expanded TDAPA policy on Medicare expenditures is also discussed. CMS notes that in 2018, the first year it paid the TDAPA, there was an estimated $1.2 billion increase ESRD PPS expenditures for two calcimimetics drugs used by 25 percent of the Medicare ESRD population. CMS states that Medicare resources are not unlimited and that TDAPA should not be paid to drugs and biological products that are not truly innovative. Using the FDA NDA classification codes, CMS seeks to target support for products that are innovative and not just new.

In light of the various comments, CMS consulted with the FDA to examine whether current inclusion of all the categories of new drug applications and pathways for biologics license applications is in keeping with the goals of the TDAPA. These goals are identified as (1) supporting innovation and helping ESRD facilities to make business changes to adopt new products; (2) providing additional payment for these facility costs; and (3) promoting competition among drugs and biological products within the ESRD PPS functional categories. CMS also considered input from a Technical Expert Panel that was convened in December 2018[2] and undertook an internal review including CMS pharmaceutical statisticians. That review identified a potential unintended consequence of paying for innovative ESRD drugs in the same

[2] In the requests for information section of this proposed rule, CMS summarizes work of the TEP on other issues. Discussion of TDAPA is not mentioned there or in the final report of the meeting issued in June 2019 and available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html

way as others (e.g., generics) could be to divert attention to the less costly duplication of drugs rather than those more expensive to bring to market, and crowd out innovation.

3. Proposed Changes to TDAPA Eligibility for Drugs

Under the proposal, the following drugs and biologicals would be excluded from eligibility for the TDAPA. The proposed eligibility rules are detailed in proposed new regulatory text at §413.234(e).

- Certain types of drugs within the broad class of those approved by the FDA under section 505 of the FD&C, as identified by the New Drug Application (NDA) classification code assigned by FDA at the time the drug is approved. The table below summarizes the detailed discussion of these proposed exclusions provided in the proposed rule.
- Generic drugs approved by the FDA under section 505(j) of the FD&C Act. An abbreviated NDA (ANDA) is the application used for a drug product that is a duplicate of a previously approved drug product (i.e., has the same active ingredients, dosage form, strength, route of administration, and conditions of use as a listed drug).

CMS notes that the proposed policy relies on the NDA classification code existing as of November 4, 2015 (FDA/CDER MAPP 5018.2, available at https://www.fda.gov/media/94381/download.) While these classifications do not necessarily reflect the extent of innovation or therapeutic advantage of a particular drug product, CMS believes that the NDA codes would provide an objective basis for it to distinguish innovative and non-innovative renal dialysis service drugs. CMS proposes that if FDA was to change the NDA classification codes, it would assess the changes and propose any needed revisions to its exclusions in the subsequent rulemaking cycle. **Comments are specifically sought on using the proposed NDA classification codes and the proposal for handling changes to the classifications by the FDA.**

In order to operationalize the proposed exclusions, CMS would modify the information required from stakeholders seeking eligibility for TDAPA[3] to also require the FDA NDA Type classified at FDA approval or state if the drug was approved by FDA under section 505(j) of the FD&C Act. The submitter would be expected to resubmit the TDAPA request if the NDA Type changed after the application was submitted to CMS. CMS expects to meet quarterly with the FDA to discuss new renal dialysis drugs and biological products that are eligible for the TDAPA.

Summary of Proposed Treatment of NDA Classification Codes for the TDAPA

NDA Classification	Meaning	Eligible for TDAPA?	CMS Rationale
Type 1	New molecular entity	Yes	Generally, are novel drugs and not line extensions. TDAPA intended to support facilities during uptake period of these types of innovative drugs.
Type 2	New active ingredient	Yes	Single enantiomer drugs covered under Type 2 can lead to fewer drug interactions in the ESRD population,

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html

NDA Classification	Meaning	Eligible for TDAPA?	CMS Rationale
			which already has a significant medication burden. These drugs are innovative.
Type 3	New dosage form	**No**	Not innovative. Inclusion might provide perverse incentives for facilities to choose new dosage form to obtain the TDAPA. Don't want to encourage "product hopping" under which manufacturers move research and development funding from one branded drug to a similar one with longer patent life.
Type 4	New combination	Yes, if at least one of the components is Type 1 or Type 2	Type 1 and Type 2 drugs merit TDAPA. Combination drugs can improve medication adherence.
Type 5	New formulation or other differences[1]	**No**	Including line extension/follow-on/"me too" products in TDAPA eligibility would not be a judicious use of Medicare resources. Would not advance TDAPA goals of increased competition and lower drug prices. "It seems that a goal of line extensions can be to thwart competition." Cites study concluding that reformulations prolong consumption of costly brand products at the expense of market entry of low-cost generics.
Type 7	Previously marketed but without an approved NDA	**No**	If a Type 7 drug is determined to be a renal dialysis service, it is likely already being used by the facility and uses Medicare resources that could be used for innovative drugs and services.
Type 8	Prescription to Over-the-Counter	**No**	Medicare does not cover over-the-counter drugs; transition from prescription to OTC is not innovative for purposes of TDAPA policy.
Type 9	New indication or claim, drug not to be marketed under type 9 NDA after approval	No, if parent NDA is Type 3, 5, 7 , or 8. Yes, if parent NDA is Type 1,2, or 4.	Type 9 is for a new indication or claim for a drug product that is currently being reviewed under a different "parent NDA," and the applicant does not intend to market the drug under the Type 9 NDA after approval. A Type 9 NDA would be excluded from eligibility if the parent type is excluded from eligibility, and included if the parent type is eligible. Type 9 NDA with a parent type of 1,2, or 4 would be a new indication for an innovative drug and should be eligible for TDAPA.
Type 10	New indication or claim, drug to be marketed under type 10 NDA after approval	Yes	A new indication for a previously submitted drug applicable to renal dialysis advances the field. Could provide savings in time-to-market research and development, which could be reflected in launch price of drug.

NDA Classification	Meaning	Eligible for TDAPA?	CMS Rationale
Type 3, in combination with Type 2 or Type 4		**No**	Rationale for Type 3 exclusion above.
Type 5, in combination with Type 2		**No**	Rationale not specifically discussed.

[1]Type 5 NDA is a product other than a new dosage form that differs from a product already approved or marketed in the US due to one of 7 characteristics. (These are spelled out in the proposed regulatory text at 413.234(e) and are abbreviated here (1) Changes in inactive ingredients that require bioequivalence studies or clinical studies for approval and product is submitted as an original NDA. (2) Duplicates product by another applicant and requires bioequivalence testing or safety or effectiveness testing for certain specified reasons. (3) Contains an active ingredient or active moiety that has been previously approved only as part of a combination. (4) Is a combination product that differs from the previous product by removal or substitution of one or more active ingredients. (5) Contains a different strength of one or more active ingredients in a previously approved or marketed combination. (6) Differs in bioavailability. (7) Involves a new plastic container that requires safety studies beyond limited confirmatory testing.
NOTES: Information on NDA classification is available at https://www.fda.gov/media/94381/download.
Type 6 (new indication or claim, same applicant) is no longer used and was replaced by Types 9 and 10.

Comments are specifically sought on whether any of the NDA types that would remain eligible for the TDAPA under the proposal should be excluded from eligibility, and whether any of the NDA types proposed for exclusion should remain eligible. As an example of the latter, CMS references the potential inclusion of drugs within NDA Type 3 with a new dosage form from intravenous to oral route of administration.

In its discussion of the proposed exclusion of generic drugs (drugs approved by the FDA under section 505(j) of the FD&C Act), CMS says that when it adopted the expanded TDAPA policy in the 2019 ESRD PPS final rule it understood that generic drugs were not innovative, but believed that including them would increase competition so that drug prices would be lower for the beneficiary. However, CMS has since concluded that bringing more generic drugs to market, though a significant component in lowering drug prices, is not in and of itself the solution. It cites literature concluding that there a limit to the impact of generic drug competition on prices, and examining the effect of "sticky pricing" in pharmaceuticals. CMS now believes that reining in launch prices by placing guardrails on line extensions, reformulations and "sticky pricing" while staying mindful of the Medicare trust fund is a better way to achieve its goals for the TDAPA policy.

4. Treatment of Biological Products.

With respect to biological products, CMS proposes no exclusions to TDAPA eligibility. That is, the current policy would be continued under which products approved under section 351 of the PHS Act would continue to be eligible for the TDAPA. This includes new biological products and those that are biosimilar to or interchangeable with a reference biological product. CMS notes that the approval process for biosimilar biological products differs from that for generic drugs and has different requirements. It believes that a categorical exclusion from TDAPA

eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product would "disadvantage this sector of biological products in a space where we are trying to support technological innovation." In the view of CMS, while the products themselves may not be innovative, the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time. CMS also notes that for biological products there is no equivalent to the NDA classification system it proposes to use to identify exclusions to TDAPA eligibility.

However, CMS intends to continue to monitor future costs of biosimilars related to renal dialysis, the TDAPA and the ESRD PPS. It understands there are similar concerns to providing TDAPA eligibility for these products as there is with generic drugs. It cites a recent case study in concluding that increased drug class competition for biosimilars did not translate into lower prices and that market failures leading to increased prices were borne solely by Medicare.[4]

5. Effect on Medicare Expenditures and Beneficiary Coinsurance

CMS believes that the proposal would reduce Medicare expenditures in 2020 because fewer drugs would be eligible for the TDAPA, and this would also result in lower coinsurance for Medicare beneficiaries.

6. Changes to Regulatory Text

In addition to the new proposed text at §413.234(e) regarding eligibility for TDAPA, CMS proposes various technical and conforming changes to regulations in §413.230.

B. Changes to TDAPA Payment

Two changes are proposed to the calculation of the TDAPA payment amount. The first change would apply to the TDAPA for calcimimetrics, which took effect on January 1, 2018. The second change would broadly condition the TDAPA payment for a product on timely submission of ASP data for the product.

1. TDAPA for Calcimimetics in 2020

Under policies finalized in the 2016 ESRD PPS final rule, an exception was made for calcimimetics in the drug designation. In general, oral-only drugs are no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. If injectable or intravenous forms of phosphate binders or calcimimetics were approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment (because these drugs are included in an existing functional category), so no additional payment would be available for inclusion of these drugs.

[4] A San-Juan-Rodriguez et al. "Assessment of Price Changes of Existing Tumor Necrosis Factor Inhibitors After the Market Entry of Competitors." JAMA Intern Med 2019. Feb18 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724390

However, CMS finalized an exception under which this process would not apply to injectable or intravenous forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the base rate to account for them. CMS finalized that when these drugs were no longer oral-only drugs, it would pay for them under the ESRD PPS using the TDAPA based on the payment methodologies in section 1847A of the Act until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not less than 2 years. Based on section 1847A, the TDAPA payment for these drugs is based on ASP + 6.

The TDAPA for calcimimetics was implemented beginning January 1, 2018. The two-year minimum period for TDAPA payment would run through December 31, 2019. However, CMS says that it is continuing to the collect the claims data needed for a rate setting analysis, and will continue to pay the TDAPA for these drugs in 2020.

In this rule, CMS proposes to reduce the basis of payment for the TDAPA for calcimimetics beginning January 1, 2020 to 100 percent of ASP, consistent with the general policy it adopted for TDAPA payment in the 2019 ESRD PPS final rule. (An exception was provided for calcimimetics.) Under the general policy, beginning January 1, 2020, the TDAPA payment calculation will be reduced from ASP + 6 to ASP+0. CMS notes that the 6 percent add-on to ASP was intended to cover administrative and overhead costs. After the initial two years of TDAPA payments at ASP+6, CMS believes that ESRD facilities would have had sufficient time to address costs associated with furnishing calcimimetics. It also notes that calcimimetics are the first drugs for which the TDAPA was paid, and this increased Medicare expenditures by $1.2 billion in 2018. CMS believes that this demonstrates uptake of these innovative drugs and it seeks to balance the goals of TDAPA with the financial burden these extra payments impose on Medicare program and beneficiaries.

2. ASP Conditional Policy for the TDAPA

CMS proposes that the TDAPA payment would not be made if CMS does not receive a full calendar quarter of ASP data for the product within 30 days after the last day of the third calendar quarter after the TDAPA is initiated for the product. Similarly, if CMS stops receiving ASP data during the period the TDAPA is in effect for the product, it will stop the TDAPA payments. In both cases, the payment would no longer be made beginning no later than two calendar quarters after CMS determines that the ASP data is not available. CMS believes that the proposed three calendar quarters provides sufficient time for a drug manufacturer to submit a full quarter of ASP data to CMS, recognizing that it may begin sales of a new product in the middle of a calendar quarter. CMS expects that once a manufacturer begins to submit ASP data, it will continue to do so for the duration of the TDAPA period.

This proposal is made out of concern that the TDAPA pricing methodology could encourage unintended consequences. That is, drug manufacturers who are not otherwise required to submit ASP data to CMS (i.e., those without a Medicaid Drug Rebate Agreement) could delay submission or withhold ASP data so that facilities would receive a higher payment basis under the TDAPA and have an incentive to purchase these drugs. Under the policies adopted for the

TDAPA, payment is based on 100 percent of ASP, but if ASP data are not available, the TDAPA is based on 100 percent of the Wholesale Acquisition Cost, and if those data are not available, payment is based on the manufacturer invoice.

Use of ASP data is preferred by CMS because it is commonly used to facilitate Medicare payment across settings and, with exceptions, is based on manufacturer sales to all purchasers. Additionally, the ASP is net of manufacturer rebates, discounts and price concessions. WAC does not include the discounts and invoice prices and may not reliably capture all discounts.

CMS notes that the HHS Office of the Inspector General found that for the third quarter of 2012, out of 45 manufacturers who are not required to submit ASP for Part B drugs, only 22 voluntarily provided such data, and at least 74 of the manufacturers with a Medicaid Drug Rebate Agreement (out of 207) did not submit all required data. MedPAC has expressed concern about under-reporting of these data and has recommended that all Part B drug manufacturers be required to report data to CMS regardless of whether they have Medicaid Drug Rebate Agreement.

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

CMS proposes a new Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS. Eligibility and payment under the TPNIES policy would generally be modeled after the new technology add-on payment (NTAP) used in the inpatient hospital PPS, including its substantial clinical improvement criteria. The proposed policy is detailed in regulatory text in a new §413.236. (Conforming and technical changes are also proposed in §413.230.)

The proposed TPNIES responds to comments CMS received from stakeholders suggesting such an adjustment because there is a lack of FDA-approved or authorized new devices for use in ESRD facilities, and following the same logic used by CMS in applying the TDAPA to encourage facility uptake of innovative ESRD-related drugs and biologicals. Some manufacturers noted that ESRD facilities have no incentive to adopt innovative equipment and supplies because no additional payment is made. CMS also believes that innovations will result from the Kidney Innovation Accelerator (KidneyX), which is a partnership between HHS and the American Society of Nephrology to accelerate innovation in the prevention, diagnosis and treatment of kidney disease. Finally, on July 10, 2019, the President signed Executive Order aimed a transforming kidney care in America, which includes proposals for the Secretary to encourage development of breakthrough technologies for kidney patients.

CMS recognizes that the proposal would increase Medicare expenditures and beneficiary coinsurance amounts. However, it believes that the proposed TPNIES would be consistent with TDAPA policy and appropriate to support ESRD facility uptake of new and innovative renal dialysis equipment and supplies.

Under the proposal, the add-on payment would be available beginning January 1, 2020 for new and innovative equipment and supplies meeting eligibility criteria described below, and added to the ESRD per-treatment base rate (after application of the wage index, low-volume facility adjustment and patient-level adjustments). As described further below, the TPNIES payment amount would equal 65 percent of a price for the item that is established by the MACs on behalf of CMS. The payment would be made for two calendar years. After the two-year period ends, there would be no modification to the ESRD base rate, and the innovative equipment or supply would be an eligible outlier service.

TPNIES Eligibility Criteria

To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item would have to 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;
4. Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures;
5. Is innovative, meaning it meets the substantial clinical improvement criteria used by CMS for the IPPS NTAP (described in the proposed regulatory text as meeting the criteria 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).

CMS notes that it is not adopting the high-cost criteria used under the IPPS NTAP (§412.87(b)(3)) because the basis of payment under the IPPS is different than under the ESRD PPS. Under the IPPS, new technology costs are eventually reflected in the MS-DRG weights, and the NTAP is intended to address the disadvantage faced by hospitals adopting high-cost technologies until the costs are reflected in the weights. The proposed substantial clinical improvement criteria are described further below.

CMS would consider whether a new renal dialysis supply or equipment meets these eligibility criteria and announce the results in the *Federal Register* as part of the ESRD PPS rulemaking. The proposed rule would include a description of the request and the final rule would include the evaluation of whether it meets eligibility criteria. An application would only be considered if it is complete and received by CMS by February 1 prior to the particular calendar year (e.g., February 1, 2021 for 2022 ESRD PPS payment beginning on January 1, 2022.)

The proposed rule describes the inpatient hospital NTAP and its substantial clinical improvement criteria in detail. Readers are referred to the ”Innovators’ Guide to Navigating Medicare” available at https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf and the FY 2001 IPPS final rule (66 FR 46913). In that final rule, CMS established the criteria that it uses to determine if a new medical service or technology represents a substantially clinical improvement over existing technologies. CMS works with its medical

officers to evaluate whether a technology represents a substantial clinical improvement. The criteria are:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. CMS also noted examples of outcomes that are frequently evaluated in studies of medical devices. For example,
    - Reduced mortality rate with use of the technology.
    - Reduced rate of technology related complications.
    - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
    - Decreased number of future hospitalizations or physician visits. More rapid beneficial resolution of the disease process treatment because of the use of the device.
    - Decreased pain, bleeding, or other quantifiable symptoms.
    - Reduced recovery time.

The TPNIES application process would be modeled after the NTAP. Manufacturers would submit all information necessary for determining that the renal dialysis equipment or supply meets the eligibility criteria. That would include FDA marketing authorization information; the HCPCS application information; studies submitted as part of the FDA and HCPCS processes; an approximate date of commercial availability; and information for the substantial clinical improvement criteria evaluation. This could include clinical trials, peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources. As noted above, CMS would announce the results of its determination as to whether the item met the criteria in the *Federal Register* as part of ESRD PPS rulemaking.

Capital-related assets (defined as those a provider has economic interest in through ownership, regardless of the manner in which they were acquired[5]) would be excluded from receiving additional payment. CMS offers examples of capital-related assets for ESRD facilities such as dialysis machines, water purification systems and systems designed to clean dialysis filters for reuse. It does not believe additional payment for capital-related assets is appropriate because the cost of these items are captured in cost reports, depreciate over time, and are generally used for multiple patients. Because the capital costs are captured in the aggregate it would be complex to establish a per-treatment cost. CMS notes that it uses capital-related cost data from cost reports in regression analyses to refine the ESRD PPS, so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment adjustments.

[5] Provider Reimbursement Manual (Pub. L. 15-1) Chapter 1, section 104.1.

In addition to comments on the proposal, CMS specifically solicits comment on the following aspects of the proposed TPNIES:

- **The proposed January 1, 2020 FDA marketing authorization date.** CMS asks whether a different date would be appropriate, for example January 2, 2019.
- **The proposed application deadline of February 1st for payment beginning in the following calendar year.[6]** CMS considered a September 1 deadline to initially give manufacturers more time but proposed the earlier date so that the policy would be implemented sooner.
- **The proposed criteria for determining new and innovative renal dialysis equipment and supplies eligible for additional payment and the possible use of different evaluative criteria and payment methodologies, which could include cost thresholds for high cost items**.
- **Whether any of the IPPS substantial clinical improvement criteria would not be appropriate for the ESRD facility setting and whether there should be additional criteria specific to ESRD.** In particular, CMS seeks comment on whether to use FDA's pre-market approval and de novo pathways as a proxy for or in place of the proposed substantial clinical improvement criteria.
- **Potential implementation challenges, such as what sources of data that CMS should utilize to assess substantial clinical improvement.**
- **The proposed process to determine substantial clinical improvement.**
- **The benefits and drawbacks of proposed substantial improvement criteria.**

TPNIES Payment Amount

The TPNIES payment amount would equal 65 percent of a price for the item that is established by the MACs on behalf of CMS. The MACs would 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.

In proposing the process for invoiced-based pricing by MACs, CMS notes the lack of available data on pricing for new and innovative equipment and supplies, such as the ASP and WAC pricing used for the TDAPA or the MS-DRG payment and cost to charge ratios used for the IPPS NTAP methodology. Charges are available, but these are reported at gross value, before allowances and discounts. Instances of the use of invoice pricing in DMEPOS and for payment

[6] The proposal makes that TPNIES adjustment effective for dates of service beginning January 1, 2020. Under the proposed application deadline applications for a 2020 adjustment would have been required by February 1, 2019. CMS does not discuss any special procedures for the 2020 payment year.

of Part B drugs and biologicals are discussed. Once there is sufficient payment data across MACs, CMS would consider setting a national price for the item through notice and comment rulemaking.

The proposed payment equal to 65 percent of the MAC-determined price is consistent with the recently adopted policy in the FY 2020 IPPS final rule to increase the maximum percentage used to determine the NTAP add-on payment amount from 50 percent to 65 percent[7].

CMS believes the proposed two-year period of payment would be a sufficient timeframe for ESRD facilities to adapt business practices so that there is "seamless access" to new innovative equipment and supplies, and would provide additional payment to account for higher costs of these items and give them a foothold in the market to compete with other equipment and supplies accounted for in the ESRD PPS base rate.

No change in the base rate is proposed once the two-year period is complete. CMS states that the intent of the TPNIES would be to provide a transition period ESRD facilities when incorporating certain new and innovative equipment and supplies and to allow time for the uptake of these innovative items. At this time CMS believes it would not be appropriate to add dollars to the ESRD PPS base rate which already includes the cost of equipment and supplies used to furnish a dialysis treatment and would be in conflict with the fundamentals of a PPS. It is not the intent of a PPS to add dollars to the base whenever something new is made available.

In addition to comments on the proposal, comments are specifically requested on:

- **Whether CMS should explicitly link the TPNIES to the IPPS NTAP maximum payment amount percentage so that any future change in that percentage would apply.**
- **Other pricing criteria and other verifiable sources of information CMS should consider.**

D. Comment Solicitation on Payment for Renal Dialysis Humanitarian Use Devices

CMS seeks comment on Medicare payment for renal dialysis services involving devices that have a humanitarian use device (HUD) designation from the FDA. Under FDA regulations, a HUD is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year." Medicare has no specific rules, regulations or instructions with regard to HUDs. CMS is particularly interested in receiving comments on HUDs that would be used in furnishing renal

[7] Under the IPPS NTAP, the additional payment amount is based on the cost to hospitals of the new technology. If the costs of the discharge exceed the full MS-DRG payment, the additional amount is the lower of 65 percent of the costs of the new technology or 65 percent of the amount by which the total covered costs of the case exceed the standard MS-DRG payment (plus outlier payments and adjustments for indirect medical education and disproportionate share hospitals). The increase in the maximum add-on payment from 50 percent to 65 percent is effective for discharges beginning October 1, 2019.

dialysis services under the ESRD PPS, any barriers to payment encountered, and past experience in obtaining Medicare payment for these items through the MACs.

E. Discontinuation of the ESA Monitoring Policy

CMS proposes to no longer apply the ESA monitoring policy (EMP), beginning January 1, 2020. This policy was adopted in the 2011 ESRD PPS final rule (75 FR 49067, 49145 through 49147). Under the policy, in calculating the 2011 ESRD PPS base rate payments, costs for ESAs were capped based on specific dose limits. Certain dosing reductions and the ESA limits are applied prior to determining outlier eligibility.

At this time, CMS believes the ESA monitoring is no longer needed. Its rationale is that utilization of ESA has decreased significantly since the implementation of the ESRD PPS, and the FDA relabeled of epoetin alfa regarding individualized dosing. CMS believes this proposal would reduce the documentation burden on ESRD facilities because they would no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity.

Under the proposal, ESRD facilities would no longer be required to report EMP-related modifiers and Medicare contractors would no longer apply dosing reduction or dose limit edits prior to calculation of outlier eligibility and they would no longer be reflected in outlier payments. Monitoring of ESAs would continue as part of CMS' general monitoring program that studies the trends and behaviors of ESRD facilities under the ESRD PPS and beneficiary health outcomes. In addition, it would closely monitor ESA usage in conjunction with phosphate binder prescribing and usage.

F. ESRD PPS Update for 2020

The proposed 2020 ESRD PPS base rate is $240.27, compared with the final 2019 rate of $235.27. As shown in the table below, this increase of 2.1 percent reflects application of an update factor of 1.7 percent (reflecting an estimated increase of 2.1 percent in the ESRD bundled input price index ("market basket") and an estimated multifactor productivity (MFP) adjustment of -0.4 percent) and a wage index budget neutrality adjustment of 1.004180. The rate is calculated as $235.27 X 1.017 X 1.004180= $240.27. The final rule update will reflect the most recent market based and productivity adjustment projections.

Proposed 2020 ESRD PPS Base Rate Update	
Base Rate Update Components	**% effect on base rate**
Market basket	+2.1
Multifactor productivity adjustment	-0.4
Subtotal: update factor	+1.7
Wage index budget neutrality adjustment (0.999506)	1.004180
Total change in base rate	+2.1
Note: The market basket and productivity adjustments are based on IHS Global Insight's Q1 2019 forecast for 2020 with historical data through Q4 of 2018.	

1. Wage Index

Under previously adopted policies, CMS will use updated wage indices for 2020. These 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. The previously adopted wage index floor of 0.5000 will apply; wage areas in Puerto Rico are currently the only ones to benefit from the floor. The labor-related share continues to be 52.3 percent, based on the 2016-based ESRD market basket.

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. 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 2020, 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 2018 claims data. The proposed 2020 outlier policy amounts and those for 2019 are shown in Table 2 of the proposed rule, reproduced below. CMS notes that beginning in 2020 the total expenditure amount includes payments made for calcimimetics under the TDAPA policy ($21.15 per treatment). As shown in the table, CMS estimates that based on 2018 data, the percentage of patient months qualifying for outlier payments in 2020 will be 9.9 percent for adult patients and 10.8 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 2018 claims, outlier payments represented about 0.50 percent of total payments, below the 1 percent target (and below the 0.8 percent reported for 2017 in the 2019 ESRD PPS final rule). CMS says that recalibration of the outlier thresholds using 2018 data is expected to result in aggregate outlier payments close to the 1 percent target in 2020. CMS notes that higher coinsurance obligations result for those beneficiaries for whom outlier payments are made.

TABLE 2: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY				
	Final outlier policy for 2019 (based on 2017 data price inflated to 2019)		**Proposed outlier policy for 2020 (based on 2018 data price inflated to 2020)**	
	Age < 18	**Age≥ 18**	**Age < 18**	**Age ≥ 18**
Average outlier services MAP amount per treatment	$34.18	$40.18	$32.27	$38.15
Adjustments:				
Standardization for outlier services	1.0503	0.9779	1.0692	0.9789
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$35.18	$38.51	$33.82	$36.60
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$57.14	$65.11	$44.91	$52.50
Patient-months qualifying for outlier payment	7.2%	8.2%	10.8%	9.9%

III. 2020 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. Therefore, for 2020 the proposed updated AKI dialysis payment rate is set to equal the 2020 ESRD PPS base rate of $240.27, adjusted by the facility's wage index.

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). 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 2022. Measure specifications 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 finalized and proposed ESRD QIP measures for PYs 2020 to 2023 appears at the end of this section of the summary.

B. Proposed Codification of Certain ESRD QIP Requirements

CMS proposes to modify the regulatory text at §413.178 to include certain previously adopted policies, and to include one new proposal. To be codified are the policy that the baseline and performance periods are automatically advanced by one year (beginning with PY 2024) and the requirement that facilities submit data to CMS on all ESRD QIP measures. Requirements for the Extraordinary Circumstances Exception (ECE) process would also be codified, including a proposed new option under which facilities could reject an exception granted by CMS under certain circumstances. Specifically, in a case where CMS has granted an exception without a facility request due to an extraordinary circumstance affecting a geographic area or an issue with a CMS data system, a facility could reject the exception. It would notify CMS that it will continue to submit data and in response CMS would notify the facility that the exception is withdrawn.

C. Requirements for the PY 2022 ESRD QIP

1. Performance Standards, Achievement Thresholds and Benchmarks for PY 2022

Table 4 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 final measures for PY 2022. These values will be updated in the final rule using more complete data. CMS notes that it is proposing in this rule to convert the standardized transfusion rate (STrR) measure from a clinical measure to a reporting measure and if that policy is finalized, there will be no performance standards in the final rule for that measure.

2. NHSN Dialysis Event Scoring Change

CMS proposes to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months. Beginning with the PY 2022 ESRD QIP, it will assess successful reporting based on the number of months facilities are eligible to report the measure. Facilities would receive credit for scoring purposes based on the percentage of eligible months they successfully report data. The proposal is made out of concern that the current requirement does not recognize the effort of new facilities and those receiving an ECE for whom a full 12 months of reporting is impossible. The table below shows the current and proposed scoring of this measure. (It combines information from proposed rule Tables 5 and 6).

Current and Proposed Reporting Requirements for the NHSN Dialysis Event Reporting Measure		
Current Policy = Number of Reporting Months	Proposed policy = Percentage of Eligible Months Reported*	Points Awarded
12 months	100%	10
6-11 months	Less than 100%, but no less than 50%	2
0-5 months	Less than 50%	0
*The term "eligible months" means the months in which dialysis facilities are required to report dialysis event data to NHSN per the measure eligibility criteria. This includes facilities that offer in-center hemodialysis and facilities that treat at least 11 eligible in-center hemodialysis patients during the performance period.		

3. Standardized Transfusion Ratio (STrR) measure

Based on concerns raised by commenters, CMS is evaluating the STrR measure, and as a result proposes to treat the measure as a reporting measure in 2022. Commenters raised concern that under the updated version of the measure to be used beginning in PY 2021, which relies on more specific ICD-10 coding, hospitals are no longer accurately coding blood transfusions, and this has negatively affected the validity of the STrR measure. CMS believes that converting this measure to a reporting measure would ensure that dialysis facilities are not adversely affected while it continues to examine the issue. Alternatives considered and rejected would have either retained STrR as a performance measure but change the scoring to ensure that no hospital received payment reduction due to this measure or used the earlier version of the measure.

Under the proposal, facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful

reporting of data, not on the values actually reported. To receive 10 points on the measure, a facility would need to report the data required to determine the number of eligible patient-years at risk and have at least 10 eligible patient-years at risk. (A patient-year at risk is a period of 12-month increments during which a single patient is treated at a given facility. A patient-year at risk can be comprised of more than 1 patient if, when added together, their time in treatment equals a year.)

CMS plans to present its analyses and measure changes to the NQF under an ad hoc review of the STrR clinical measure later this year before making a final decision regarding further implementation in the ESRD QIP. It notes that any substantive changes to the STrR that result from this process may also require a MAP review prior to any future implementation effort.

4. Clarifications Regarding Medication Reconciliation (MedRec) Reporting Measure

CMS proposes to correct the formula presented in the 2019 ESRD PPS final rule for scoring the Medication reconciliation (MedRec) reporting measure (previously finalized for addition to the ESRD QIP beginning in PY 2022) to clarify that the measure addresses facility months and not patient months. CMS further clarifies that for this measure facilities with a CMS Certification Number (CCN) Open Date before the October 1st prior to the performance period (which, for the PY 2022 ESRD QIP, would be a CCN Open Date before October 1, 2019) must begin collecting data on the measure.

5. Update to the Eligibility Requirements for Scoring ESRD QIP Measures

Table 7 in the proposed rule displays the proposed eligibility requirements for scoring the ESRD QIP measures and reflects the proposed change in the NHSN Dialysis Event reporting measure. Specifically, no CCN open date requirement would apply for this measure.

6. Payment Reductions

CMS estimates that based on the proposed performance standards, a facility would have to meet or exceed a TPS of 53 for PY 2022 to avoid a payment reduction. The estimates are based on data for 2017; the final rule will update this table using data from 2018 which are not yet available, so these amounts may change. The estimated scale of reductions is shown in Table 8 of the proposed rule, reproduced here.

TABLE 8 –PAYMENT REDUCTION SCALE FOR PY 2022 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total Performance Score	Reduction
100 – 53	0.0%
52 – 43	0.5%
42 – 33	1.0%
32 – 23	1.5%
22 or lower	2.0%

7. Data Validation

CMS proposes to continue the NHSN validation study previously adopted for PY 2022 as a permanent feature of the ESRD QIP and using the previously adopted methodology for this study, which samples 300 facilities which submit 20 patient records covering 2 quarters of data. (82 FR 50766 through 50767). The other validation study of CROWNWeb data was previously made a permanent feature of the ESRD QIP, with 10 points deducted if a facility is selected for validation but does not submit the requested records.

D. Requirements for the PY 2023 ESRD QIP

No new measures are proposed for addition to the ESRD QIP for PY 2023. CMS proposes to establish 2021 as the performance period for PY 2023 for all measures; 2019 as the baseline period for purposes of calculating the achievement threshold, benchmark, and the minimum TPS; and CY 2020 as the baseline period for purposes of calculating the improvement threshold. Beginning with PY 2024, CMS proposes to adopt automatically a performance and baseline period for each year that is 1-year advanced from those specified for the previous payment year. Performance standards for PY 2023 will be published in the 2021 ESRD PPS final rule. As previously finalized, 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 MedRec reporting measure will continue to be used in PY 2023. No changes are proposed to the scoring of measures or in measure weights, except CMS notes that its proposed correction of the use of facility days for the MedRec measure would continue in PY 2023 and beyond if finalized.

Summary Table: ESRD QIP Measure Sets				
	PY2020	**PY2021**	**PY2022**	**PY 2023 (Proposed)**
Clinical Care Measure Domain*				
Kt/V Dialysis Adequacy Comprehensive measure	X	X	X	X
Vascular Access Type Measure Topic:				
Maximizing Placement of AV Fistula	X**	X	X	X
Minimizing Use of Catheters as Chronic Dialysis Access	X**	X	X	X
Hypercalcemia	X	X	X	X
Standardized Transfusion Ratio (STrR)	X	X	X	X
Ultrafiltration Rate reporting measure		X***	X	X
Patient & Family Engagement Measure Domain				
ICH CAHPS measure	X	X	X	X
Care Coordination Measure Domain				
Standardized Readmission Ratio (SRR)	X	X	X	X
Standardized Hospitalization Ratio (SHR)	X	X	X	X
Clinical Depression Screening and Follow-up		X***	X	X
Safety Domain				
NHSN Bloodstream Infection (BSI)	X	X	X	X
NHSN Dialysis Event reporting measure	X	X	X	X
Percentage of Patients Waitlisted			X	X

Summary Table: ESRD QIP Measure Sets				
	PY2020	**PY2021**	**PY2022**	**PY 2023 (Proposed)**
Medication Reconciliation reporting measure			X	X
Reporting Measure Domain		Removed		
Serum Phosphorus	X	Removed		
Anemia Management	X	Removed		
Clinical Depression Screening and Follow-up	X	Moved		
Pain Assessment and Follow-up	X	Removed		
NHSN Healthcare Personnel Influenza Vaccination	X	Removed		
Ultrafiltration Rate	X	Moved		
*This table is organized around the ESRD QIP domains as finalized for PY 2021. The three domains for PY 2020 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. Beginning in PY 2021 the reporting domain will have no measures and will be removed. ** In PY 2020, the measures in this topic are AV Fistula and Catheter ≥ 90 days. ***Measure moved from reporting domain.				

V. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-filling)

A. Background

Manufacturers and stakeholders have raised concerns about CMS' processes for establishing fees for new DMEPOS items. CMS currently uses a process referred to as "gap-filling" to fill in the gap in the reasonable charge data for new DMEPOS items, which are newly covered. In accordance with statute,[8] the gap-filling process is used to estimate what Medicare would have paid for the item under the reasonable charge payment methodology (1986 and 1987 are used as the "base period" for DME).[9] To the extent CMS determines that a comparable item exists, then this item would be used to price the newly covered DMEPOS item.

Major stakeholder concerns related to gap-filling DMEPOS fee schedule amounts have been: (1) how CMS determines that items and services are comparable; (2) sources of pricing data other than fees for comparable items; (3) timing of fee schedule calculations and use of interim fees; (4) public consultation; (5) pricing data and information integrity; and (6) adjustment of newly established fees over time.

B. Code or Item Comparability Determinations

CMS states that it has heard frequently from manufacturers that do not agree that their newly developed DMEPOS item is comparable to older technology DMEPOS items and services. In order to develop a more standard approach, CMS undertook a review of the major components and attributes of DMEPOS items that it evaluates when determining whether items are comparable.

[8] Section 1842(b) of the Act and its regulation at 42 CFR 405.502.

[9] The current gap-filling methodology (used by contractors to set DEMPOS fee schedule amounts) can be found at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100-04).

CMS proposes to establish five main categories of components or attributes to determine if the new DMEPOS item is comparable to older existing DMEPOS items(s) for gap-filling purposes: physical components; mechanical components; electrical components (if applicable); function and intended use; and additional attributes and features. CMS details these components and various attributes in Table 9 of the proposed rule (reproduced below). A new product does not need to be comparable within each category, and CMS states that there is no prioritization of the categories. By establishing a set framework, CMS believes this will improve the transparency and predictability of establishing fees for new DMEPOS items.

TABLE 9: Comparable Item Analysis (Any combination of, but not limited to, the categories below for a device or its subcomponents)	
Components	**Attributes**
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/Tolerance, Weight
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hardness, Load Capacity, Flow-Control, Permeability, Strength
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezoelectric, Power, Power Source, Resistance
Function and Intended Use	Function, Intended Use
Additional Attributes and Features	"Smart", Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive

CMS also believes that such a process would create a more transparent process for stakeholders and allow a more efficient exchange of information between stakeholders and CMS on the various DMEPOS items and services.

CMS propose to codify this comparability requirement at §414.238(b).

C. New HCPCS Codes That Can Be Mapped to a Previous DMEPOS Fee Schedule Amount

As a general rule, if a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing. The gap-filling process only applies to items not assigned to existing HCPCS codes with established fee schedule amounts and items that were not previously paid for by Medicare under either a deleted or revised HCPCS code.

CMS details its approach to mapping fee schedule amounts based on different kinds of coding changes.

- When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item.

- When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.
- When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code).
- When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

CMS proposes to codify the continuity of pricing when HCPCS codes are divided or combine at §414.236.

D. New HCPCS Codes for Items and Services Without a Fee Schedule Pricing History

1. Sources of Pricing Data Other Than Fees for Comparable Items

When a new item lacks a Medicare pricing history and CMS is unable to identify comparable items with existing fee schedule amounts (as described above), CMS relies on other sources of pricing data to calculate the DEMPOS fee schedule amount for the new item. The current program instructions specify that supplier price lists can be used—catalogs and other retail price lists—as well as appropriate commercial pricing. Commercial pricing can include verifiable information from supplier invoices and non-Medicare payment data and payments made by Medicare Advantage plans. In each case, CMS would follow its gap-filling approach and deflate the prices listed in supplier price lists to the fee schedule base period (1986 or 1987), and then apply the covered item update factors (as specified in statute) to establish the current fee schedule amounts.[10] CMS proposes to codify the use of supplier and commercial price lists and this gap-filling approach at §414.238(c).

In addition to using information from supplier or commercial price lists, CMS proposes that technology assessments may be used to determine the relative supplier costs of furnishing new DMEPOS items compared to existing DMEPOS items. Under its proposal, these assessments would be performed by biomedical engineers, certified orthotists and prosthetists, and others knowledgeable about the costs of DMEPOS items and services. CMS notes that it may be necessary for it to use a separate technology assessment contractor to conduct these assessments.

Once the relative cost of the new item is determined, CMS proposes to establish a pricing percentage based on the results of the technology assessment. For example, if the technology assessment determines that the cost of the new DMEPOS item is twice the cost of the existing DMEPOS item, the pricing percentage would be equal to 200. If the fee schedule amount for an existing DMEPOS item is $500, then the fee schedule amount for the new DMEPOS item would

[10]Covered item update factors are specified in section 1834(a)(14) of the Act.

be $1,000. Likewise, if the pricing percentage was equal to 75 percent then the fee schedule amount for the new item would equal $375 ($500 multiplied by 0.75).

CMS proposes that technology assessments would be used whenever it is necessary to determine the relative cost of a new item in circumstances when the supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new item.

CMS proposes to codify its ability to use technology assessments to price new DMEPOS items at §414.238(d).

2. Adjustment of Fees Over Time

CMS proposes that if within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula discussed above. CMS believes this is necessary to ensure that supplier prices better reflect a market that is more established, stable, and competitive than the market and prices for the item at the time CMS initially gap-filled the fee schedule amounts.

CMS states in cases where supplier or commercial prices used to establish original gap-filled amounts increase or decrease by 15 percent or more after the initial fee schedule amounts are established, this would generally mean that these amounts would be grossly excessive or deficient within the meaning of section 1842(b)(8)(A)(i)(I) of the Act. CMS would then make an adjustment to the fee schedule amounts in accordance with its regulations at §405.502(g). Under these requirements, CMS could determine that a special payment limit is warranted. CMS must publish in the Federal Register a proposed and final notice of any special payment limits before it adopts the limits, with at least a 60-day comment period on the proposed notice.[11]

VI. Standard Elements for a DMEPOS Order; Master List of DMEPOS Items Potentially Subject to Face-to Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

A. Background

As background, claims for DMEPOS consistently show high improper payment rates as measured by the Comprehensive Error Rate Testing (CERT) program. In 2018, for example, DMEPOS claims had an improper payment rate of 35.5 percent, accounting for approximately 8.2 percent of the overall Medicare FFS improper payment rate.[12] A common reason for an improper payment is lack of documentation to support the services or supplies billed to Medicare. Over time, CMS has developed rules and guidance intended to ensure compliance

[11] The proposed notice must explain the factors and data considered in determining the payment amount is grossly excessive or deficient and the factors and data considered in determining the special payment limits. The final notice must explain the factors and data considered and respond to public comment.

[12] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSuplementalImproperPaymentData.pdf

with its requirements, limit waste, fraud, and abuse, and ensure that beneficiaries can access DMEPOS items to meet their specific needs.

CMS believes that the explicit identification of information to be included in a written order/prescription, for payment purposes, promotes uniformity among practitioners and precision in rendering intended items, and promotes program integrity goals. Likewise, CMS believes that prior authorization supports ongoing efforts to safeguard beneficiaries' access to medically necessary items and services, while reducing improper Medicare billing and payments. CMS states its proposal is intended to streamline the existing requirements and reduce provider or supplier confusion, while maintaining the concepts of practitioner involvement, order requirements, and a prior authorization process. Combined these efforts are intended to strengthen program integrity efforts.

B. Update of Definitions Related to DMEPOS Benefit Requirements

CMS proposes to update §410.38(c) to include the following terms: physician, treating practitioner, DMEPOS supplier, written order/prescription, face-to-face encounter, power mobility device (PMD), Master List, and Required Face-to-Face Encounter and Written Order Prior to Delivery. These proposed definitions are detailed in the table below.

Term	**Proposed Definition**
Physician §410.38(c)(1)	Physician as defined in section 1861(r)(1) of the Act.
Treating practitioner §410.38(c)(2)	Physicians as defined in section 1861(r)(1) of the Act and non-physician practitioners (that is, PAs, NPs, and CNSs) as defined in section 1861(aa)(5) of the Act.
DMEPOS supplier §410.38(c)(3)	An entity with a valid Medicare supplier number, including an entity that furnishes these items through the mail.
Written order/prescription §410.38(c)(4)	An order/prescription that is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.
Face-to-Face encounter §410.38(c)(5)	An in-person or telehealth encounter between the treating practitioner and the beneficiary.
Power Mobility Device §410.38(c)(6)	A covered item of DME that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.
Master List §410.38(c)(7)	List of DMEPOS items that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act that meet specified criteria in proposed §414.234(b). The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.
Required Face-to-Face Encounter and Written Order Prior to Delivery §410.38(c)(8)	List of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery, and communicated to the public via a 60-day Federal Register notice.

C. Proposed Revisions to the Master List

1. Creating the Master List

CMS' proposal would develop one master list of items potentially subject to prior authorization and/or face-to-face encounter and written order prior to delivery. This would combine three lists created by former rules: (1) April 2006 rule (71 FR 17021) established face-to-face examination and written order prior to delivery requirements for Power Mobility Devices; (2) November 2012 final rule (77 FR 81674) created a list of Specified Covered Items always subject to face-to-face encounter and written order prior to delivery requirements; and (3) December 2015 final rule (80 FR 81674) based on certain inclusion criteria found at §414.234 that would potentially be subject to prior authorization upon selection.

CMS proposes to create one list of items known as the Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements," or the "Master List."

CMS proposes for the Master List at §414.234(b)(1) the following inclusion criteria:

(1) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of $500 or greater, or an average monthly rental fee schedule of $50 or greater,[13] or identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period, that are:
   - Identified as having a high rate of fraud or unnecessary utilization in an OIG or GAO report that is national in scope and published in 2015 or later, or
   - Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(2) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:
   - Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or
   - Exceeding a 30 percent increase in payment, or

(3) Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

[13] These amounts are adjusted annually for inflation using CPI-U and reduced by 10-year moving average of changes in annual economy wide private nonfarm business multifactor productivity (MFP)

Illustrative examples of how the criteria would be applied are provided on pages 194-195 of the display copy.

CMS explains its rationale with respect to the proposed cost and spending thresholds. It believes that while the November 2012 and December 2015 final rules included higher cost thresholds ($1,000/$100 rental thresholds), CMS notes that programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items. Thus, CMS proposes the $500/$50 rental thresholds based on an analysis of the current fee schedule cost of DMEPOS items when compared with known vulnerabilities. Based on its analysis of low-cost items, CMS found that 10 items individually account for at least 1.5 percent of DMEPOS allowed costs, and thus CMS used this as its proposed cumulative threshold.

CMS also notes its objective to focus on more current data for identifying items on the Master List. It redefines the timeframe for identifying items in OIG and GAO reports to 2015 or later, in CERT reports to 2018 or later. CMS previously captured reports as far back as 2007. It also added new Master List inclusion criteria to capture aberrant billing practices, and set its spending and claims volume thresholds at amounts that would avoid capturing items with very low payments or very few claims.

Table 10 in the proposed rule (pages 209-231 in the display copy) details the 413 items on the proposed Master List that are potentially subject to a face-to-face encounter and a written order prior to delivery. This is an increase of 306 items from the previous list. The Master List serves as a library of DMEPOS items from which items may be selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

2. Notice and Maintenance of the Master List

CMS proposes at §414.234(b)(2) that the Master List would be self-updating, at a minimum, annually. CMS believes that its current standard process in which items on the list expire after 10 years if they have not otherwise been removed is appropriate. It clarifies that any item currently being included on the list as a result of an GAO, OIG, or CERT report would be maintained on the Master List from the date of the most recent publication.

The processes currently specified in §414.234(b)(2) would be maintained with two exceptions: (1) the list would be updated as needed and more frequently than annually, and (2) technical changes would be made to address the proposed new cost thresholds and report years. CMS states it would maintain its current process and publish any additions or deletions to the Master List in the Federal Register and on the CMS website.

3. Required Face-to-Face Encounter and Written Order Prior to Delivery List

a. Creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List

Statute prohibits payment for motorized or power wheelchairs unless a practitioner conducts a face-to-face examination and writes an order for the item.[14] The Secretary, as specified in statute, can also require a practitioner have a face-to-face encounter and written order communicated to the supplier prior to delivery for other specified covered items of DMEPOS. In its analysis of one year of claims, CMS found that about 97 percent of beneficiaries receiving DMEPOS have had a recent face-to-face encounter.

CMS proposes to revise §410.38(d)(1) and §410.38(d)(2) to limit the face-to-face encounter and written order prior to delivery conditions of payment to only those items selected from the Master List and included on the "Required Face-to-Face Encounter and Written Order Prior to Delivery List." In this way, CMS states that it will have a broader list of potential items that could be selected, but expects only a subset of items from the Master List to be subject to the Required Face-to-Face Encounter and Written Order Prior to Delivery List, based on those items identified to be of highest risk. By tailoring the list in this way, CMS believes it can reduce any potential provider impact—and could even decrease the scope of impacted items and providers. The Master List would include statutorily identified items, as well as any other items posing potential vulnerability to the Trust Fund, as identified via the proposed Master List inclusion criteria.

CMS proposes at §410.38(c), in the definition of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the factors that it may consider when determining which items may be appropriate to require a face-to-face encounter and written order prior to delivery. Specifically, CMS states it may consider operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis. CMS notes that it has not proposed an all-inclusive list of factors to account for the fluidity of program operations and associated vulnerabilities, and believes this is critical to protect beneficiaries, the program, and industry.

CMS solicits comments on both its underlying presumption that the list should not be exhaustive, as well as the factors it should consider when selecting an item from the Master List and including it on the Required Face-to-Face Encounter and Written Order Prior to Delivery List.

CMS makes several other proposals in this section to clarify requirements:

- Telehealth services currently are permitted to be used to satisfy the DME face-to-face encounter requirements. CMS proposes at §410.38(d)(2) that telehealth services used to meet DMEPOS face-to-face encounter requirements must meet the requirements found at §410.78 and §414.65 to support payment of the DMEPOS claim.
- CMS proposes at §410.38(d)(3) to clarify the documentation necessary to support the face-to-face encounter and associated claims for payment. This documentation includes

[14] Section 1834(a)(1)(E)(iv) of the Act.

the written order/prescription and documentation to support medical necessity, which may include the beneficiary's medical history, physical examination, diagnostic tests, findings, progress notes, and plans for treatment. Documentation from a face-to-face encounter conducted by a treating practitioner, as well as documentation created by an orthotist or prosthetist, becomes part of the medical records and if the notes corroborate, together they can be used to support medical necessity of an ordered DMEPOS item.

- CMS proposes to revise §410.38 to apply the 6-month timeframe to all items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (including PMDs, which previously required a 45-day timeframe) for uniformity purposes. Since the industry has become accustomed to the 6-month timeframe, it believes this timeframe is relevant, and changing it would create unnecessary confusion. Therefore, if finalized as proposed, a face-to-face encounter would be consistently required within 6 months of a written order prior to delivery for those items for which a face-to-face encounter is required.[15]

The Paperwork Reduction Act Record of Information Collection for medical review (CMS-10417; OMB-0938-0969) covers the burden for responding to documentation requests, generally. **CMS does not believe this proposed rule would create any new burdens for the medical review process, but seeks comments on this assumption.**

b. Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List

CMS proposes at §410.38(c)(8) that it would publish a 60-day Federal Register notice and post on the CMS' website any item on the Master List that is selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. Any DMEPOS item included on this list would be subject to the face-to-face encounter and written order prior to delivery requirement as a national condition of payment and claims for those items would be denied if the condition of payment is not met. CMS also proposes at §410.38(e) to allow the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, unless these requirements for the items were required by statute. CMS notes that if it suspends or ceases the face-to-face encounter and the written order prior to delivery requirement for any item(s), it would provide stakeholder notification of the suspension on the CMS website.

[15] The 6-month timing requirement does not supplant other policies that may require more frequent face-to-face encounters for specific items. For example, the National Coverage Determination 240.2 titled "Home Use of Oxygen" requires a face-to-face examination within a month of starting home oxygen therapy.

D. Required Prior Authorization List

a. Creation and Application of the Required Prior Authorization List

CMS proposes to limit prior authorization to a subset of items on the Master List as currently specified at §414.234(a)(4). The subset of items requiring prior authorization are referred to as the Required Prior Authorization List, and currently includes 45 items.[16]

CMS proposes, similar to its current requirements at §414.234(c)(1)(ii), that it may decide to select and implement prior authorization of an item(s) nationally or, in collaboration with the DME MACs locally. It proposes to revise this section to state that all suppliers (either nationally or within a contractor jurisdiction) would initially be subject to prior authorization for items identified through a Federal Register notice and posted to CMS' website. CMS may later elect, however, to exempt suppliers that have demonstrated compliance.

CMS proposes certain factors it may consider when selecting an item from the Master List and including it on the Required Prior Authorization List. Factors CMS may consider include geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis in selecting items for national or local implementation. **CMS solicits comments on the proposed factors and whether the factors could be over-inclusive or under-inclusive.**

CMS makes several other clarifications in this section on how the Required Prior Authorization List is applied.

- CMS clarifies that the prior authorization program would continue to apply in all competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive Bidding Program.
- CMS notes that any accessory included on a prior authorization request submitted for an item on the Required Prior Authorization List, may nonetheless receive a prior authorization decision for operational simplicity even if the accessory is not on the Required Prior Authorization List. The inclusion of such items is voluntary and does not create a condition of payment for items not present on the Required Prior Authorization List.
- CMS also proposes that the items currently subject to prior authorization would be grandfathered into the prior authorization program, if this rule is finalized as proposed, until the implementation of the first Required Prior Authorization List (which would be published subsequent to the rule).
- CMS proposes to retain the documentation requirements for submitting prior authorization requests at §414.234(d), and makes further technical refinements at §410.38 and §414.234(e).

[16] The current list can be found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/DMEPOS_PA_Required-Prior-Authorization-List.pdf

- CMS proposes to maintain the authority to suspend or cease the prior authorization requirement generally or for a particular item or items at any time without undertaking a separate rulemaking, as described in current §414.234(f). CMS would publish a notice in the Federal Register and post notification of the suspension on the CMS website and include the date of suspension.

b. Notice of the Required Prior Authorization List

Section §414.234 currently requires CMS to inform the public of items included on the Required Prior Authorization List in the Federal Register with 60-day notice before implementation. CMS is not proposing any changes to this section. In addition, all other prior authorization processes described in §414.234 not mentioned in the proposed rule remain unchanged.

E. Standardizing the Written Order/Prescription

CMS notes it has adopted different requirements for orders for different items of DMEPOS through several regulations and subregulatory guidance. To simplify order/prescription requirements and to reduce confusion, CMS proposes at §410.38(d)(1) to adopt one set of required written order/prescription elements for orders/prescriptions for all DMEPOS items.

CMS believes that a standardized order requirement is appropriate and would help promote compliance and reduce the confusion associated with complying with multiple, different order/prescription requirements for DMEPOS items. The required timing for the order to be provided (from the treating practitioner to the supplier) would continue to vary for DMEPOS items. CMS proposes at §410.38(d) that for those items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery of the item (per statutory requirement); for all other DMEPOS items, a written order/prescription must be communicated to the supplier prior to claim submission.

CMS proposes at §410.38(d)(1)(i) that the standardized order/prescription require the elements listed here:

- Beneficiary Name or Medicare Beneficiary Identifier (MBI).
- General Description of the item.
- Quantity to be dispensed, if applicable.
- Date.
- Practitioner Name or National Provider Identifier.
- Practitioner Signature.

CMS notes that these required standardized order elements are generally written on a prescription/order; however, it recognizes that these required elements may be found in the beneficiary's medical record. CMS proposes at §410.38(d)(1) that if the rule is finalized as proposed, DME MACs shall consider the totality of the medical records when reviewing for compliance with standardized order/prescription elements.

CMS also states that while the standardized elements are conditions of payment, other additional information may be added to the order/prescription that might be helpful for clinical practice and

quality of care. For example, route of administration—such as whether oxygen is delivered via nasal cannula or face mask is not required as a condition of payment, but may be indicated for good clinical practice.

CMS states that current §410.38(d), (e) and (f) contain written order and documentation requirements specific to equipment that is used for treatment of decubitus ulcers, seat-lifts, and transcutaneous electrical nerve stimulator units. CMS believes that the requirements found at §410.38(d), (e) and (f) are appropriate for inclusion in the standardized written order/prescription and medical record documentation requirements outlined in the proposed rule. Thus, CMS proposes to delete the coverage requirements currently outlined in §410.38(d), (e) and (f), and to replace sections §410.38(d) and (e), with its proposed conditions of payment and process for suspending the face-to-face encounter and written order prior to delivery requirements, respectively.

VII. DMEPOS Competitive Bidding (CBP) Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas.[17] CMS proposes to revise the existing DMEPOS Competitive Bidding Program (CBP) regulations in §414.422(d) on change of ownership (CHOW) in recognition of the fact that CHOWs may occur on shorter timeframes than its regulations previously contemplated. CMS also propose to revise §414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Proposed Amendments

In § 414.422(d) CMS proposes the following amendments:

- Add the acronym "CHOW" after the title of the paragraph and use the acronym throughout the section instead of using "change of ownership".
- Remove the notification requirement at paragraph (d)(1) because CMS no longer believes it is necessary for it to be notified 60 days in advance when a contract supplier is negotiating a CHOW. CMS states that it recognizes that this requirement was too onerous.
- Remove the distinction of a "new entity" from paragraph (d)(2)(ii) in its entirety, and retain the successor entity requirements in paragraph (d)(2)(i) with changes. CMS proposes to revise the requirement to submit the documentation described in §414.414(b) through (d) from 30 days prior to the anticipated effective date of the CHOW to instead require submission prior to the effective date of the CHOW. CMS further proposes to change the requirement on submission of a signed novation agreement 30 days before the CHOW to instead require that the novation agreement be submitted by the successor entity no later than 10 days after the effective date of the CHOW. CMS also proposes

[17]Based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR Part 414, Subpart F.

that the successor entity must submit a novation agreement that states that it assumes all obligations under the contract.

- Remove the phrase "new qualified" before "entity" and replace it with the term "successor" in paragraph (d)(3) as this is applicable to all successor entities. CMS also proposes to add the term "may" to make it clear that the transfer of the entire contract to a successor entity is at CMS' discretion upon CMS' review of all required documentation.
- Revise paragraph (d)(4) by removing the "e.g." parenthetical after "distinct company" to retain only the example of a subsidiary, and noting it as "for example" as CMS realized that it is the clearest example. CMS proposes to remove the reference to "new qualified" before "entity" and replace it with the term "successor," as the resulting entity in a transfer of a portion of the contract may not result in a "new" entity but would always result in a "successor" entity. In addition, CMS proposes to remove the phrase "new qualified owner who" in paragraph (d)(4)(i) and replace it with "successor entity that" to align with the language used throughout §414.422(d).
- Revise paragraph (f)(2) to specify that the request for a hearing must be "submitted to" the CBIC rather than "received by" the CBIC. Hearing requests can now be submitted using a secure online method. Furthermore, this revision aligns with language used throughout §414.423.

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

VIII. Requests for Information

This section of the proposed rule includes three Requests for Information (RFIs); two related to ESRD and one related to DMEPOS.

A. RFI on ESRD Data Collection

In December 2018 Acumen, a CMS data contractor, led a TEP discussion on the collection of data on composite rate costs for the purpose of refining the case-mix adjustment in the ESRD PPS. The proposed rule summarizes the topics discussed and the panel's conclusions. The panel addressed components of dialysis treatment costs and limitations of current data collection; data collection options; improving the accuracy of charges; collection of data on duration of dialysis treatment; capturing variation in costs associated with complex patients; and facility-level costs. The TEP report was released in June 2019 and is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html.

CMS seeks input on options for improving the reporting of composite rate costs for the ESRD PPS. It believes that improvements in reporting of both patient-level and facility-level costs are needed. Comments are invited on all the options proposed during the TEP as well as novel approaches, and CMS agrees with the TEP that the benefits of improving the ESRD PPS case-mix adjustment model must be weighed against facility burden that might result from changes to claims and cost reporting.

Commenters are invited to respond to a lengthy series of specific questions and requests set forth in the proposed rule under five main categories:

1. Components of dialysis treatment costs
2. Collection of duration of treatment data
3. Collection of data to identify sources of variation in treatment costs associated with complex patients
4. Collection of facility-level data
5. Specific questions raised during the TEP regarding itemizing the use of composite rate drugs on claims; rejection of claims by Medicare Advantage and other secondary payers; specific changes to the cost reports, and other issues.

B. ESRD Wage Index

CMS notes that it has frequently received comments from stakeholders regarding certain aspects of the ESRD PPS wage index values and its impact on payments. It invites comments on any concerns regarding the wage index and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS. No specific questions are enumerated in the proposed rule.

C. Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries (Section 50414 of the Bipartisan Budget Act of 2018)

1. Background

Section 1847(a)(2)(A) of the Act mandates competitive bidding programs for "covered items" and supplies used in conjunction with DME such as blood glucose monitors used by beneficiaries with diabetes. The supplies used with these blood glucose monitors (such as blood glucose test strips and lancets) are referred to under the DMEPOS CBP as diabetic supplies or diabetic testing supplies. In the April 10, 2007 final rule published in the Federal Register titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (72 FR 17992), which implemented the DMEPOS CBP, CMS established regulations to implement competitions on a regional or national level for certain items such as diabetic testing supplies that are furnished on a mail order basis.

2. Current Issues

The Bipartisan Budget Act of 2018 (BBA) was enacted on February 9, 2018, and section 50414 of the BBA amended section 1847(b)(10)(A) of the Act to establish additional rules for the competition for diabetic testing strips. Section 1847(b)(10)(A) of the Act now requires that for bids to furnish diabetic testing strips on or after January 1, 2019, the volume for such products be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

The OIG reports to CMS the Medicare Part B market share of mail order diabetic test strips before each round of the Medicare national mail order CBP, and pursuant to this new requirement, the OIG will now report on the non-mail order diabetic test strip Medicare Part B market. On January 19, 2019, the OIG released a report that documented the Medicare Part B market share of mail order diabetic test strips for the 3-month period of April through June 2018. On March 19, 2019, the OIG released another report that documented the Medicare Part B market share of non-mail-order diabetic test strips for the same 3-month period. These data briefs represent OIG's third round of diabetic test strip Medicare market share reports since 2010, but this is the first series of reports that includes non-mail-order diabetic test strip data.[18]

3. Comment Solicitation

Because section 1847(b)(10)(A) of the Act now requires the use of "multiple sources of data," CMS requests comments on other potential sources of data (sources other than the OIG) that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. CMS requests comments on other potential sources of data because the word "multiple" in the phrase "multiple sources of data" could mean that it should use more than one source of data, and that the OIG is one source of data. CMS therefore requests comments on other potential sources of data regarding the mail order and non-mail order Medicare markets for diabetic testing strips through this request for information. In particular, CMS seeks data that:

- Has a sufficient sample size, and is unbiased and credible;
- Separately provides the market shares of the mail-order Medicare Part B market, and the non-mail order Medicare Part B market (does not combine the two markets into one); and
- Includes market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

IX. Regulatory Impact Analysis

A. Impact of Changes in ERSD PPS Payments

Medicare program payments for ESRD facilities in 2020 are estimated to total $11.1 billion, reflecting an expected 1.7 percent increase in fee-for-service Medicare dialysis beneficiary enrollment.

Table 20 of the proposed rule provides the accounting statement showing estimated transfers of costs and savings resulting from the proposed policies. Medicare payments to ESRD facilities for both the ESRD PPS and the payments for AKI would increase by $160 million in 2020; beneficiary coinsurance payments will increase by $50 million, for a total of $210 million. This total excludes the effect of proposed changes in the TDAPA eligibility criteria, conditioning the TDAPA on ASP data submission, or providing a transitional add on payment for innovative

[18]These two reports can be found at OIG's website. See https://oig.hhs.gov/oei/reports/oei-04-18-00440.asp and https://oig.hhs.gov/oei/reports/oei-04-18-00441.asp.

renal dialysis equipment and supplies. CMS says that the effects of those policies cannot be determined due to the uniqueness of innovative drugs, equipment and supplies.

Table 11 in the proposed rule shows the estimated impact on ESRD payments in 2020 by various types of ESRD facilities. The estimates are based on 2018 data from the Part A and Part B Common Working Files as of February 15, 2019. 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 Proposed Rule Changes in 2020 Payment to ESRD Facilities (from Table 11)

Facility Type	Number of Facilities	Number of Treatments (millions)	Effect of 2020 Changes in Outlier Policy	Effect of 2020 Wage Index, Wage Floor, and Labor Share Changes	Effect of 2020 Rate Update	Effect of 2020 Changes to TDAPA*	Total Effect of 2020 Proposed Changes
All Facilities	7,386	44.6	0.3%	0.0%	1.7%	-0.4%	1.6%
Type							
Freestanding	6,995	42.7	0.3%	0.0%	1.7%	-0.4%	1.5%
Hospital-based	391	1.9	0.6%	0.0%	1.7%	-0.3%	1.9%
Ownership							
Large dialysis organization	5,603	34.5	0.3%	0.0%	1.7%	-0.4%	1.5%
Regional chain	927	5.7	0.3%	0.1%	1.7%	-0.5%	1.6%
Independent	512	2.9	0.3%	-0.1%	1.7%	-0.4%	1.5%
Hospital-based	305	1.5	0.6%	0.0%	1.7%	-0.3%	1.9%
Facility Size (Treatments)							
Less than 4,000	1206	2.5	0.3%	0.1%	1.7%	-0.4%	1.7%
4,000 to 9,999	2,644	11.9	0.3%	0.1%	1.7%	-0.4%	1.6%
10,000 or more	3,159	29.8	0.3%	0.0%	1.7%	-0.5%	1.5%
*Impact of proposal to reduce the TDAPA for calcimimetics from ASP+6 to ASP+0. Impact of other proposed changes to TDAPA cannot be determined.							

Payments to ESRD facilities for dialysis treatments provided to patients with AKI are estimated to total $42 million in 2020. Table 12 in the proposed rule shows the impact of the changes in payments for dialysis services furnished to AKI patients by type of facility. That table shows an estimated total of 172,700 treatments will be provided to beneficiaries across 4,372 facilities. CMS notes that the 20 percent beneficiary coinsurance required for AKI in an ESRD facility is less than in an outpatient hospital setting because the Medicare payment rates for the hospital outpatient setting are higher.

B. Estimated Impact of ESRD QIP in PY 2021

For PY 2022, CMS estimates that the payment reductions from not receiving the full update under the ESRD QIP program under the proposed rule would total $13.9 million across the 1,506 facilities (22 percent of the 7,099 ESRD facilities) that it estimates would receive a reduction. The same total is estimated for PY 2023. The tables below, reproduced from the proposed rule, show the estimated distribution of payment reductions for PY 2022 and the impact by facility type. (With respect to the latter, only a portion of the table is shown here.) For almost three-quarters of the facilities receiving a payment reduction, the estimated reduction is 0.5 percentage points. Only 9 facilities are estimated to receive the maximum 2 percent penalty.

Overall, CMS estimates the payment reductions will represent about 0.14 percent of payments in PY 2022; 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 2022; this is higher than estimated for PY 2021 in the final rule last year because of re-estimates, not due to any proposed changes.

Table 13: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	5,370	78.10%
0.5%	1,116	16.23%
1.0%	325	4.73%
1.5%	56	0.81%
2.0%	9	0.13%

Note: Excludes 223 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 2022 (from Proposed Rule Table 15)

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	7,099	1,506	-0.14%
Facility Type:			
Freestanding	6,681	1,407	-0.13%
Hospital-based	418	99	-0.22%
Ownership Type			
Large Dialysis	5,400	1,068	-0.12%
Regional Chain	881	192	-0.14%
Independent	485	165	-0.26%
Hospital based (non-chain)	327	81	-0.24%
Facility Size (Treatments)			
Less than 4,000	1,246	193	-0.14%
4,000 to 9,999	2,666	439	-0.10%

Impact of QIP Payment Reductions to ESRD Facilities for PY 2022 (from Proposed Rule Table 15)			
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**
10,000 or more	3,147	866	-0.17%

C. DMEPOS

The proposed rule would establish a gap-filling methodology for new items and services. The fiscal impact cannot be determined due to the uniqueness of new items and their costs.