

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

On November 8, 2019, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a final 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) (84 FR 60648-60809).

Along with routine updates for 2020 payments under the ESRD PPS and for acute kidney injury, the final rule modifies policies under the transitional drug add-on payment adjustment; adds a new transitional add-on payment for new and innovative equipment and supplies; discontinues the erythropoiesis-stimulating agent (ESA) monitoring policy; and makes changes to the ESRD QIP. For DMEPOS, the final rule develops policies on how Medicare pricing is determined for new DMEPOS items; develops a single list of items potentially subject to a face-to-face encounter and written order prior to delivery, and/or prior authorization requirement; and revises the existing DMEPOS Competitive Bidding Program regulations to address change of ownership issues. CMS also summarizes comments received from its requests for information addressing ESRD data collection, the ESRD PPS wage index, and sources of market-based data measuring sales of diabetic testing strips.

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-F.html>.

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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 finalized involving modifications to the transitional drug add-on payment adjustment; addition of 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. General 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 category¹, 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

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>.

505 of the Federal Food, Drug and Cosmetic (FD&C) Act (drugs) or section 351 of the Public Health 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 Policy Changes for 2020

In the ESRD PPS proposed rule for 2020, CMS proposed to narrow the eligibility of new drugs for the TDAPA. A lengthy discussion was 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 noted 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 were also discussed. CMS noted that in 2018, the first year it paid the TDAPA, there was an estimated \$1.2 billion increase ESRD PPS expenditures due to the use of two calcimimetic drugs, which were used by 25 percent of the Medicare ESRD population. CMS stated 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 New Drug Application (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 following goals of the TDAPA: (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 (TEP) that was convened in December 2018² and undertook an internal review including CMS pharmaceutical statisticians.

² In the requests for information section of this 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

That review identified paying for innovative ESRD drugs in the same way as others (e.g., generics) could have the potential unintended consequence of crowding out innovative and more expensive drugs for drugs that are less costly to duplicate.

3. Finalized Changes to TDAPA Eligibility for Drugs

In this rule CMS finalizes its proposed changes to eligibility of drugs for the TDAPA. Under the final rule, the following drugs and biologicals will be excluded from eligibility for the TDAPA beginning January 1, 2020. The eligibility rules are detailed in 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 NDA classification code assigned by FDA at the time the drug is approved. Specifically, the exclusion applies to drugs with an NDA classified by the FDA as Type 3, 5, 7 or 8; Type 3 in combination with Type 2 or Type 4; Type 5 in combination with Type 2; or Type 9 when the parent NDA is a Type 3, 5, 7 or 8. The table below summarizes the detailed discussion of these exclusions.
- Generic drugs approved by the FDA under section 505(j) of the FD&C Act. CMS notes that 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 will rely 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>.) If FDA changes the NDA classification codes, CMS will assess the changes and propose any needed revisions to its exclusions in the subsequent rulemaking cycle.

In order to operationalize the exclusions, CMS will modify the information required from stakeholders seeking eligibility for TDAPA³ 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 is expected to resubmit the TDAPA request if the NDA Type changes 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. CMS understands that FDA will meet with manufacturers for discussion regarding the NDA types that may be considered for their applications.

CMS expects detailed analyses of future drug product utilization, pricing and payments and anticipates proposing further refinements to the TDAPA in future rulemaking.

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

Summary of Final Rule Treatment of NDA Classification Codes for the TDAPA and CMS Rationale

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, 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.

NDA Classification	Meaning	Eligible for TDAPA?	CMS Rationale
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.
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.
<p>¹Type 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 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.</p> <p>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.</p>			

Regarding the exclusion of generic drugs (drugs approved by the FDA under section 505(j) of the FD&C Act), CMS explains 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 is 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. Response to Comments

CMS reports that commenters were generally supportive of the policy changes, and it responds to many comments and suggestions, some of which are highlighted here. Regarding concerns that the NDA classifications are administrative and not intended to distinguish innovative and non-innovative drugs, CMS says that they provide an objective basis for targeting Medicare resources to innovative drugs and biological products and foster competition within the ESRD

functional categories. While the classifications themselves are not subject to rulemaking, CMS plans to propose changes through rulemaking if the classifications are changed.

CMS believes that the TDAPA should be applied only to truly innovative drugs and biologicals. With respect to the suggested inclusion of Type 5 NDA drugs, CMS believes that this may cause more attention to be diverted to the less costly duplication of existing drugs that could crowd out innovative drugs. It states similar concerns about new dosage forms (Type 3 NDA drugs). By contrast, Type 10 NDA drugs are viewed by CMS as innovative because a new indication of a previously submitted renal dialysis drug advances the field. Type 7 drugs would not advance the goals of the TDAPA because they are already on the market and may already be used in ESRD facilities. Regarding access to innovative treatments, CMS also notes that beneficiaries have access to all FDA-approved drugs regardless of whether the ESRD facility received the TDAPA.

CMS responds to MedPAC and other commenters who opposed the use of the NDA classification codes to determine TDAPA eligibility. MedPAC suggested instead the use of the substantial clinical improvement (SCI) standard used by CMS for new technology payment under the inpatient hospital prospective payment system (IPPS). CMS disagrees with the use of an SCI standard because it believes that ESRD beneficiaries are uniquely complex patients and the question of whether one drug is more effective than another depends each patient's characteristics. Therefore, it believes that use of an SCI standard for TDAPA eligibility would be too rigid and limiting.

Some comments suggested increases to the ESRD PPS base rate at the end of the TDAPA eligibility period. MedPAC suggested adjusting the TDAPA amount for products assigned to a functional category to reflect the amount already included in the base rate. CMS responds that it continues to believe that adding dollars to the base rate for products that fall within existing functional categories is contrary to the principles of prospective payment. It views the TDAPA as providing a transition period for uptake of the new drug.

5. Treatment of Biological Products

No changes are made to TDAPA eligibility with respect to biological products. That is, the current policy is 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 will 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

6. Effect on Medicare Expenditures and Beneficiary Coinsurance

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

7. Changes to Regulatory Text

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

B. Changes to TDAPA Payment

Two changes are finalized to the calculation of the TDAPA payment amount. The first change applies to the TDAPA for calcimimetics, which took effect on January 1, 2018. The second change broadly conditions 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.

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

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>

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 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 finalizes a reduction in 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 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 the Medicare program and beneficiaries.

Responding to commenters' concern that many facilities purchase products at prices well above the ASP, CMS understands the concern but notes that the purpose of the TDAPA policy is not to offset business losses or enhance profits. It also points out that there are dollars in the ESRD PPS per treatment base rate for products that fall into an existing functional category. CMS says it does not intend that its payment policy interfere in the physician-patient decision making process about choice of treatments, and it expects that ESRD facilities will follow the physician's plan of care for the patient. CMS intends to closely monitor drug utilization at the facility and beneficiary level regarding access, choices and prices. MedPAC supported the proposal and discussed the difference in rationale for the ASP+6 developed for payment in a physician office setting and use in payment for ESRD facilities.

2. ASP Conditional Policy for the TDAPA

CMS finalizes that the TDAPA payment will not be made if it 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 will no longer be made beginning no later than two calendar quarters after CMS determines that the ASP data are not available. CMS believes that the 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.

The change is effective January 1, 2020, meaning that for a renal dialysis drug or biological product for which CMS is currently paying the TDAPA, if it does not receive the latest full calendar quarter of ASP data for the product beginning on that date CMS will no longer apply the TDAPA no later than 2 calendar quarters after it determines that the ASP data are not available.

This policy change is made out of concern that 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. CMS also cites its concerns about increases in Medicare expenditures for calcimimetics and the lack of current reporting of ASP data. 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.

In responding to comments, CMS emphasizes that it believes the policy will incentivize ASP reporting and that ESRD facilities have the ability to influence manufacturers to submit ASP data due to manufacturers' desire for market share. CMS clarifies that it will apply this policy on an individual product basis. MedPAC suggested that CMS go further by either requiring all Part B drug manufacturers to report ASP data or by not applying the TDAPA to any eligible drug from a noncompliant manufacturer, not just the drug for which ASP data has not been reported. CMS believes the policy it is finalizing appropriately conditions the TDAPA for a product on receiving data for that product, but it will take these suggestions into consideration for future rulemaking.

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

With changes from the proposed rule, CMS finalizes 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 is generally modeled after the new technology add-on payment (NTAP) used in the inpatient hospital PPS, including its substantial

clinical improvement (SCI) criteria. The policy is detailed in regulatory text in a new §413.236. (Conforming and technical changes are also made in §413.230.)

The TPNIES was developed in response 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 an Executive Order aimed at transforming kidney care in America, which includes proposals for the Secretary to encourage development of breakthrough technologies for kidney patients.

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

Under the final rule, the add-on payment will 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 will equal 65 percent of a price for the item that is established by the MACs on behalf of CMS. The payment will be made for two calendar years. After the two-year period ends, there will be no modification to the ESRD base rate, and the innovative equipment or supply will be an eligible outlier service.

TPNIES Eligibility Criteria

To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item must meet all the following requirements:

1. Has been designated by CMS as a renal dialysis service under §413.171;
2. Is new, meaning it is granted marketing authorization by the FDA on or after January 1, 2020;
3. Is commercially available by January 1 of the year in which the payment adjustment would take effect;
4. Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;
5. Is innovative, meaning it meets the substantial clinical improvement criteria used by CMS for the IPPS NTAP (described in the 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 will 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 will include a description of the request and the final rule will include the evaluation of whether it meets eligibility criteria. An application will 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) and marketing authorization must occur by September 1 prior to the particular calendar year (September 1, 2021 in this example). The September 1st date is offered in response to comments to clarify that while the marketing authorization submission to the FDA must have occurred by the time the TPNIES application is made to CMS, the FDA authorization itself need not occur until September 1 of that year to be in time for inclusion in the ESRD PPS final rule.

CMS finalizes its proposal to establish a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria in §412.87(b)(1). 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 specific process to determine whether the renal dialysis equipment or supply meets the eligibility criteria is codified at §412.236(b) with a reference to the SCI criteria in §412.87(b)(1).

The final 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 substantial 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 is modeled after the NTAP. Manufacturers must submit all information necessary for determining that the renal dialysis equipment or supply meets the eligibility criteria. That includes 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.

All of the comments CMS received supported the establishment of the TPNIES to spur innovation for new dialysis equipment and supplies. Most commenters, though, raised concern about the exclusion of capital-related assets. CMS acknowledges that there is innovation and improvement in dialysis machines and peritoneal dialysis cyclers and in the efficiency and effectiveness of water purification systems, but does not believe that it is appropriate to provide the TPNIES for items where the costs are captured in cost reports, depreciate over time, and are generally used for multiple patients. In addition, because capital costs are captured in the aggregate it would be complex to establish a per-treatment cost for these items.

Some commenters, including MedPAC, raised questions regarding treatment of leased capital assets. CMS says it does not have enough information on financial and leasing arrangements used by ESRD facilities for this equipment including (1) items that are purchased and owned as capital assets; (2) assets acquired through a capital lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board guidance on leases;⁵ or (4) equipment obtained through an operating lease and recorded as an operating expense. CMS plans to gather information on how ESRD facilities obtain capital equipment in future meetings of its TEP.

CMS states that it did not intend for capital-lease assets to be eligible for TPNIES at this time. It notes that §413.130(b)(1) “Introduction to capital-related costs,” specifies that leases and rentals are includable in capital related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. In the future, CMS will review how capital-related assets are treated under Medicare, including regulations at §412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital lease and the newly implemented guidance for finance lease arrangements, to determine if

⁵ FASB Accounting Standards Update: No. 2016-02, February 2016; Leases (Topic 842); An Amendment of the FASB Accounting Standards Codification.
https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true

similar policies would be appropriate under the ESRD PPS.

A commenter suggested that the treatment of capital assets would exclude most medical equipment from the TPNIES, but CMS disagrees. It says that there “could be” a supply or piece of equipment that is purchased outright by the ESRD facility that may be able to withstand repeated use over the treatment month and lasts less than a year, and that does not fall under the definition of capital-related asset in §413.236.

In response to comments, CMS finalized the addition of §413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies, with 5 modifications:

- It clarifies that applicants must receive FDA marketing authorization by September 1 and not February 1;
- It clarifies that “commercially available” means available by January 1 of the particular calendar year, the year in which the payment adjustment would take effect;
- It clarifies that the HCPCS application needs to be submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;
- It clarifies that “particular calendar year” means the year in which the payment adjustment would take effect; and
- It omits the reference to the application of the TPNIES in the calculation of the per treatment payment amount because it does not believe it is necessary in light of its changes to §413.230.

TPNIES Payment Amount

The TPNIES payment amount will equal 65 percent of a price for the item that is established by the MACs on behalf of CMS. The MACs will 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 establishing 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 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 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.⁶

CMS believes the two-year period of payment will be a sufficient timeframe for ESRD facilities to adapt business practices so that there is “seamless access” to new innovative equipment and supplies, and will 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.

There is no change in the base rate once the two-year period is complete. CMS states that the intent of the TPNIES is to provide a transition period for 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 is not 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. It is not the intent of a PPS to add dollars to the base whenever something new is made available.

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

CMS sought comment in the proposed rule 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 was particularly interested in receiving comments on HUDs that would be used in furnishing renal dialysis services under the ESRD PPS, any barriers to payment encountered, and past experience in obtaining Medicare payment for these items through the MACs. Most commenters expressed the concern that lack of Medicare reimbursement for HUDs impedes access to these treatments for Medicare beneficiaries.

CMS received comments from a broad array of stakeholders including a device manufacturer, a medical device manufacturing association, a drug manufacturer, a non-profit provider, a professional society, a national dialysis stakeholder organization, and a patient advocacy organization. Most agreed that CMS needed to ensure a reimbursement pathway for devices with a HUD designation, that coverage includes such devices as required to be used in the ESRD facility for ESRD or other conditions related to renal dialysis, and that the devices should be

⁶ 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.

separately reimbursed at invoice cost, and not as part of a bundle. In response, CMS states it will consider these comments as it contemplates future policies related to this issue.

E. Discontinuation of the ESA Monitoring Policy

CMS finalizes its proposal 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 epoetin alfa regarding individualized dosing. CMS believes this policy will reduce the documentation burden on ESRD facilities because they will no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity.

ESRD facilities will no longer be required to report EMP-related modifiers. Medicare contractors will no longer apply dosing reduction or dose limit edits prior to calculation of outlier eligibility and they will no longer be reflected in outlier payments. Monitoring of ESAs will 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 will closely monitor ESA usage in conjunction with phosphate binder prescribing and usage.

Several commenters were supportive of the proposal to no longer apply the EMP under the ESRD PPS, but some sought clarification of whether hemoglobin or hematocrit value codes are still required on Medicare claims. MedPAC opposed this proposal expressing concern about the potential for overuse of drugs paid under the TDAPA policy. MedPAC urged CMS to establish a formal monitoring policy for all renal dialysis drugs and biological products that are paid under the TDAPA to address the potential for overuse. CMS in its response clarifies that ESRD facilities will need to continue reporting hemoglobin or hematocrit values as it is necessary for the ESRD Quality Incentive Program. CMS states that it believes that with its near-real-time claims monitoring it will have the ability to closely track ESRD facility behaviors and can take action if it sees something concerning.

F. ESRD PPS Update for 2020

The final 2020 ESRD PPS base rate is \$239.33, compared with the final 2019 rate of \$235.27. As shown in the table below, this increase of 1.7 percent reflects application of an update factor of 1.7 percent (reflecting an estimated increase of 2.0 percent in the ESRD bundled input price index ("market basket") and an estimated multifactor productivity (MFP) adjustment of -0.3 percent) and a wage index budget neutrality adjustment of 1.000244. The rate is calculated as $\$235.27 \times 1.017 \times 1.000244 = \239.33 .

Final 2020 ESRD PPS Base Rate Update	
Base Rate Update Components	% effect on base rate
Market basket	+2.0
Multifactor productivity adjustment	-0.3
Subtotal: update factor	+1.7
Wage index budget neutrality adjustment (1.000244)	1.000244
Total change in base rate	+1.7
Note: The market basket and productivity adjustments are based on IHS Global Insight's Q3 2019 forecast for 2020 with historical data through Q2 of 2019.	

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 final 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 makes 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 are updated using 2018 claims data. The 2020 outlier policy amounts and those for 2019 are shown in Table 2 of the final rule, reproduced below. CMS notes that beginning in 2020 the total expenditure amount includes payments made for calcimimetics under the TDAPA policy (\$21.03 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 10.4 percent for adult patients and 11.4 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 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)		Final 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	\$30.95	\$37.33
Adjustments:				
Standardization for outlier services	1.0503	0.9779	1.0655	0.9781
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$35.18	\$38.51	\$32.32	\$35.78
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$57.14	\$65.11	\$41.04	\$48.33
Patient-months qualifying for outlier payment	7.2%	8.2%	11.35%	10.38%

Commenters sought clarification from CMS on why and how calcimimetic payments are incorporated into the outlier methodology and calculations. In response, CMS clarifies that it did not propose any changes to the outlier policy methodology, nor did it make any changes to the methodology when calculating the fixed-dollar loss amounts. It notes that including the TDAPA expenditures in this outlier calculation results in a larger than expected outlier payment compared to a scenario in which these TDAPA expenditures are not included. CMS states, however, that the TDAPA is part of the ESRD PPS, and expenditures for the TDAPA are ESRD PPS expenditures. CMS finalizes its updated outlier thresholds (as shown in Table 2 above).

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 final updated AKI dialysis payment rate is set to equal the 2020 ESRD PPS base rate of \$239.33, 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 ESRD QIP measures for PYs 2020 to 2023 appears at the end of this section of the summary.

B. Codification of Certain ESRD QIP Requirements

CMS finalizes its proposal, with one technical change, to modify the regulatory text at §413.178 to include certain previously adopted policies, and to incorporate a new policy. 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 are also codified, including a 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.

CMS incorporates one technical change at §413.178(d)(5) that clarifies that it will not consider an ECE request unless the facility making the request has complied with §413.178(d)(4), which requires the requesting facility to provide certain information, such as contact information, date the facility will start submitting data, and evidence on the impact of the extraordinary circumstance, among other required information.

C. Requirements for the PY 2022 ESRD QIP

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

Table 4 in the final 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. CMS notes that it finalized its proposal to convert the standardized transfusion rate (STrR) measure from a clinical measure to a reporting measure and thus there are no performance standards in the final rule for that measure.

2. NHSN Dialysis Event Scoring Change

CMS finalizes its proposal 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 will receive credit for scoring purposes based on the percentage of eligible months they successfully report data. The policy change 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 revised scoring of this measure. (It combines information from final rule Tables 7 and 8.)

Current and Revised Reporting Requirements for the NHSN Dialysis Event Reporting Measure		
Current Policy = Number of Reporting Months	Revised 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 in the past, CMS evaluated the STrR measure, and as a result proposed 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 (i) retained STrR as a performance measure but changed the scoring to ensure that no hospital received payment reduction due to this measure or (ii) used the earlier version of the measure.

After consideration of commenter’s concerns, including responses from the proposed rule, CMS finalizes its proposal to convert the STrR clinical measure to a reporting measure and to update the scoring methodology, as proposed. Under this policy, facilities that meet previously finalized minimum data and eligibility requirements will 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 will 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 also states that it will seek NQF review of the STrR clinical measure and have submitted the measure to NQF for review, and that any information gleaned will be used to support any future policies.

4. Clarifications Regarding Medication Reconciliation (MedRec) Reporting Measure

CMS does not finalize its proposal to change 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. Commenters argued that “patient-months” is more consistent with the NQF’s definition, and disagreed with CMS’s assertion that using “facility months” is more appropriate for a reporting measure. CMS was persuaded by commenters’ concerns.

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

Table 9 in the final rule displays the eligibility requirements for scoring the ESRD QIP measures and reflects the change in the NHSN Dialysis Event reporting measure. Specifically, no CCN open date requirement will apply for this measure.

6. Payment Reductions

CMS estimates that based on the finalized performance standards, a facility would have to meet or exceed a TPS of 55 for PY 2022 to avoid a payment reduction. The estimates are based on data for 2018. The estimated scale of reductions is shown in Table 11 of the final rule, reproduced here.

TABLE 11 –FINALIZED PAYMENT REDUCTION SCALE FOR PY 2022 BASED ON THE MOST RECENTLY AVAILABLE DATA	
Total Performance Score	Reduction
100 – 54	0.0%
53 – 44	0.5%
43 – 34	1.0%
33 – 24	1.5%
23 or lower	2.0%

7. Data Validation

CMS finalizes its proposals 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 added to the ESRD QIP for PY 2023. CMS finalizes its proposals to establish the performance and baseline period. Specifically, CMS establishes 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 2020 as the baseline period for purposes of calculating the improvement threshold. Beginning with PY 2024, CMS adopts a performance and baseline period for each year that is automatically advanced 1 year 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 were implemented to the scoring of measures or in measure weights.

Summary Table: ESRD QIP Measure Sets			
	PY2021	PY2022	PY 2023
Clinical Care Measure Domain*			
Kt/V Dialysis Adequacy Comprehensive measure	X	X	X
Vascular Access Type Measure Topic:			
Maximizing Placement of AV Fistula	X	X	X
Minimizing Use of Catheters as Chronic Dialysis Access	X	X	X
Hypercalcemia	X	X	X
Standardized Transfusion Ratio (STrR)	X	X***	X***
Ultrafiltration Rate reporting measure	X**	X	X
Patient & Family Engagement Measure Domain			
ICH CAHPS measure	X	X	X
Care Coordination Measure Domain			
Standardized Readmission Ratio (SRR)	X	X	X
Standardized Hospitalization Ratio (SHR)	X	X	X
Clinical Depression Screening and Follow-up	X**	X	X
Safety Domain			
NHSN Bloodstream Infection (BSI)	X	X	X
NHSN Dialysis Event reporting measure	X	X	X
Percentage of Patients Waitlisted		X	X
Medication Reconciliation reporting measure		X	X
*This table is organized around the ESRD QIP domains as finalized for PY 2021. The two domains for PY 2021 are the clinical measure domain (with two subdomains: patient and family engagement/care coordination and clinical care), and the safety measure domain. Beginning in PY 2021 the reporting domain will have no measures and will be removed.			
**Measure moved from reporting domain.			
*** CMS converted the STrR clinical measure to a reporting measure for PY 2022.			

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,⁷ 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).⁸ To the extent CMS determines that a comparable item exists, the item will 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;

⁷ Section 1842(b) of the Act and its regulation at 42 CFR 405.502.

⁸ The current gap-filling methodology (used by contractors to set DMEPOS fee schedule amounts) can be found at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100-04).

(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.

CMS finalizes its proposal to establish five main categories of components or attributes to determine if the new DMEPOS item is comparable to older existing DMEPOS item(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 12 of the final 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 12: 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 its comparability framework will 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 codifies this comparability requirement at §414.238(b).

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

CMS finalizes its proposal, without modification, to codify the continuity of pricing when HCPCS codes are divided or combined at §414.236.

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.

This approach maps 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.

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

CMS finalizes its proposal to codify the use of supplier and commercial price lists and its gap-filling approach at §414.238(c). 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 DMEPOS 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 will 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.⁹

CMS did not finalize its proposal to use technology assessments to price new DMEPOS items at §414.112(d) and §414.238(d). As discussed below, CMS states that it wants additional information for consideration of this issue in the future.

⁹Covered item update factors are specified in section 1834(a)(14) of the Act.

CMS had proposed that technology assessments could 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 noted that it could be necessary for it to use a separate technology assessment contractor to conduct these assessments.

2. Adjustment of Fees Over Time

CMS finalizes its proposal, without modification, that if within 5 years of establishing fee schedule amounts using supplier or commercial prices, the price of the item decreases by less than 15 percent, a one-time adjustment to the fee schedule amount is made using the new price. The new prices for such items will 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 (the agency's inherent reasonableness authority). 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.¹⁰

This provision is codified at §414.112.

E. Summary of Public Comments and Responses on Establishing Payment Amounts for New DMEPOS Items and Services

CMS received over 30 comments from suppliers, manufacturers, and associations or organizations representing suppliers and manufacturers on its comparable item analysis framework, gap filling methodology, continuity of pricing, sources of pricing data, and its one-time adjustment for gap-filled payment amounts.

Comparable Item Analysis Framework

Commenters expressed reservations and provided additional feedback to CMS on its proposed framework to determine if an item in a new HCPCS code is comparable to items in an existing HCPCS code. Suggestions for additional criteria include, among others, service intensity of the item, value to patient care, digital technologies, and clinical outcomes. Some commenters

¹⁰ 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.

expressed concern whether CMS and/or contractors had the required expertise to make these determinations, and believed that manufacturers, stakeholders, and beneficiaries should have a say in final pricing. CMS states in its response that it believes that the five categories capture the main categories that should be considered and that CMS already considers many of the suggestions provided in its evaluation of an item.

Gap-filling Methodology

Many commenters recognized that most of the gap-filling methodology proposal had been available in program guidance and implemented, but did not support adding regulations which codify the program guidance. Others expressed concern that the methodology is not a reasonable methodology given that it uses this approach to address more than a 30-year span between the base year of 1986 to 1987 and 2020. In response, CMS believes that it is important for transparency to have regulations in place to address the pricing of new DMEPOS to create a firm basis for establishing fee schedule amounts in accordance with the statute. With respect to the more than 30-year span between the fee schedule base year of 1986 and 1987 and items furnished in 2020, CMS notes that the statute (sections 1834(a) and (h) of the Act) specifically require that fee schedule amounts for DMEPOS items be based on average reasonable charges from 1986 and 1987.

Continuity of Pricing

Commenters were generally supportive of CMS' proposal for continuity of pricing when existing HCPCS codes are divided or combined. One commenter from a trade organization stated that its use must be reserved only for those instances where there is direct relationship between the former HCPCS code(s) and the new HCPCS code(s). Otherwise, the resulting fee schedule calculations could be either inadequate or excessive. Other commenters expressed concern that the proposed continuity of pricing can lock in historical levels of reimbursement when establishing fee schedule amounts for new items. CMS agrees that the use of pricing continuity when establishing new fees must only be reserved for those instances where such a direct relationship exists. It provides several examples within its response. For example, if the code for a cane is divided into codes for cane handle, cane staff, and cane tip, CMS states there is a direct relationship between the three new codes for the cane handle, cane staff, and cane tip and the old code for cane since the cane handle, cane staff, and cane tip were all three previously combined in the one code for the cane. CMS does not agree with commenters that its proposal locks-in historical levels of reimbursement that are not appropriate. To the extent the technology innovations results in a situation where the item has risen to the point where the fee schedule amounts are grossly deficient, CMS states it could use its statutory inherent reasonableness authority (at 1842(b)(8) and (9)) to establish a different fee schedule amount.

Source of Pricing Data

Some commenters disagreed with CMS' concern that manufacturer suggested retail prices (MSRPs) are inflated and without merit with one commenter going as far as to suggest that CMS rescind any contractor instruction to discontinue utilizing MSRPs in the gap-filling process. Many commenters expressed concern about the use of technology assessments for use in establishing fee schedule amounts for new DMEPOS items. They believed the proposal lacked

sufficient detail on how the technology assessment process would work and what impact it might have on payment. Commenters also questioned the potential expertise of a third-party to make such a determination. In response to the use of MSRPs, CMS emphatically states that it does not believe that MSRPs represent a valid and reliable proxy for supplier charge or market prices for furnishing DMEPOS items, and thus, will not use them to set fee schedule rates. CMS appreciates the feedback about the use of technology assessments, and decides not to finalize this proposal in order to consider additional information for potential use in future rulemaking.

One-time Adjustment for Gap-filled Payment Amounts

Most commenters opposed CMS' proposal to apply a one-time adjustment to fee schedule amounts if the price of the item decreases by less than 15 percent within 5 years of establishing the initial fee schedule amount. Commenters, for example, pointed out that this approach is not balanced, and that the same price decrease policy should apply when prices increase. CMS disagrees and believes that it is appropriate to make a one-time adjustment to the fee schedule amounts as long as the same pricing sources are used and the new prices are not lower than the initial prices by 15 percent or more. CMS does not believe a similar adjustment is necessary to account for increases as the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time.

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

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.¹¹ 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 with its requirements; limit waste, fraud, and abuse; and ensure that beneficiaries can access DMEPOS items to meet their specific needs.

CMS believes that, for payment purposes, the explicit identification of information to be included in a written order/prescription promotes uniformity among practitioners, precision in rendering intended items, and 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 that its final rule streamlines the existing requirements and reduces 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.

¹¹ See <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSupplementalImproperPaymentData.pdf>.

B. Update of Definitions Related to DMEPOS Benefit Requirements

CMS finalizes the definitions, as proposed, in §410.38(c) except for the modification in the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery definition. In response to comments, CMS agreed that a longer notification may be appropriate in some cases, and thus changed the wording from a fixed 60-day period to a list that is effective “no less than 60 days” following its publication. All the other definitions were finalized: physician, treating practitioner, DMEPOS supplier, written order/prescription, face-to-face encounter, power mobility device (PMD), and Master List. These definitions, as finalized, are detailed in the table below.

Term	Definition
Physician §410.38(c)(1)	Physician has the same meaning as in section 1861(r)(1) of the Act.
Treating practitioner §410.38(c)(2)	Physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are 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 items through the mail.
Written order/prescription §410.38(c)(4)	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)	DMEPOS items that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in §414.234 of this chapter. 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 List §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. The list of items is published in the Federal Register and posted on the CMS website. <i>The list is effective no less than 60 days following its publication.</i> When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

C. Revisions to the Master List

1. Creating the Master List

CMS’ finalizes its proposal to develop one master list of items potentially subject to prior authorization and/or face-to-face encounter and written order prior to delivery. This combines

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.

This list of items will be 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 also finalizes the following inclusion criteria for the Master List at §414.234(b)(1):

- (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,¹² 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 CERT Medicare Fee-for-Service 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 will 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
 - An amount 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.

Illustrative examples of how the criteria will be applied are provided on pages 356-357 of the display copy.

CMS explains its rationale with respect to the 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, the \$500/\$50 rental

¹² These amounts are adjusted annually for inflation using CPI-U and reduced by a 10-year moving average of changes in annual economy wide private nonfarm business multifactor productivity (MFP).

thresholds are based on its 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 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, and 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 will avoid capturing items with very low payments or very few claims.

Table 13 in the final rule details the 413 items on the 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.

Several commenters were supportive of CMS' proposal to harmonize the three lists through the creation of one Master List, but they expressed concern that the extended length of the list was indicative of CMS' intent to use prior authorization more frequently, and worried about potential delays in patient care. CMS notes in reply that the longer Master List grants the ability to impose conditions of payment to mitigate emerging program integrity vulnerabilities, but it is not indicative of any known plans to widely increase prior authorization. Items will only move to the Required Prior Authorization List after consideration of the regulatory factors—including item utilization, cost, and other analyses – and will be subject to a minimum 60-day notice. Other commenters requested greater transparency in identifying how an item was selected for inclusion. CMS states that identifying the underlying reasons for inclusion on a current list is not feasible, due to the varying inclusion criteria, the potential for items to meet multiple factors, and the ever evolving nature of the list.

2. Notice and Maintenance of the Master List

CMS finalizes its proposal at §414.234(b)(2) that the Master List will 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 will be maintained on the Master List from the date of the most recent publication.

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

CMS did not receive any comments on this issue, and is finalizing this section, as proposed.

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.¹³ The Secretary, as specified in statute, can also require a practitioner to 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 finalizes its proposal 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 will include statutorily identified items, as well as any other items posing potential vulnerability to the Trust Fund, as identified via the Master List inclusion criteria.

CMS also finalizes its proposal 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 finalizes 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 finalizes its proposal 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 finalizes its proposal 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 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.

¹³ Section 1834(a)(1)(E)(iv) of the Act.

- CMS finalizes its proposal 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 will create unnecessary confusion. Therefore, a face-to-face encounter will 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.¹⁴

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 final rule will create any new burdens for the medical review process.

Commenters urged CMS to ensure that the burden of providing face-to-face encounter documentation falls upon the beneficiary's treating practitioner and not community pharmacists who may dispense items of durable medical equipment and supplies. Other commenters urged CMS to permit remote patient monitoring using digitally enabled equipment to satisfy the requirement for face-to-face encounters. In response, CMS agrees that the beneficiaries' practitioner is charged with creating the documentation of the face-to-face encounter, but CMS notes that it did not propose to amend its longstanding practice whereby additional documentation requests are generally sent to the entity requesting Medicare payment. CMS notes that removing the face-to-face requirement for digitally enhanced items is not within its regulatory purview, but the statute does allow for the face-to-face encounter to be conducted through the use of telehealth in accordance with section 1834(m) of the Act.

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

CMS revises the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery List to say "The list of items is published in the Federal Register and posted on the CMS website. This list is effective no less than 60 days following its publication." This provision is codified at §410.38(c)(8). Any DMEPOS item included on this list will 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 will be denied if the condition of payment is not met. CMS finalizes its proposal 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 will provide stakeholder notification of the suspension on the CMS website.

¹⁴ 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.

Commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. CMS agrees that in some cases, a longer notification timeframe may be more appropriate. Thus, CMS changes the timeframe from a 60-day public notice timeframe to one that was no less than 60 days.

D. Required Prior Authorization List

1. Creation and Application of the Required Prior Authorization List

CMS finalizes the creation and application process of the Required Prior Authorization List, as proposed.

CMS finalizes its proposal 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.¹⁵

CMS finalizes a policy that is similar to its current requirements at §§414.234(c)(1)(ii) whereby it may select and implement prior authorization of an item(s) nationally or in collaboration with the DME MACs locally. It revises this section to state that all suppliers (either nationally or within a contractor jurisdiction) will 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 finalizes its proposal to consider certain factors 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 makes several other clarifications in this section on how the Required Prior Authorization List is applied.

- CMS clarifies that the prior authorization program will 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.

¹⁵ 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 also states that the items currently subject to prior authorization will be grandfathered into the prior authorization program, until the implementation of the first Required Prior Authorization List (which will be published subsequent to the rule).
- CMS retains the documentation requirements for submitting prior authorization requests at §414.234(d), and makes further technical refinements at §410.38 and §414.234(e).
- CMS maintains 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 will publish a notice in the Federal Register, post notification of the suspension on the CMS website, and include the date of suspension.

Some commenters suggested that CMS reserve prior authorization for aberrant billers who participate in standard data collection or consider compliance incentives to waive prior authorization and face-to-face requirements for providers that meet such standards. CMS notes that its prior authorization program is item-based and targets over-utilized items billed by applicable standards. CMS states that in the future it may elect to exempt suppliers demonstrating compliance from prior authorization requirements. Commenters expressed a desire for supplies to be given prior authorization at the outset of care with affirmative decisions being extended across multiple Medicare payments, in order to prevent undue burden and potential interruptions in care. CMS states in response that claims for subsequent and serial rental items will be covered under the initial prior authorization decision for time periods stated in NCDs, LCDs, statutes, regulations, and CMS-issued manuals and publications. In response to a comment that prior authorization should be extended to all related options, supplies, and accessories, CMS notes that while it is implementing changes to voluntarily include accessories, reviewers are limited in their review to the documentation submitted with the request.

2. 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 maintaining its current process. In addition, all other prior authorization processes described in §414.234 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 finalizes its proposal, with modifications, at §410.38(d)(1) to adopt one set of required written order/prescription elements for orders/prescriptions for all DMEPOS items. Several commenters suggested refinements to the language to be used for the standardized order/prescription elements. Commenters provided feedback to CMS that the term “date” is not sufficiently specific for reviewers and billing entities. CMS agrees and changes the term “date” to “order date”. Another commenter suggested that CMS update the required elements of the standardized order/prescription to specify that “Practitioner Name or National Provider Identifier (NPI)” refers to the *treating* practitioner. CMS agrees and updates the term to clarify that the practitioner signing the document and including his or her name be the treating practitioner

CMS believes that a standardized order requirement is appropriate and will 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) will continue to vary for DMEPOS items. CMS finalizes 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 finalizes at §410.38(d)(1)(i), with the modification described above, 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.
- Order Date.
- Treating Practitioner Name or National Provider Identifier.
- Treating 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 finalizes at §410.38(d)(1) that 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. Thus, CMS deletes the coverage requirements currently outlined in §410.38(d), (e) and (f), and replaces sections §410.38(d) and (e), with its 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.¹⁶ CMS proposed to revise the existing DMEPOS Competitive Bidding Program (CBP)

¹⁶Based on the payment rules that are set forth in section 1847 of the Act and 42 CFR Part 414, Subpart F.

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 proposed to revise §414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Amendments

In §414.422(d) CMS finalizes the following proposed amendments without change:

- Adds the acronym “CHOW” after the title of the paragraph and use the acronym throughout the section instead of using “change of ownership”.
- Removes 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.
- Removes the distinction of a “new entity” from paragraph (d)(2)(ii) in its entirety, and retains the successor entity requirements in paragraph (d)(2)(i) with changes. CMS finalizes its proposal 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. It changes 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. The successor entity must submit a novation agreement that states that it assumes all obligations under the contract.
- Removes the phrase “new qualified” before “entity” and replaces 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.
- Revises 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. Removes the reference to “new qualified” before “entity” and replaces 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 removes the phrase “new qualified owner who” in paragraph (d)(4)(i) and replaces it with “successor entity that” to align with the language used throughout §414.422(d).
- Revises 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 received comments in support of its CHOW proposals to remove the 60-day requirement and to require submission of the novation agreement within 10 days of the effective date of the CHOW. CMS did not receive comments on any other proposals for CHOW.

VIII. Requests for Information

This section of the final rule describes and summarizes comments received from 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 final 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 sought 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 were 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 were 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; and
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.

CMS received extensive comments on these issues from about 9 stakeholders and an additional 35 comments that indirectly addressed the RFI for data collection. CMS provides a short synopsis of the comments in the final rule, but provides a more detailed summary of comments received on its website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html. CMS does not respond to comments, but states that it will consider them for future rulemaking. The summary provides a brief synopsis of these comments in the table below.

Topic	Comments
Refinement to the components of composite rate costs	Some expressed the view that the use of the composite rate component to price the cost of dialysis treatment was outmoded and counter to the objective of the bundled system.

Topic	Comments
	Several commenters objected to the use of the two-equation payment model that uses facility-level regression analysis of facility cost reports to determine the cost per treatment.
Little variation found in charges	Commenters claimed charges for individual treatments were hard, if not impossible, to capture and doing so would cause undue burden for facilities.
Patient-level factors contributing to higher costs	<p>General agreement that adjustments for the use of isolation rooms for patients with active HBV infection and for patients in their initial months of dialysis treatment were warranted.</p> <p>CMS also received comments on the current case-mix adjusters, with many comments expressing concern that the methods used to derive them were flawed and not empirically based.</p>
Facility-level adjusters and suggested changes to cost reports	Commenters agreed that the Low Volume Payment Adjuster (LVPA) and rural adjustments needed refinement. There was also agreement that the ESRD network fees and all bad debt be added to cost reports as revenue reduction, and general agreement that cost reports needed to be revised to improve accuracy and consistency of reporting.
Reporting of composite rate items on the consolidated billing list	Commenters expressed that the lack of HCPCS codes for oral drugs prevents their reporting on claims.
Billing problems and Medicare Advantage	Commenters stated that Medicare Advantage and some other secondary payers rejected claims if they included certain items, including oral medications which did not have a HCPCS code.
Special considerations: pediatric dialysis facilities	Commenters were supportive of a pediatric case-mix adjuster and urged significant revisions to cost reports to more accurately capture the costs of treating this special population.

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 invited 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 were enumerated in the proposed rule.

CMS received comments from six stakeholders on this issue. Several commenters expressed concern about the data lag issues that they believe undermine the accuracy of the ESRD PPS wage indices. While they were generally supportive of the methodology used to determine the wage indices and the application of the wage index floor, they stated the wage index calculation data did not adequately capture in a timely manner higher wages due to state and municipality minimum wage increases and overall economic growth. CMS also received comments that it should recognize the higher labor costs borne by small and independent facilities and facilities located in rural regions.

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

Section 50414 of the BBA of 2018 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.¹⁷

3. Comment Solicitation

Because section 1847(b)(10)(A) of the Act now requires the use of “multiple sources of data,” CMS requested 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 requested comments on other potential sources of data because the word “multiple” in the phrase “multiple

¹⁷These 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>.

sources of data” could mean that it should use more than one source of data, and that the OIG is one source of data. In particular, CMS sought 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.

4. Summary of Public Comments and Response

CMS received 6 comments from suppliers, industry representative groups, and others in response to this solicitation. None of the comments received included data, or readily available sources of data that could be used to fulfill the statutory requirements. Commenters noted that any survey of current Medicare Part B claims for diabetic testing strips would not accurately represent the overall market because reduced payment rates have caused suppliers to offer beneficiaries fewer product options. CMS stated that it will take into account comments it received as it contemplates future policies.

IX. Regulatory Impact Analysis

A. Impact of Changes in ESRD PPS Payments

Medicare program payments for ESRD facilities in 2020 are estimated to total \$10.3 billion, reflecting an expected 1.4 percent increase in fee-for-service Medicare dialysis beneficiary enrollment.

Table 23 of the final rule provides the accounting statement showing estimated transfers of costs and savings resulting from the policies. Medicare payments to ESRD facilities for both the ESRD PPS and the payments for AKI would increase by \$170 million in 2020; beneficiary coinsurance payments will increase by \$40 million, for a total of \$210 million. This reflects a \$220 million increase from the payment rate update, a \$50 million increase due to the updates to the outlier threshold amounts, and a \$60 million decrease due to the change in the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. This total excludes the effect of changes in the TDAPA eligibility criteria, conditioning the TDAPA on ASP data submission, or providing a transitional add-on payment for innovative 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 14 in the final 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 September 18, 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 Finalized Changes in 2020 Payment to ESRD Facilities (from Table 14)

Facility Type	Number of Facilities	Number of Treatments (millions)	Effect of 2020 Changes in Outlier Policy	Effect of 2020 Wage Index	Effect of 2020 Rate Update	Effect of 2020 Changes to TDAPA*	Total Effect of 2020 Final Changes
All Facilities	7,442	45.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Type							
Freestanding	7,050	43.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Hospital-based	392	2.0	0.8%	0.0%	1.7%	-0.3%	2.1%
Ownership							
Large dialysis organization	5,698	35.1	0.4%	0.0%	1.7%	-0.4%	1.6%
Regional chain	930	5.7	0.4%	0.1%	1.7%	-0.5%	1.7%
Independent	502	2.9	0.4%	0.0%	1.7%	-0.4%	1.7%
Hospital-based	304	1.5	0.8%	0.0%	1.7%	-0.3%	2.2%
Facility Size (Treatments)							
Less than 4,000	1,385	2.1	0.4%	0.0%	1.7%	-0.3%	1.8%
4,000 to 9,999	2,804	12.3	0.4%	0.0%	1.7%	-0.4%	1.7%
10,000 or more	3,219	30.7	0.4%	0.0%	1.7%	-0.4%	1.6%
*Impact of policy to reduce the TDAPA for calcimimetics from ASP+6 to ASP+0. Impact of other changes to TDAPA cannot be determined.							

Payments to ESRD facilities for dialysis treatments provided to patients with AKI are estimated to total \$40 million in 2020. Table 15 in the final 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 247,200 treatments will be provided to beneficiaries across 4,707 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 2022

For PY 2022, CMS estimates that the payment reductions from not receiving the full update under the ESRD QIP program under the final rule will total \$18.2 million across the 1,871 facilities (about 26.1 percent of the 7,164 ESRD facilities with data to calculate a TPS) that it estimates would receive a reduction. The same total is estimated for PY 2023. The tables below, reproduced from the final 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 19 facilities are estimated to receive the maximum 2 percent penalty.

Overall, CMS estimates the payment reductions will represent about 0.17 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 \$211 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 policy changes.

Table 16: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions		
Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	5,293	73.88%
0.5%	1,339	18.69%
1.0%	432	6.03%
1.5%	81	1.13%
2.0%	19	0.27%
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 Final Rule Table 18)			
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	7,164	1,871	-0.17%
Facility Type:			
Freestanding	6,807	1,764	-0.17%
Hospital-based	357	107	-0.23%
Ownership Type			
Large Dialysis	5,487	1,286	-0.15%
Regional Chain	897	264	-0.19%
Independent	490	227	-0.36%
Hospital based (non-chain)	276	87	-0.25%
Facility Size (Treatments)			
Less than 4,000	1,117	230	-0.15%
4,000 to 9,999	2,620	510	-0.12%
10,000 or more	3,149	1,019	-0.20%

C. DMEPOS

The final rule codifies its gap-filling methodology for new items and services. The fiscal impact cannot be determined due to the uniqueness of new items and their costs. In addition, this rule streamlines the requirements for ordering DMEPOS items and the process to identify certain DMEPOS items for a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these provisions also could not be estimated as this rule only identifies items that are potentially subject to these conditions of payment.