Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After Transitional Drug Add-On Payment Adjustment (TDAPA)

Background on Transitional Drug Add-on Payment Adjustment (TDAPA)

Section 217(c) of the Protecting Access to Medicare Act of 2014 required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. In the CY 2019 ESRD PPS final rule, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ‘‘parent NDA’’ is a Type 3, 5, 7, or 8, effective January 1, 2020.

Current Payment for New Renal Dialysis Drugs and Biological Products After TDAPA Period Ends

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the base rate will not be modified for such products. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

Suggestions for Possible Methodologies for an Add-on Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products Within an Existing Functional Category

Interested parties have noted several concerns with TDAPA since the CY 2019 rule. A large number of interested parties have noted that the payment cliff that occurs after the TDAPA period ends makes it difficult to sustain the expense of these therapies, and thus could negatively affect

beneficiary access to care. They have also cautioned that payment concerns adversely impact the uptake of these therapies, as providers may be reluctant to furnish certain services which may become unavailable in the future. Lastly, commenters have also called for rate-setting adjustments after the end of the TDAPA period for drugs and biological products that are in an existing functional category. One coalition of dialysis organizations has expressed that the current base rate is not adequate to support the addition of new drugs and biological products to

existing functional categories, and that an adjustment to the base rate would be needed. They have also cautioned that without a base rate adjustment, the outlier pool would no longer serve its desired purpose. Other interested parties also noted that lack of additional dollars to the base rate could result in lack of access to those most in need of such treatment.

. To date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. There have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result CMS does not yet have data on other drugs or biological products in order to evaluate the specific risks and access challenges that interested parties have raised. Furthermore, CMS has stated in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and there will be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. A central objective

of the ESRD PPS and of prospective payment systems in general is for facilities to be efficient in their resource use.

In the CY 2023 ESRD PPS proposed rule (87 FR 38522), we explained that we are considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends, to address the concerns that interested parties have raised over the years. We noted that Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. We sought information from the public about issues of payment after the TDAPA and potential approaches within our authority to address the concerns that interested parties have raised in the past.

In the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we described four potential options for calculating an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends in order to align resource use with payment. We solicited comment on whether the options presented would be sufficient, which option would be most appropriate, and whether we should consider other options as well. We noted that the methods presented differ in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. We also noted that under these potential

options, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

- Option 1: Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products.
- Option 2: Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA.
- Option 3: Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS.
- Option 4: Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA.

As noted above, we sought information from the public regarding ways to potentially address issues of payment after the end of the TDAPA, to address the concerns that interested parties have raised in the past. We asked for feedback on the potential

approaches above, and sought to solicit information that will better inform future modifications to the methodology. More specifically, the RFI asked if an add on payment adjustment was necessary and why, and what criteria should constitute eligibility for renal dialysis drugs or biologicals to be included in the calculation of this add on payment. CMS also asked interested parties which of the four options above would be the most appropriate, and if the commenters suggested any methodologic changes or if there are other methodologies CMS should consider.

Public Comments Received in Response to the CY 2023 ESRD PPS Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After TDAPA Period Ends

In the CY2023 ESRD PPD RFI responses for calculation of an add-on payment adjustment, all but one interested party applauded CMS for their consideration and responsiveness to long held concerns, and stated that an add-on payment after the TDAPA period ends is necessary, in order to encourage innovation in kidney care, and to protect beneficiary access to innovative products. To further support the point that the add-on is needed, commenters noted their skepticism in the effectiveness of the PPS' current mechanisms of accounting for the costs of these new drugs. One professional organization and one large dialysis organization cited a Moran Company study that suggests the existing funds designated to each functional category would not support incorporating even modestly priced new drugs or biological products into the base rate. Similarly, commenters did not believe that the outlier adjustment nor the market basket updates could adequately account for these costs. Several organizations noted that if drugs and biological products with significant costs were adopted under the outlier policy, the threshold to qualify would increase dramatically, thus adversely

affecting access to products traditionally covered under this adjustment. Commenters expressed that this may also present a threat to health equity, as most beneficiaries that rely on the outlier adjustment are Black and Brown, and already experience health inequities. The market basket is seen as equally ineffectual, as several commenters cited a Moran study suggesting that the drug proxies historically used in updating the base rate have not adequately accounted for the costs of non-ESA drugs under existing functional categories. Generally, commenters concurred with an add-on payment in place of base rate modification, as base rate modifications would call for money to be removed from the rest of the bundle, and these new, and high cost drugs may be used by a small percentage of beneficiaries, thus, spreading the payment across the bundle would not support drug utilization. Many commenters suggested that the add-on payment adjustment for renal dialysis drugs and biological products should not be budget neutral and should include new money to support long-term adoption of innovative drugs and biological products.

In contrast, the Medicare Payment Advisory Commission (MedPAC) expressed strong opposition to the introduction of an add-on payment adjustment, based on its belief that an add-on payment would threaten the integrity of the bundle. MedPAC noted that bundled payments encourage clinicians to be judicious with the care they furnish, and that including all items and services with similar functions in the bundle reduces overutilization incentives, and pressures manufacturers to lower prices. MedPAC also noted that they believe the current policy that mandates TDAPA payment for drugs already in an existing functional category is duplicative, as the cost of providing these types of drugs already in a functional category is reflected in the base rate. Further, MedPAC identified that the ESRD PPS bundle may have to be rebased to recognize new products, and noted that the its annual payment adequacy updates can inform CMS of mis-alignments in payment. In Chapter 6 of their March 2022 report

(https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v2_SEC.pdf), MedPAC noted that they anticipate that most dialysis payment adequacy indicators will remain positive. In addition, the report states that their analysis of access indicators shows that beneficiaries' access to care remains favorable. These indicators include the capacity of providers to meet beneficiary demand, changes in the volume of services, and the marginal profitability of Medicare dialysis beneficiaries under the PPS. MedPAC's recommendation for CY 2023 is that Congress should update the 2022 Medicare ESRD PPS base rate by the amount determined under current law. Also noted in MedPAC's RFI response was the fact that CMS did not solicit feedback on various other parameters of the add-on adjustment, such as the length of the add – on payment, and whether it would be updated annually. Finally, MedPAC suggested that CMS could consider a methodology closer to that of the ESRD PPS Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES); where CMS pays a reduced percentage of the estimated incremental cost of a new item or service as a risk-sharing mechanism with dialysis providers, and to provide disincentive for dramatic increases in drug prices.

In response to the request for information about what criteria CMS should establish to determine which renal dialysis drugs or biological products should be included in the calculation for a potential add-on payment adjustment after TDAPA, some groups noted that all new drugs and biological products that fall into an existing functional category should be eligible, while others suggested that all new drugs and biological products that are renal dialysis services, regardless of functional category status, should be eligible. Commenters in support of the latter suggestion made that case that paying for all new renal dialysis drugs and biological products using an add-on payment would better ensure patient access to these renal dialysis services. For

the small number of drugs and biological products that would fall outside of current functional categories, commenters stated that making an add-on payment would better support patients' access to these renal dialysis services than would the current policy of adding money to the base rate. Commenters largely agreed that the reconciliation methodology should compare the drug/biological on TDAPA with the subset of formerly separately billable drugs that clinicians would consider relevant when furnishing care. Most interested parties suggested CMS use drugs with the same FDA clinical indication to offset the adjustment, in the interest of transparency and objectivity. However, MedPAC and one pharmaceutical company noted that they do not believe that FDA determination and functional categories should be the basis of TDAPA eligibility, as CMS should make these determinations based on the specific needs of the Medicare population. Both of these groups also called for a methodology that would ensure new money is added to the bundle only for products that offer significant clinical improvements for patients.

With regard to the four potential methodologies presented in the RFI, Option 1 did not receive positive comments or support from any interested party, though commenters cited several concerns. Chief among concerns that interested parties raised was that this methodology assumes that there is a relationship between the drug or biological product that was paid for using the TDAPA and all other formerly separately billable drugs and biological products, where according to commenters no such relationship exists. Several professional organizations likened this to CMS' construction of the TPNIES offset methodology, where it was deemed inappropriate to reconcile expenditures on home dialysis machines with anything other than home dialysis machines. One large dialysis organization also suggested that Option 1 had the potential to reduce the value of the add-on payment below the amount sufficient for providers to reliably provide the drug, and would require the ESRD PPS to be recalibrated after each time a

TDAPA period expires. One coalition of dialysis organizations noted that changes in drug utilization can occur during the TDAPA period due to exogenous factors, such as supply chain shortages or the effects of a PHE, and that Option 1 could confound these external circumstances with a direct response to the presence of the TDAPA drug.

In contrast, interested parties expressed more support for Option 2, as it creates a data standard by which to offset the adjustment. However, some interested parties called upon CMS to more clearly define the phrases "empirically attributed" and "statistically associated with", or they suggest CMS adopt clear data terminologies agreed upon by expert data analysts and require a statistically significant relationship between utilization of the renal dialysis drug or biological product under TDAPA and those other formerly separately billable drugs with the same FDA approved clinical indications. One non-profit dialysis association maintained that utilization/expenditures for drugs in a functional category may change due simply to clinical or market forces unrelated to TDAPA, and suggest that Option 2 would not control for this occurrence. They also suggest that the language, as written, implies that an entire functional category could be the basis for comparison of the TDAPA product, which, in the commenter's view, would be inappropriate, as products included in the same functional category may have very different clinical indications. Most interested parties suggest that, though it is a marginal improvement compared to Option 1, CMS not pursue this methodology, on the basis that utilization trends between the drug coming off of TDAPA and its comparator drugs may be coincidentally rather than causally related, and that clinical practices must serve as the basis of the policy regarding an add-on payment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends.

Option 3 received explicit support among commenters. They greatly appreciated that CMS was proposing to include clinical standards in conjunction with data standards in determining the TDAPA add on offset amount, but objected to the use of "end action effect" as this language is not an objective clinical standard, introduces uncertainty, and may establish the comparator group as an entire functional category. Similarly, interested parties called for clarity in use of the phrase "data – driven", as this not an objective statistical standard. Most stakeholder groups argued that drugs with the same FDA clinical indications should be the basis of comparison, while others (MedPAC and one pharmaceutical organization) argued that CMS is better positioned to make these determinations, as they are aware of the unique needs of the Medicare population, unlike the FDA.

Option 4 was recognized for its transparency, ease of implementation, and ability to provide the greatest amount of resources to the ESRD PPS in terms of acquisition of new drugs/ biologicals. It received few comments of support, however, most other commenters recognized that Option 4 does not consider the money already in the base rate designated for drug costs in existing functional categories and deemed this method fiscally irresponsible, as the adoption of a new drug/biological product could reduce utilization of existing drugs.

In addition to the suggestions above, interested parties also had general suggestions in order to improve the quality of data for an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends, and suggestions for successful and timely implementation. Interested parties suggested the TDAPA period be extended to three years, as was done for calcimimetics from CY2018-CY2020, in order to collect sufficient price and utilization information. One professional association suggested that CMS collect information on both Medicare payment as

well as facility costs in order to better understand the effect of the TDAPA drug/ TPNIES equipment on facility finances. One large dialysis organization urged CMS to ensure that reporting policies be standardized to minimize mis-alignments in utilization data collection, as some CMS policies require utilization reporting based on the number of pills, while others rely on dosage units. Additionally, commenters strongly encouraged CMS to finalize an add-on payment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends by CY 2024, because TDAPA eligibility for existing TDAPA drugs will conclude on 3/31/2024. Several commenters called for the add-on adjustment to take effect immediately after the TDAPA period closes, while one professional organization suggested that the TDAPA add – on amount be made public to interested parties 6 months prior to the end of the drug's TDAPA eligibility. Several interested parties also urged that any add-on payment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends should be updated annually to account for inflationary changes. One professional organization suggested that this could be done through the ESRD market basket, or through proxy drug indices specific to the relevant type of drug.

Lastly, a number of commenters took the opportunity to highlight that the same access to care and payment uncertainties present with TDAPA also apply to the TPNIES policy in their responses to this RFI. A non-profit dialysis association stated that CMS should consider either base rate modification or the addition of an add-on payment that reflects the additional costs of technologies paid for using the TPNIES after the payment period ends, as is being considered for TDAPA. Similar to the call to finalize the methodology for an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories

after the TDAPA period ends by January 1, 2024, interested parties pointed out that a technology that currently is being paid for using the TPNIES will lose TPNIES eligibility in 2024. This commenter strongly suggested that CMS propose a base rate adjustment or an add-on payment adjustment in the CY 2024 ESRD PPS proposed rule for new and innovative equipment and supplies that are capital-related assets, and specifically home dialysis machines, after the TPNIES period ends. Finally, a provider advocacy organization recommended that CMS's rate-setting process should consider the settings and patient populations associated with new technologies that are paid for using the TPNIES. They expressed that TPNIES payment for certain technologies may be adequate for in-center treatments but insufficient to support a single patient dialyzing at home.