KIDNEY CARE PARTNERS

July 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1782–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (Proposed Rule). This letter focuses on the ESRD CY 2024 ESRD PPS policies related to the market basket increase and its impact on the workforce crisis, as well as the proposals related to the post-Transitional Drug Add-on Payment Adjustment (TDAPA) add-on payment adjustment. Our comments on the other proposals in the Proposed Rule, the acute kidney injury reimbursement rate, the ESRD QIP, and the ETC Model will be provided in separate letters.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

I. KCP Requests that CMS Address the Failure of the Market Basket to Reflect Actual Inflationary Costs by Adopting a Forecast Error Adjustment Policy.

The proposed market basket update in the Proposed Rule does not account the substantial increase in costs that dialysis facilities are facing and that other indicators of health care inflation reflect. The increases in labor costs have been particularly dramatic between 2020 and the present. As we discuss further below, if CMS does not act to address the disconnect between the market basket and actual inflation, the negative impact on patient access will exacerbate existing health care inequities that dialysis patients face. Given the exigencies of the situation, KCP asks CMS to adopt a forecast error adjustment similar to the

one used in the Skilled Nursing Facility (SNF) PPS. Just as CMS did for the SNFs in FY 2004,[1] the agency would make a cumulative market basket forecast adjustment reflecting the underforecast since the 2019 rebasing of the ESRD PPS, which would encompass forecast misses from 2019 through 2022 (the most recent year when actual market basket inflation data are available). However, if CMS wished to go back to the beginning of the ESRD PPS, as it did with the SNF PPS,[2] KCP would support that option as well. This policy would also be applied prospectively as well. Taking this step beginning in CY 2024 is critical important given the significant difference between the proposed market basket update and the documented higher costs dialysis facilities are actually experiencing.

The kidney community faces an unprecedented workforce crisis that has been made worse by rising costs of supplies and equipment. Facilities struggle to find qualified health care professionals, including nurses, dieticians, and dialysis technicians, as they compete against other providers with more resources and non-health care employers (including non-health care employers) who offer lower stress workplaces and higher wages funded by these employers' ability to increase prices charged to consumers. Dialysis providers who rely primarily on Medicare rates cannot adjust the rates at which they are reimbursed to address increases in labor, equipment, and supplies. Given that the rates for Medicare, the primary payer for the vast majority of dialysis patients, have not acknowledged or acted on the exponential increases in labor costs in particular, facilities are struggling to maintain the staff patients need in order to receive dialysis treatments.

The crisis is having a negative impact on patient access to dialysis services, both home and in-center. Unless it is resolved, it will likely lead to greater inequities for dialysis patients the majority of whom are people of color, in medically underserved areas, or low-income. The Kidney Care Council, a member of KCP, has been tracking the impact of the current labor crisis during the last few years. KCC members report having to reduce the number of shifts or chairs available for patients. Many facilities have had to turn patients away or limit admissions because of the staffing shortage. Physicians report having difficulty finding openings for dialysis patients when trying to discharge them from a hospital stay and some patients have had to remain in the hospital extra days until a spot becomes available. Moreover, hundreds of dialysis facilities have had to close their doors entirely because they could not find the staff to ensure patient safety.

The challenges dialysis providers face is not surprising given that the Medicare annual inflationary update has not kept pace with actual inflation. USRDS data show that Medicare spending for outpatient dialysis services has decreased by essentially 10 percent between 2010-2020.[3] Figure 1 shows how the market basket has failed to keep pace with the CPI or health care inflation.

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[1] 68 *Fed. Reg.* 46036, 40655 (Aug. 4, 2003).
[2] 68 *Fed. Reg.* at 40655.
[3] USRDS. Annual Report 2022. Figure 9.6a.

Figure 1: ESRDB Market Basket Updates Compared to Other Measures of Inflation[4]

MB Base Year	2008			2012				2016				2020
ESRD PPS Final Rule	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023*
Adjusted Final MB	2.1	2.3	0	0	0.2	0.6	0.3	1.3	1.7	1.6	1.9	1.7
Inflation (CPI)	2.1	1.5	1.6	0.1	1.3	2.1	2.4	1.8	1.2	4.7	8.0	NA
Health Care Inflation	3.2	2	3	2.6	4.1	1.8	2	4.6	1.8	2.2	4.0	NA

* The 2023 are proposed at this time.

Moreover, during the last two rulemaking cycles the ESRD PPS market basket updates have not kept pace with the market basket increases other Medicare providers receive as *Figure 2* shows.

Figure 2: Comparison of Medicare FY and CY Market Basket Update Amounts for FY/CY 23 and FY/CY 24

Payment Calendar	Rule	MB Update	Productivity Adjustment	Total update
FY22	IPPS	2.7	0.7	2.0
FY22	SNF	2.7	0.7	2.0
FY22	IRF	2.6	0.7	1.9
FY22	IPF	2.7	0.7	2.0
FY22	LTCH	2.6	0.7	1.9
CY22	HH	3.1	0.5	2.6
CY22	ESRD	2.4	0.5	1.9
FY23	IPPS	4.10%	0.30%	3.80%
FY23	SNF	3.90%	0.30%	3.60%
FY23	IRF	4.20%	0.30%	3.90%
FY23	IPF	4.10%	0.30%	3.80%
FY23	LTC	4.10%	0.30%	3.80%
CY23	HH	4.10%	0.10%	4.00%
CY23	ESRD	3.10%	0.10%	3.00%
FY24	IPPS	3.00%	0.20%	2.80%
FY24	SNF	2.70%	0.20%	2.50%
FY24	IRF	3.20%	0.20%	3.00%

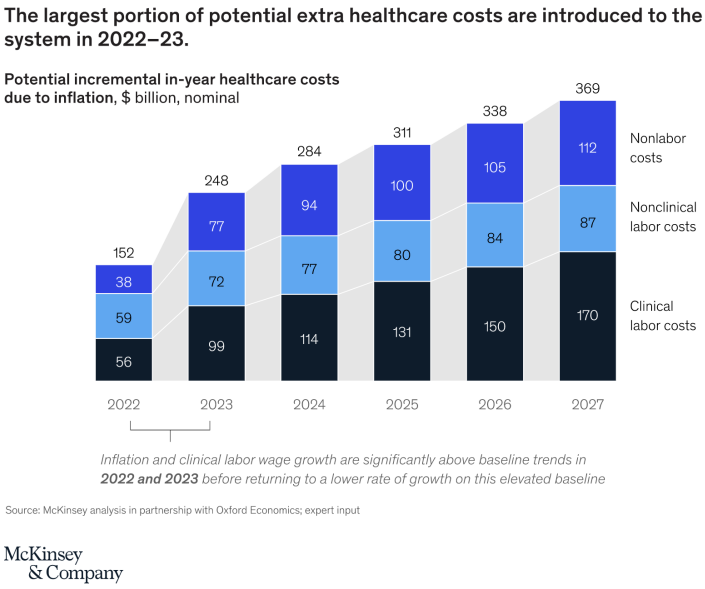
[4]CPI and CHI data available at: (https://www.usinflationcalculator.com/.

Payment Calendar	Rule	MB Update	Productivity Adjustment	Total update
FY24	IPF	3.20%	0.20%	3.00%
FY24	LTC	3.10%	0.20%	2.90%
CY24	HH	3.00%	0.30%	2.70%
CY24	ESRD	2.00%	0.30%	1.70%

In each year, the ESRD PPS falls significantly short of the update provided by the other Medicare market baskets.

Financial expert analyses paint a bleak picture for the kidney care community. PricewaterhouseCoopers' Health Research Institute estimates that health care costs will rise 7 percent in 2024 as providers face substantially higher expenses. The group estimated health care cost increases for 2022 and 2023 of 5.5 percent and 6 percent respectively.[5] McKinsey & Company have described the increasing costs of supplies and ongoing supply chain issues. They also predict serious gaps in the health care workforce that will lead to higher wages and benefits, but that could also be so dramatic that these "[l]abor shortages could lead to access risks from site-of-care closures and increased wait times."[6] *Figure 3* shows that clinical labor costs are the largest portion of health care costs in the system for 2022 and 2023.

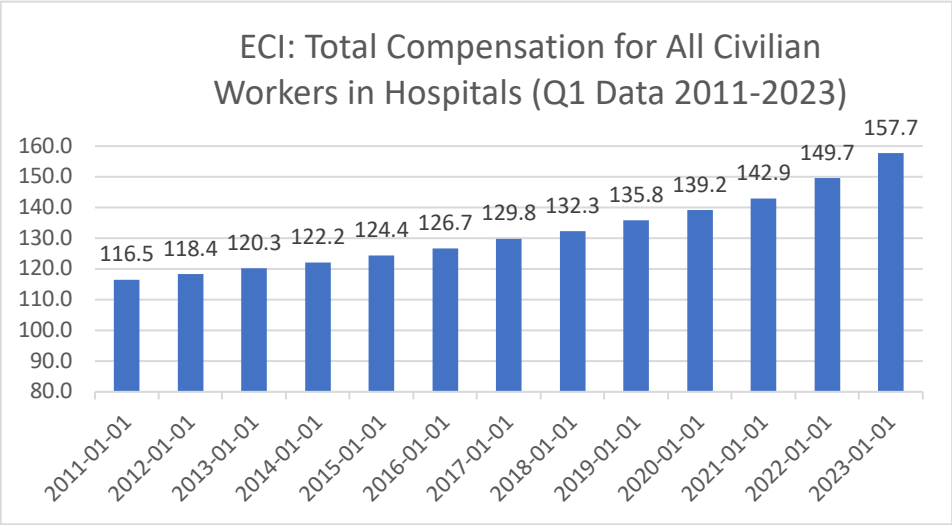
Figure 3: McKinsey & Company Assessment of Potential Extra Health Care Costs



[5]https://www.healthcaredive.com/news/healthcare-costs-rise-7-percent-2024-PwC/654287/
[6]The gathering storm: The transformative impact of inflation on the healthcare sector, Sept. 19, 2022 https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector

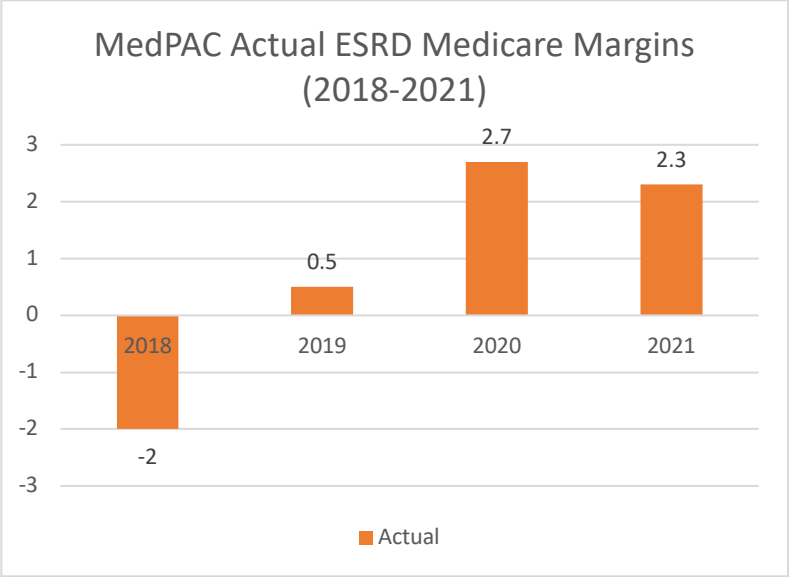
Yet, the Proposed Rule would set the market basket increase at only 1.7 percent.

While the ESRD PPS market basket proxies may not have caught up to the faster-than-expected rise in labor costs, the BLS ECI for All Civilian Workers in Hospitals show the rising costs since 2011.



The annual MedPAC margin analysis show that there has been very little cushion in the system to allow dialysis facilities to adjust to significant swings in cost.

Figure 4: MedPAC Calculation of Actual Margins



Note for 2018-2019, MedPAC calculated the margins with and without the TDAPA add-on. This chart includes the margins without the TDAPA add-on being included. Similarly, the 2020 margin does not include the pandemic relief that some, but not all dialysis facilities accepted.

Unfortunately, this crisis perpetuates the health care inequities many dialysis patients already experience. CMS recognizes that these patients are "disproportionately young, male, and African-American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting."[7] CMS should prioritize address this crisis as part of its efforts to reduce and eliminate health inequities facing Medicare beneficiaries. Additionally, this crisis is exacerbated by the fact that many other payment systems covering dialysis patients are dependent on the ESRD PPS to form their own payment schedules. The use of this payment system and replication of the error could affect more than 80% of dialysis patients and the payment made for the care they receive.

Given the significant disconnect between the proposed market basket update of 2.0 percent (or 1.7 percent after the productivity adjustment is applied) and the documented higher costs dialysis facilities are actually experiencing, KCP believes CMS should work with the kidney care community to understand why the market basket implemented just over 10 years ago has failed to reflect these very real and well-document increases in cost. However, addressing the short-comings of the current market-basket will require a multi-year process. Patients who are already experiencing reduced access to dialysis simply do not have time to wait for that process to conclude before CMS takes action. Thus, KCP asks that CMS adopt the forecast error adjustment in the final rule for CY 2024. As discussed below, adopting this policy would be a logical outgrowth of the Proposed Rule or could be part of a final rule with a comment period would allow stakeholders to provide comments, but also allow the proposal to be finalized and take effect January 1, 2024.

As we recommended in last year's rulemaking cycle and several meetings during the past year, KCP urges CMS to adopt a forecast error adjustment similar to the one used in the Skilled Nursing Facility (SNF) PPS. Just as CMS did for the SNFs in FY 2004,[8] the agency would make a cumulative market basket forecast adjustment reflecting the underforecast since the 2019 rebasing of the ESRD PPS, which would encompass forecast misses from 2019 through 2022 (the most recent year when actual market basket inflation data are available). However, if CMS wished to go back to the beginning of the ESRD PPS, as it did with the SNF PPS,[9] KCP would support that option as well. If CMS were to implement the 2019-2022 proposal, the total adjustment based on the difference between the market basket forecast and the actual market basket increase from 2019 to 2022 would be an increase of a little more than 4.0 percent.[10]

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[7]Display Copy 6 (quoting 87 FR 67183).
[8]68 *Fed. Reg.* 46036, 40655 (Aug. 4, 2003).
[9]68 *Fed. Reg.* at 40655.
[10]Based on the way CMS calculates the SNF forecast error, we believe the actual adjustment would be approximately a 4.29 percent increase.

Figure 5: 2019-2022 Retrospective Application of Forecast Error Adjustment

MB Base Year	2016				Unadjusted Total Forecast Miss (percentage points)
ESRD PPS Final Rule	2019	2020	2021	2022	
Unadjusted Final MB Update	2.1	2	1.9	2.4	
Actual MB Inflation (per IGI Global methodology)	2.3	1.9	3.1	5.1	
Final MB Update Compared to Actual (forecast error)	-0.2	0.1	-1.2	-2.7	-4.0

As CMS did with the initial application of the adjustment for SNFs, we ask CMS to calculate the cumulative forecast error and compared it to the threshold as a total percentage rather than applying the threshold on a year-by-year basis for the initial adjustment.

For subsequent years, KCP recommends that CMS continue the use of the forecast error adjustment and apply a threshold to these annual rate adjustments of +/- 0.5 percentage points, which is the same percentage CMS finalized for the SNF forecast error in 2003.[11] We also support applying the adjustment uniformly, meaning that the adjustment is applied not only when the forecasted percent change is lower than the actual percent change, but also in those instances where the forecasted percent change is higher than the actual percent change. The Proposed Rule preamble suggests that "[h]istorically, the positive differences between the actual and forecasted market basket increase in prior years have offset negative differences over time."[12] However, The Moran Company analysis of the forecast and actual market basket increases since 2012 (the beginning of the ESRD PPS) as published by CMS demonstrate this statement is not accurate.

Figure 6: ESRDB Market Basket Updates Compared to Historical Data

MB Base Year	2008			2012				2016				2020
ESRD PPS Final Rule	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023*
Unadjusted Final MB Update	3	2.9	3.2	2.1	1.8	2.1	1.9	2.1	2	1.9	2.4	3.1
Actual MB Inflation (per IGI Global methodology)	3.4	3	2.3	2.2	2	1.3	1.9	2.3	1.9	3.1	5.1	3.8**
Final MB Update Compared to Actual (forecast miss)	-0.4	-0.1	0.9*	-0.1	-0.2	0.8	0	-0.2	0.1	-1.2	-2.7	-0.7

*Note: the negative percentages indicate the forecast produced an under-estimate of the actual inflationary costs, while a positive number indicates that the forecast produced and over-estimate of inflationary costs. *CMS has not*

[11] 68 *Fed. Reg.* at 46058.
[12] Display Copy 22.

*published the difference between the forecasted and actual inflation percentage for 2014; The Moran Company estimated the difference for this table. **Based on the Q4 2023 forecast.*

When take together with or without applying a threshold of +/- 0.5 percentage points, the system does not even out. In fact, if the threshold is not applied, the forecast missed the mark by a cumulative 3.8 percentage points since the inception of the ESRD PPS. If the threshold is applied, the miss is a cumulative 2.9 percentage points. Both of these errors represent a significant amount of resources not allocated correctly.

In the Proposed Rule, CMS expresses concern that adopting a forecast error policy would be contrary to the nature of a prospective payment system and that applying a forecast error could introduce unpredictability into the ESRD PPS.[13] CMS raised a similar set of concerns when it proposed the forecast adjustment to the SNF PPS. "[A] potential disadvantage of establishing a forecast error adjustment, in that it would inevitably introduce an element of uncertainty regarding the amount of future updates. This uncertainty, in turn, would tend to detract from the prospective nature of the SNF payment system."[14] After careful consideration, the agency dismissed these concerns, essentially noting that any potential disadvantage was outweighed by the benefit of the policy. CMS explained the benefit of the policy in the preamble for the FY 2004 SNF PPS final rule.

> in making the 3.26 percent adjustment, we are not providing a source of new industry funding. Instead, we are correcting an underforecast of pricing levels that resulted in lower payments than we would otherwise have made if actual, instead of forecast, data were used. To a great extent, this underforecast reflects the faster-than-expected growth in wages and benefits for nursing home workers since the start of the SNF PPS, as a result of continued rapid growth in the health sector and the shortage of nurses. As a result of these market conditions, SNFs have already incurred expenses at a higher-than-forecasted level. Our overarching Medicare integrity goal is to pay the appropriate amount, to the correct provider, for the proper service, at the right time. Adjusting for this difference between the forecasted and actual market basket values is consistent with that goal.[15]

Thus, CMS concluded that addressing "faster-than-expected growth in wages and benefits for nursing home workers" and achieving CMS' "overarching Medicare integrity goal…to pay the appropriate amount, to the correct provider, for the proper service, at the right time" supported the adoption of the proposed forecast adjustment.

[13]Display Copy 21-22.
[14]68 *Fed. Reg.* 34768, 34770 (June 10, 2003).
[15]68 *Fed. Reg.* 46058.

These policy reasons that underly the decision to adopt the forecast adjustment into the SNF PPS rate-setting system support adopting a similar policy for the ESRD PPS. As CMS notes in the Proposed Rule, one of its goals is to refine the ESRD PPS so that CMS pays providers more accurately.[16] As noted above, the reason that the ESRD market basket forecast has missed the actual increase in the market basket inflation is because of exponential growth in workforce costs. The Proposed Rule seems to recognize that using more recent data to reflect the "outlook regarding the U.S. economy and expected price inflation" is important.[17] However, the Proposed Rule fails to take the next step in the analysis that CMS did when considering the policy for the SNF PPS. It does not consider whether the potential concerns are outweighed by the benefit of adjusting the unprecedented market conditions that have led dialysis facilities to already incur expenses at higher-than-forecasted levels. If CMS were to undertake this analysis, it should conclude as it did in 2003, that the forecast error adjustment is appropriate and will promote patient access to the clinical teams necessary to provide dialysis and support better patient quality of life. Moreover, adopting the forecast adjustment would allow the agency to address a serious threat to health equity for a population already experience more than its fair share of challenges based on sociodemographic factors. There was no precedent to adjust for market basket forecast error in the annual SNF PPS update prior to 2004 either,[18] yet CMS adopted the adjuster nonetheless. After all, the goal of a PPS rate-setting systems is to "ensure that the payment rates appropriately reflect changes over time in the price of goods and services."[19]

Although CMS has not raised concerns about it having statutory authority to implement this policy, KCP offers that the ESRD PPS statute, as the SNF PPS statute does, provides sufficient authority for CMS to make this adjustment. First, as CMS notes throughout the Proposed Rule as part of its proposal to adopt a pediatric adjustment, as well as the post-TDAPA payment add-on adjustment, the ESRD PPS does allow CMS to provide adjusters.[20] Second, in the preamble to the SNF FY 2004 proposed rule CMS cites section 1888(e)(5) of the Social Security Act (SSA) and the language that directs CMS to establish a market basket index for SNFs that "…reflects changes over time in the price of an appropriate mix of goods and services."[21] The exact same language in section 1881(b)(14)(F):

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[16]*See* Display Copy 109 (CMS has repeatedly indicated a desire to ensure accuracy in the payment system. For example, in the Proposed Rule, CMS proposes to collect "time on machine" data to support its efforts to "evaluate and monitor the accuracy of our payments for patient-level adjustment factors." (Page 109). The preamble also notes that the data would "allow [CMS] to more precisely estimate the average costs of the various above-mentioned components of a renal dialysis treatment that cannot currently be captured." (Page 125).
[17]Display Copy 22.
[18]*See* Display Copy 22 ("there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update").
[19]68 *Fed. Reg.* 34769.
[20]Display Copy 68.
[21]68 *Fed. Reg.* 34769.

> the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that **reflects changes over time in the prices of an appropriate mix of goods and services** included in renal dialysis services.

Because CMS concluded in 2003 that "[t]he use of a forecast market basket percentage change in consistent" with the SNF text,[22] the agency should apply the same analysis for purposes of the ESRD PPS text.

B. Including a Forecast Error Adjustment in the CY 2024 Final Rule Is a Logical Outgrowth from the Proposed Rule.

KCP believes that CMS could finalize the forecast error adjustment in the CY 2024 final rule for the ESRD PPS. Doing so would be the logical outgrowth of the preamble discussion on pages 21-22 of the Display Copy. CMS describes how the forecast error for a market basket is updated as "the actual market basket increase for a given year less the forecasted market basket increase," cites a guidance document providing further explanation of the forecast error, and shares data about what the forecast miss has been during the most recent years for which actual market basket inflation is available.[23]

Although CMS states in the preamble that it is not proposing to apply a forecast error payment adjustment for CY24, finalization of such an adjustment would nevertheless be a logical outgrowth of the proposed rule. As the U.S. Supreme Court opined in *Long Island Care at Home, Ltd. v. Coke*, "[t]he object, in short, is one of fair notice,"[24] *i.e.*, whether the agency's possible course of action was "reasonably foreseeable."[25] In *Allina Health Services v. Sebelius*, the D.C. Circuit explained that "[a] final rule is a logical outgrowth if affected parties should have anticipated that the relevant modification was possible."[26]

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[22] 68 *Fed. Reg.* 34769.
[23] Display Copy 22.
[24] 551 U.S. 158 at 174.

[25] *In Long Island Care*, the Department of Labor proposed a rule that would have continued a limited exception from the Fair Labor Standards Act (FLSA) for some companion workers. After receiving critical comments, the Department finalized a policy subjecting all companion workers hired by third parties to FLSA requirements. Finding that the final policy was a "logical outgrowth" of the proposal, the Court reasoned that "[s]ince the proposed rule was merely a proposal, its presence meant the Department was considering the matter; after that consideration the Department might choose to adopt the proposal or withdraw it." 551 U.S. at 175. The Court noted that the Department withdrew the proposal regarding employees of "covered enterprises," thereby exempting all companion workers hired by third parties from the FLSA and opined, "[w]e do not understand why such a possibility was not reasonably foreseeable." *Id.*

[26] 746 F.3d 1102, 1107 (D.C. Cir. 2014) (citing *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1080 (D.C. Cir. 2009) (citations omitted)). *Allina*, in which the D.C. Circuit concluded that the final rule was not a logical outgrowth of the proposed rule, is distinguishable because: (1) it involved the agency's reconsideration of a longstanding

The D.C. Circuit's 2022 opinion in *Brennan v. Dickson* is instructive.[27] There, the court upheld a final rule that abandoned an agency's proposed measurement and implemented another it had specifically rejected in the initial rulemaking.[28] Noting that, while an agency cannot require interested parties to "divine [its] unspoken thoughts" on a final rule "surprisingly distant" from that proposed, the D.C. Circuit found that the implementation of the initially rejected measurement "was no surprise."[29] The plaintiffs challenging the final rule argued that, since the agency had requested comment on whether both measurements should be used, this gave "no indication" that the rejected measurement alone could be used. In rebutting this argument, the court commented that "it remains a mystery how requiring one altitude measurement rather than both could be prejudicial" and that the plaintiff had notice of, and opportunity to comment on, the measurement that was rejected in the proposed rule.[30]

Likewise, the D.C. Circuit recently held that where even an "extreme differential treatment" that was not proposed in an initial notice would have been "foreseeable,"[31] the more limited differential treatment in the final rule was a logical outgrowth of the notice.[32] In *Great Lakes Communication Corp. v. FCC*, the agency adopted a "last-minute proposal" from

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policy and not implementation of a new policy; and (2) the notice in question proposed to "clarify" an existing practice, which "[did] not suggest that a potential underlying major issue [was] open for discussion." *Id.* at 1108. As the D.C. Circuit explained, the estimated financial impact of the proposed rule did not reflect the "hundreds of millions of dollars" of impact ultimately caused by the final rule, which "would doubtless have triggered an avalanche of comments, in contrast to the mere 26 pages that were actually submitted." *Id.*

By contrast, the CY 2024 ESRD PPS proposed rule presents the opposite situation and will almost certainly trigger a significant number of comments. In *Allina*, hospitals were not incentivized to comment because the agency's initial proposal "was disposed to codify an interpretation that was favorable" and "there was no reason for the hospitals to fear that another party would offer comments opposed to such an interpretation." 584 F.3d at 1108.

[27] 45 F.4th 48 (D.C. Cir. 2022).

[28] In *Brennan*, the preamble to the proposed rule at issue stated:

> **The FAA considered and rejected a requirement to indicate the control station's geometric altitude**. . . . Barometric pressure altitude is a more precise measurement than geometric altitude and is the standard altitude reference for aviation.

84 Fed. Reg. 72438, 72473 (Dec. 31, 2019) (emphasis added). However, in the final rule, the FAA abandoned the barometric pressure altitude measurement and instead implemented the geometric altitude measurement it specifically rejected in the proposed rule.

[29] 45 F.4th at 69.

[30] *Id.* at 69-70.

[31] 3 F.4th 470 (D.C. Cir. 2021).

[32] *Id.* at 478.

interested stakeholders "too late for adverse comment."[33] The court focused its inquiry on whether it could "fairly be said that the differential treatment was a logical outgrowth of the notice."[34] Acknowledging that the agency had not "explicitly suggest[ed] differential treatment," the D.C. Circuit still concluded that such treatment was a "logical outgrowth" of the initial notice.

Based on the above, it is reasonably foreseeable that CMS would, after reviewing comments and data submitted in response to the NPRM, decide to change course and apply a forecast error payment adjustment to the CY 2024 ESRDB market basket update. In the preamble to the proposed rule, CMS notes:

> if more recent data become available after the publication of this proposed rule and before the publication of the final rule . . . we would use such data, if appropriate, to determine the CY 2024 market basket percentage increase and productivity adjustment to the final rule.[35]

This clearly indicates that the door remains open for CMS to modify CY 2024 payment amounts based on data submitted during the comment period

In addition, CMS's discussion of the forecast error payment adjustment issue clearly gave interested parties fair notice that it was under consideration and that modifications to the initial proposal were possible, thereby triggering the need to submit comments.[36] Finally, applying a forecast error payment adjustment would not result in any unfair surprise, particularly since it would result in an across-the-board payment increase for all dialysis facilities. To paraphrase the D.C. Circuit in *Allina*, "[t]here is no obvious constituency opposed to greater compensation for [dialysis facilities]." 746 F.3d at 1108; *cf. Brennan*, 45 F.4th at 70 (commenting that "[i]t remain[ed] a mystery" how implementing the policy in question "could be prejudicial").

However, if CMS believes it should obtain additional comments on the proposal, KCP recommends that it include the proposal in the final rule (designated as an interim final rule) and provide a 30-day comment period for interested stakeholders before finalizing the policy

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[33] *Id.*

[34] 3 F.4th at 478.

[35] Display Copy 21.

[36] The agency acknowledges that "many commenters requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate" during the CY2023 rulemaking process, despite the fact that the proposed rule for that year made no mention whatsoever of the potential for such an adjustment. *See* Display Copy at 21; 87 Fed. Reg. 38464 (June 28, 2022). Clearly, if commenters raised this issue *sua sponte* during the CY2023 rulemaking, the agency's statement that it is not proposing a forecast error payment adjustment for CY2024 should generate even more comments on the subject.

for CY 2024. Given that the kidney care community, particularly dialysis providers, overwhelmingly support adopting the policy as described by KCP and other stakeholders in previous rulemaking and this comment letter, there appears little risk that CMS would encounter significant opposition to the policy. As the *Federal Register* indicates in "A Guide to the Rulemaking Process":

> When an agency finds that it has good cause to issue a final rule without first publishing a proposed rule, it often characterizes the rule as an "interim final rule," or "interim rule." This type of rule becomes effective immediately upon publication. In most cases, the agency stipulates that it will alter the interim rule if warranted by public comments. If the agency decides not to make changes to the interim rule, it generally will publish a brief final rule in the Federal Register confirming that decision.[37]

Addressing the health inequities created by the workforce crisis is good cause. This regulatory vehicle would provide stakeholders with sufficient opportunity for comment and CMS with the opportunity to change the policy, if needed, but not wait until the next rulemaking cycle and risk additional loss of dialysis shifts and facility closures that place dialysis patients at risk.

II. KCP Recommends that CMS Adopt a New Money Post-TDAPA Add-on Payment Adjustment with Modifications to Protect Patient Access and Address Inequities in Access to Innovative Treatment Options.

KCP is pleased that CMS recognizes the community's concerns that new money is needed post-TDAPA for innovative drugs and biologicals that are within functional categories. CMS acknowledges how the existing post-TDAPA payment policy hinders patient access to innovative therapies and that "additional support may be needed to assure continued access to such [TDAPA] drugs and biological products for Medicare beneficiaries and to support ESRD facilities' long-term planning and budgeting."[38] However, the proposed post-TDAPA payment add-on adjustment will not provide sufficient resources to support such planning and budgeting and, as a result will not support further innovation to benefit dialysis patients.

Unless it is modified, the policy will unfortunately perpetuate the inequities dialysis patients have experienced when it comes to having access to innovative treatment options. Researchers and manufacturers will be unwilling to enter a market when the overwhelmingly dominate payer does not provide an appropriate reimbursement amount for new products. The proposal methodology leads to a ridiculous outcome in which CMS would reimburse facilities 9 cents a treatment for a new, innovative product. Expensive medications used by a small percentage of individuals are not supported by the current payment system or proposed

[37] https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf
[38] 88 *Fed Reg.* 42430, 42459 (June 30, 2023).

adjustment. No other Medicare payment system fails to recognize and support innovation in such a way. At the same time it is preventing patients with less common conditions by the post-TDAPA policy, CMS is implementing a time-consuming data collection policy related to the time on machine and implementing a large adjustment (30%) for pediatric patients to better align payment with resource use. It is unclear why the post-TDAPA methodology would also not strive to achieve the goal of ensuring that reimbursement rates are more accurate and directing money to those patients who need additional services.

KCP has serious concerns about three aspects of the proposal that seek to:

(1) treat all patients and products the same by applying the add-on adjustment across all patients;

(2) cut the adjustment amount by 35 percent, an arbitrary amount, not linked to what is actually in the currently in the base rate; and

(3) sunset the new money after three years.

These aspects of the proposed policy are particularly harmful in the context of the Medicare ESRD program, which serves a population that CMS describes as "disproportionately young, male, and African-American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting."[39] Moreover, these aspects of the policy do not support CMS' goal for the ESRD PPS, which it summarizes as seeking to "address health equity for beneficiaries with ESRD who are also members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial and ethnic minorities."[40] As the former Health and Human Services Chief Technology Officer Ed Simcox noted, "The pace of innovation in kidney care has been unacceptable."[41] As the preamble also states, "CMS aims to ensure all individuals have access to equitable care and coverage."[42] As such, we ask that CMS finalize the revisions to the post-TDAPA add-on adjustment policies outlined in this letter and that are a logical outgrowth of the policy outlined in the Proposed Rule.

KCP recommends adopt the following policies to address the inequity in access to innovation that individuals who require dialysis face:

(1) Calculate the adjustment amount using the number of treatments with claims for the TDAPA drug as the denominator and applying the add-on payment

[39]Display Copy 6 (quoting 87 *Fed Reg.* 67183).
[40]Display Copy 6.
[41]https://www.kidneyx.org/about-kidneyx/.
[42]Display Copy 122.

amount only to claims for patients who actually receive the product, especially when a small portion of the ESRD population medically requires the drug. This modification would more closely align the amount reimbursed with the cost of providing the drug;

(2) Calculate the offset to the add-on amount that accounts for the actual spending for products in the drug's functional category that are directly impacted by the innovative product, especially to address the situation when there is little to no money in the current payment amount to support a product; and

(3) Allow the post-TDAPA adjustment to apply on an ongoing basis, similar to the way CMS applies the complexity adjustment in the hospital outpatient department setting.

Unfortunately, if these three aspects of the policy are not addressed, CMS' intent to make sure that beneficiaries have access to new drugs and biological products[43] and for the ESRD PPS to be able "to reflect new drugs and biological products developed or changes in standards of practice"[44] cannot be achieved. Policies that do not promote sustainable reimbursement pathways will also likely result in new research and development dollars flowing disproportionately into other areas of healthcare with more healthy and sustainable reimbursement.

Below we provide more detail about these recommends and note that the complete post-TDAPA payment adjustment policy would do the following:

- Adopt an add-on payment amount for TDAPA drugs or biologicals within an existing functional category specifically to adjust the ESRD PPS payment amount (which CMS does in the Proposed Rule).
    - As described below this add-on adjustment would function in a manner similar to complexity adjustment used in the HOPPS that applies to the comprehensive APCs. It essential creates a "second bundle" specific to patients with the condition being treated. We also discuss below how CMS would be able to implement safeguards if other innovative products for the particular condition were to become available in the future.

- Use new money to fund the add-on adjustment, as CMS proposes.

[43]Display Copy 82.
[44]Display Copy 82.

- Calculate the add-on adjustment at the end of the TDAPA period using the most recent ASP (*i.e.,* the last quarter of ASP under TDAPA) and utilization data from the last 12-month period of TDAPA (define based on claims where the drug was provided), which is similar to what CMS proposes and was subject to comment as part of the CY 2023 RFI.

- Offset the base amount of the adjustment using a case-by-case evaluation of the product to avoid cutting the amount too much for some products and too little for others, consistent with CMS' stated desire to pay more accurately.[45]

- Update the amount annually using either the market basket or the appropriate pharmaceutical proxy, as CMS proposes.

- Make the add-on adjustment permanent and not limited to three years as proposed.

- Implement the add-on at the end of the TDAPA period, as CMS proposes, so that there is no gap in payment.

- In the specific case of Korsuva, for which the policy has been not to provide an adjustment after the TDAPA period ends, extend the TDAPA period for a full two years to address the significant downward pressure that the no new money policy has had on the utilization of the product.

A. The Final Post-TDAPA Add-On Adjustment for Functional Category Drugs Should Avoid Perpetuating Unsubstantiated Assumptions about Physician Behavior, the Ability of Innovative Products to Drive Efficiencies in Unrelated Areas of Treatment, and the Ability of a Single Base Rate without Adjustment to Support Patients with Less Common Conditions.

It appears that these three problematic aspects of the proposed post-TDAPA add-on policy rest on unsubstantiated assumptions that recent data do not substantiate. First, the proposal assumes that physicians are agnostic as to payment policy and will prescribe drugs even if CMS does not adequately reimbursed facilities for the product. CMS' own data show this not to be the case. The recent transition from the SNF Resource Utilization Group payment system to the Patient-Driven Payment Model demonstrated the effect of a misaligned payment policy. Specifically, higher reimbursement for patients who received certain rehabilitative therapy resulted in an overutilization of these therapies in many cases, while nursing and other

[45] *See* Display Copy 109 (CMS has repeatedly indicated a desire to ensure accuracy in the payment system. For example, in the Proposed Rule, CMS proposes to collect "time on machine" data to support its efforts to "evaluate and monitor the accuracy of our payments for patient-level adjustment factors." (Page 109). The preamble also notes that the data would "allow [CMS] to more precisely estimate the average costs of the various above-mentioned components of a renal dialysis treatment that cannot currently be captured." (Page 125).

services declined When CMS transformed Medicare-covered skilled nursing from a therapy-driven model to one that has more emphasis on nursing, better payments for medically complex patients, and increased focus on length of stay, the utilization of therapy dropped.[46] Given this recognized fact, CMS policy should put patients first and recognize that practice follows payment as well.

Second, these policies assume that all innovative products will reduce other ERSD spending in the same way and by at least 35 percent. That is inherently false. Not all drugs will have the same impact on the other items and services that patients require. An example of the inappropriateness of this blanket reduction assumption is detailed in our discussion of the case study of Korsuva below. The fact that there is essential no money in the base rate for treating the small percentage of patients with CKD-associated pruritus (CKD-aP) means that the actual offset to the add-on should be at or near zero and not 35 percent.

Clinical experts agree that Korsuva will not offset spending related to other drugs, items, or services in the base rate. This situation could be true for other drugs or biologicals in the future. Thus, there is no justification for such a substantial cut that will have a negative impact on patient access. CMS should take a patient-centered approach that seeks to provide resources as accurately as possible to support the utilization of innovative products for dialysis patients. Given the small number of new products (which CMS recognizes[47]), this approach should not be a significant burden to CMS; any increase in analysis will be more than offset by the benefits to ESRD patients.

Third, these policies seem based on the incorrect assumption that spreading new money across all 400,000 or so dialysis patients will be sufficient to support the use of products that provide innovative treatments intended to address diseases or conditions that affect only a small percentage of the patient population. As CMS has repeatedly noted, the base rate is constructed by including the item and services that the average patient receives.[48] As a result, it fails to address the needs of the non-average patient. While the outlier policies can address the

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[46]86 *Fed. Reg.* 19954, 19986 ("Moreover, we do believe that there is clear evidence that PDPM alone is impacting certain aspects of SNF patient classification and care provision. For example, through FY 2019, the average number of therapy minutes SNF patients received per day was approximately 91 minutes. Beginning almost immediately with PDPM implementation (and well before the onset of the pandemic), the average number of therapy minutes SNF patients received per day dropped to approximately 62, a decrease of over 30 percent. Given both the immediacy and ubiquity of this change in the SNF data, without any concurrent change in the SNF population, it is clear that this overall decrease in the amount of therapy services provided to SNF patients is a result of PDPM implementation and not other factors.")

[47]Display Copy 85 (CMS notes that only one drug to date has been added to the bundle and that only one other drug has received TDAPA. This discussion recognizes that there is unfortunately very little innovation in the treatment of ESRD patients when it comes to drugs and biologicals. The Department also recognizes this fact through its continued partnership with the community through KidneyX, which seeks to incentivize the innovation that has been lacking. *See* https://www.kidneyx.org/about-kidneyx/)

[48]Display Copy 85-86.

issue in limited cases, The Moran Company has demonstrated previously,[49] the budget neutral outlier policy is not sufficient to address the needs of these patients. CMS acknowledges the inadequacy of the outlier payment policy and "recognize[s] that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries."[50] CMS also correctly acknowledges the market basket update may not be appropriately accounting for new renal drugs and biologics given "uncertainty about future trends in the expenditures for new renal dialysis drugs and biological products."[51]

Other Medicare payment systems, such as the hospital outpatient prospective payment system (HOPPS), recognize this reality and address issues with multiple bundles (*e.g.,* there are hundreds of Diagnostic Related Groups (DRGs) in the inpatient payment system and multiple Ambulatory Payment Classification (APCs)) or adjustments (*e.g.* the complexity adjustment to the comprehensive APC)).

The preamble includes a paragraph that seems to allude to an agency concern that the current base rate amount may no longer align with the utilization and price of services and items reimbursed under that rate.[52] This language may be in reference to adding funding to the base rate for calcimimetics. Yet, this situation was particularly unique and should not be the basis for a policy that will impact patient access to other therapies. For example, calcimimetics came into the bundle because an IV equivalent to a previously oral-only medication became available, eliminating the oral medication's oral-only status. In addition, the drugs were added to the bundle based on the price and utilization of branded drugs only, even though generic

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[49] *See* KCP. "KCP PPS Comment Letter Part 1 Final (Aug. 4, 2022)(" For example, if the outlier pool were used instead of an add-on adjustment, the proportion of the outlier payments associated with patients receiving any new drug would likely increase so substantially that the current base rate would be eroded. Based its analysis of the inclusion of the first new drugs into the bundle, The Moran Company found that many patients whose treatments historically qualified for outlier payments would no longer qualify under the current policy due to the significant increase in the outlier threshold. Any new product that qualifies for the outlier pool and has a significant cost associated with it will lead to higher threshold amounts. This result will make it more difficult for the outlier pool to support the costs associated with other products, because those costs alone may no longer meet the higher threshold. This situation could lead to the outlier pool being primarily consumed by a single group of services. The problem would be substantially worse if there were no adjustment to the rate to cover the cost of the average patients receiving the new drug or biological.")

[50] 88 *Fed. Reg.* 42458-59.

[51] 88 *Fed. Reg.* 424549.

[52] Display Copy 86 ("We also noted that price changes to the ESRD PPS bundled payment are updated annually by the ESRDB market basket update, which includes a pharmaceutical cost category weight. In addition, we explained that our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time for some high volume formerly separately billable renal dialysis drugs, relative to overall market basket growth. Therefore, we stated that we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.")

oral medications were also becoming available. It would be inappropriate to assume this scenario would be relevant to TDAPA drugs within existing functional categories.

The current bundled amount has resulted in low and at times negative Medicare margins, which means there are not extra dollars to compensate for an adjustment that is inappropriately assessed. As the discussion on labor notes, the market basket and contractor projections of the market basket increase have woefully missed the mark in reflecting actual cost increases. In addition, MedPAC's Medicare margins for ESRD facilities have been negative or very low during the last decade and projected to be -0.4% in 2024.[53]

KCP applauds CMS for agreeing with commenters' concerns that "the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs."[54] If CMS wishes to address and eliminate the longstanding inequity dialysis patients experience, then it should implement policies that support innovative treatment options by accurately accounting for them in the payment system.

B. KCP Supports Many Aspects of the Proposed Post-TDAPA Add-On Adjustment for Functional Category Drugs, but Strongly Urges CMS (1) Not to Spread the Funding Across All Patient Claims, (2) to Establish the Rate with a More Accurate Offset, When the Product Is Not Used, and (3) to Make the Adjustment Permanent.

KCP urges CMS not to rely on these false assumptions and adopt the following add-on policy for new drugs or biologicals that fall within a functional category after the TDAPA period ends. We support the outlined goals for the post-TDAPA add-on payment adjustment that seek to make sure that "payment after the TDAPA is not a barrier to Medicare beneficiaries' access to such new product" and the agency's desire "to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period."[55] We also understand and support efforts to incentivize the efficient use of resources. However, our comments highlight that there is a difference between promoting efficiencies and providing inadequate funding for a program that results in serious access issues for patients. Unfortunately, the three aspects of the proposed post-TDAPA payment add-on adjustment would lead to woeful underfunding for certain drugs or biologicals and will perpetuate existing barriers to patients accessing innovation. This section details our concerns and the specific modifications to the current proposal that could address them.

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[53] *See* MedPAC's *Report to the Congress* for years 2019-2023. Specifically, MedPAC calculated the actual margin for 2018 as -2.0 percent; for 2019 with the TDAPA add-on at 0.5 percent; for 2020 without the TDAPA add-on at 2.7 percent; and for 2021 without the TDAPA add-on at 2.3. The MedPAC projected margin for 2024 is -0.4 percent.

[54] Display Copy 91.

[55] Display Copy 93.

The modifications we offer in this section would allow CMS to avoid the highlighted problem and to achieve its goals – including its desire to incentivize efficient use of resources – for the post-TDAPA payment add-on policy. As noted in the summary to this section, we recommend that CMS:

- Adopt an add-on payment amount for TDAPA drugs or biologicals within an existing functional category specifically to adjust the ESRD PPS payment amount (which CMS does in the Proposed Rule).
    - As described below this add-on adjustment would function in a manner similar to complexity adjustment used in the HOPPS that applies to the comprehensive APCs. It essentially creates a "second bundle" specific to patients with the condition being treated. We also discuss below how CMS would be able to implement safeguards if other innovative products for the particular condition were to become available in the future.

- Use new money to fund the add-on adjustment, as CMS proposes.

- Calculate the add-on adjustment at the end of the TDAPA period using the most recent ASP and utilization data (define based on claims where the drug was provided), which is similar to what CMS proposes and was subject to comment as part of the CY 2023 RFI.
    - For example, the calculation would use the total spend for the product during the TDAPA period divided by the total number of treatments that include TDAPA claims for the drug. This amount would then be the base amount of the add-on adjustment.

- Offset the base amount of the adjustment using a case-by-case evaluation of the product to avoid cutting the amount too much for some products and too little for others, consistent with CMS' stated desire to pay more accurately.[56]

- Update the amount annually using either the market basket or the appropriate pharmaceutical proxy, as CMS proposes.

- Make the add-on adjustment permanent and not limited to three years as proposed.

- Implement the add-on at the end of the TDAPA period, as CMS proposes, so that there is no gap in payment.

[56] *See* Display Copy 109 (CMS has repeatedly indicated a desire to ensure accuracy in the payment system. For example, in the Proposed Rule, CMS proposes to collect "time on machine" data to support its efforts to "evaluate and monitor the accuracy of our payments for patient-level adjustment factors." (Page 109). The preamble also notes that the data would "allow [CMS] to more precisely estimate the average costs of the various above-mentioned components of a renal dialysis treatment that cannot currently be captured." (Page 125).

1. Addressing Concerns Raised in the Preamble.

Before providing more detail about the recommendations outlined above, it is important to address two major concerns CMS expresses about these recommendations in the Proposed Rule.

a. Addressing CMS' Concerns about Beneficiary Copayment Obligations Does Not Account for Patient Choice and Is Inconsistently Applied in the Proposed Rule.

First, we acknowledge the Agency's concern about the potential increase in the copayment amount beneficiaries would incur because of a new adjustment.[57] We recognize that anytime there is an adjustment that increases the payment amount, beneficiaries may experience a higher copayment under the Medicare statute. This has been true for TDAPA and TPNIES and would be true for pediatric patients for whom the proposed 30 percent pediatric adjustment would be applied. Yet, CMS has chosen to support payment for those policies because they are important to protect access to particular services or products.

The post-TDAPA add-on serves equally important patient-centered policy priorities, namely protecting patient access to innovative drugs and biologicals. As described in the case study below, the actual impact on ESRD beneficiaries is much less than it would be for other Medicare beneficiaries given that only 24 percent of beneficiaries do not have some type of coverage for their coinsurance obligations already.[58] Moreover, patients and physicians should be the ones to make the choice whether a medical treatment is appropriate for a patient and, thus, whether the coinsurance amount is something they wish to assume. The federal government should not take that choice away from the patient. The proposed policy unfortunately underfunds the current TDAPA product (and could result in a similar situation for future drugs or biologicals) and, thereby, functions as a *de facto* elimination of coverage and access for the innovative drug.

b. CMS Payment Policy in Other Programs Provides Precedent for KCP's Recommendations and Is Consistent with CMS' Statutory Authority for the ESRD PPS.

In establishing a permanent add-on adjustment for post-TDAPA functional category drugs, CMS would not be unbundling these products; rather, it would be acknowledging that patients who are treated with the product designated for a particular condition require more services than the average dialysis patient. The CMS proposal in contrast disincentivizes the appropriate treatment of patients with less common disease or conditions.

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[57] Display Copy 98-99.

[58] MedPAC. *Report to the Congress.* (Mar. 2023).

There is precedent within the Medicare system to tailor bundled amounts to meet the needs of patients who require different clinical treatments that create differential resource use from the average patient. For example, the HOPPS payment structure provides a more patient-centric approach than the ESRD PPS by defining payment in terms of clinically and resource comparable payment groups.[59] The HOPPS system also allows CMS to address low volume items and services with higher rates, except when a drug or biological is designated as an orphan drug.[60] In addition, CMS applies complexity adjustments to comprehensive APCs to address the higher costs associated with the intensity of certain procedures. When certain codes that are deemed eligible are included on a claim, a complexity adjuster is applied to the comprehensive APC.[61] KCP's recommendation for the post-TDAPA add-on policy to be applied similarly when the drug is included on the claim. Thus, there is precedent within the Medicare payment system to support higher adjustments to a base rate bundle when the intensity of services required by an individual patient is higher than the average patient around which the bundle (or package in this case) was constructed.

To be clear, KCP is not asking CMS to adopt the HOPPS payment structure for the ESRD program; however, it should serve as an example of, and precedent for, tailoring a bundled (or packaged in the case of APCs) system to support innovation and patient-centered decision-making.

KCP's recommendation is also consistent with the statutory restriction that there be a single payment made under the Title for renal dialysis services[62] because the post-TDAPA add-on would function as an adjustment in a manner similar to the complexity adjustments in the HOPPS setting. This approach does not "unbundle the bundle" but rather services to provide more accurate funding for patients who require services that are not necessary for the average patients that the current bundle defines. An adequate payment in post-TDAPA phase will also provide predictability and consistency for facilities to support beneficiary access to innovative therapies. Absent adequate payment, beneficiary access to innovative products will remain unacceptably low.

As CMS notes in the preamble, it has sufficient authority to apply adjusters to the base rate for policy purposes.[63] We agree that addressing the chronic inequities in accessing innovative treatment options should qualify as a rationale for applying an adjustment for innovative products when they are added to the payment system.

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[59] 42 C.F.R. § 419.31(a)(1).

[60] 42 C.F.R. § 419.31(a)(2).

[61] 42 C.F.R. § 172(h).

[62] 42 U.S.C. § 1395rr(b)(14)(A)(i).

[63] Display Copy 68.

2. KCP's Specific Recommended Modifications to the Post-TDAPA Payment Add-on Adjustment Policy.

As stated above, KCP recommends that CMS adopt the following three modifications to the Proposed Rule to support dialysis patient access to innovative drugs and biologicals and to address inequities in the current payment model. We provide more detail in the follow sections related to CMS:

(1) Calculate the adjustment amount using the number of treatments with claims for the TDAPA drug as the denominator and applying the add-on payment amount only to claims for patients who actually receive the product, especially when a small portion of the ESRD population medically requires the drug. This modification would more closely align the amount reimbursed with the cost of providing the drug;

(2) Calculate the offset to the add-on amount that accounts for products in the drug's functional category that are directly impacted by the innovative product to address the situation when there is little to no money in the current payment amount to support a product; and

(3) Allow the adjustment to apply on an ongoing basis, similar to the way CMS applies the complexity adjustment in the hospital outpatient department setting.

a. CMS Can Make the ESRD PPS More Patient-Centered by Having the Adjustment Money to Follow the Patient When Calculating the Amount of the Adjustment and Reimbursing Facilities.

CMS proposes to calculate the add-on adjustment using all dialysis patients in the denominator (not only those who received the drug) and not to direct the post-TDAPA payment add-on adjustment to those patients who require the innovative drug or biological. The former materially dilutes the payment amount by spreading the adjustment amount over all dialysis patients and the latter results in the base rate being increased slightly for all patients, but leaves facilities without sufficient funding for patients who require the product. The inequity in this approach will be most felt by those patients who require more resources than the average patient and creates an unnecessary barrier to accessing innovative treatment options.

The agency takes this approach because it has concerns that a "payment for an individual claim [that is] dependent on individual utilization of the new renal dialysis drug or biological product" would neither "appropriately align incentives for ESRD facilities" nor "support competition with existing drugs."[64] However, this one-size-fits all approach is

[64]Display Copy page 93.

unnecessary and the fears unwarranted. CMS has been able to thread the needle to protect patient access, especially low volume drugs or biologicals, in other prospective payment systems (such as the HOPPS as described above). The RFI in the CY 2023 ESRD PPS proposed rule contained suggestions that would allow the ESRD PPS to provide similar protections while also addressing the chronic inequities dialysis patients face. In light of the enormous barriers innovators have faced in the kidney care area and its negative impact on people of color, the medically underserved, and low-income individuals, we asked CMS to adopt a policy that does not create new barriers to accessing innovation.

Allowing the post-TDAPA payment add-on adjustment amount to be calculated using only claims that include the TDAPA drug or biological or applying the adjustment amount only to claims that include codes for product would not be inconsistent with the principles of a prospective payment system (PPS).

First, we recognize that an objective of a PPS system is to encourage providers to be "efficient in the use of their resources."[65] However, efficiency is not synonymous with a blanket policy that adds so little money to the existing payment amount that it creates financial barriers to facilities being able to make a product available for patients. It is not efficient to reimburse providers for items or services not provided, particularly when the item or service is not used by the average patient. While there might be some product in the future that offsets items and services already in the bundle such that spreading the adjustment across all patients provides sufficient resources for its adoption, that scenario is not always the case, as the Korsuva case-study below demonstrates. We urge CMS to recognize the serious inequities this population of patients experience and adopt a policy that allows for CMS to consider drugs using data that is specific to the patients who require the drug and not generalized to all dialysis patients.

Similarly, it is also not efficient to add dollars to the payment amount that are so substantially below the cost of the product that providers are placed in the impossible position of not being able to provide the product. As described below in the Korsuva case-study, adding roughly 9 cents to every dialysis claim will not incentivize the adoption or continued use of this drug. Because Korsuva's use does not reduce the use of other items or services in the bundle (other than eliminating the need to spend less than $1 per treatment on generic Benadryl or a corticosteroid), facilities will not be able to find efficiencies sufficient to offset the cost. However, if the adjustment were calculated using only claims with the drug listed and used to reimburse only to claims that rely upon the product, CMS would be able to easily identify overutilization patterns based on the clinical trials data available and the TDAPA period. As discussed below, the offset methodology proposed by KCP (that is consistent with options CMS included in its 2022 RFI), the use of ASP+0 percent rather than ASP+6 percent, and utilization

[65] Display Copy page 98.

reviews based on empirical data serve as guardrails to help prevent the overestimation of the amount of the adjustment.

Given historic fluctuations in utilization, we recognize CMS's desire to avoid policies that would overestimate the post-TDAPA add-on payment adjustment amount.[66] Yet, applying the post-TDAPA adjustment to all claims may result in higher expenditures for CMS under certain circumstances that it would not experience if CMS were to use a more direct offset methodology. In the case of a low-utilization drug, CMS would be paying the vast majority of claims more money than needed to care for the patient while disincentivizing the use of the product for those patients who require it. The preamble suggests that the bundle as currently constructed reflects all of the costs that facilities incur accurately. However, CMS' own data demonstrate that the proposal to not have the money follow the patient will result in a significant misalignment between payment and costs. For new, innovative drugs or biologicals that address long-standing gaps in treatments, it is not accurate or appropriate to assume that the current payment amount reflects the costs of these innovative treatments. To support patient access to these products, it is not enough to account for costs associated with "changes in [facilities'] businesses to adopt such products."[67] The cost of the product must be considered in comparison to what is in the functional category already. If there is no real competitor to the product, there is no opportunity for competition. When there is no competitor and/or essentially no money in the bundle for a product, spreading the new money across all patients will simply perpetuate the inequities those patients who have been living with no treatment options have had to endure. In addition, it creates an almost insurmountable barrier that will incentivize researchers and manufactures to avoid using their time, talent, and resources to develop new drugs and biologicals for kidney care patients. This outcome contradicts the goals that KCP and the agency have sought to achieve through the implementation of TDAPA and KidneyX. Respectfully, it is also out of sync with the agency's "commitment to advance health equity by supporting access to renal dialysis services."[68]

To avoid policies that create inappropriate incentivizes that are particularly difficult to manage in a program that has not kept pace with inflationary costs, CMS should be more targeted in its approach to establishing the adjustment amount. Specifically, KCP recommends that CMS:

(1) Calculate the adjustment amount by taking the total spend for the drug or biological during the TDAPA period and dividing it by the total number of treatments when the product was used as represented on facility claims during that same period. This approach would provide an accurate per treatment cost of the product.

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[66] *See* Display Copy 99.

[67] Display Copy 99.

[68] Display Copy 100.

(2) Using that per treatment amount, apply the post-TDAPA payment add-on adjustment to claims with the HCPCS code for the product, similar to the way the HOPPS applies the complexity adjustment to the APC when certain codes attach to those claims.
- This approach would eliminate concerns about overestimating the utilization of the product because it would limit the adjustment to those claims that use the product. If the product were not used, CMS would not apply the adjustment.
- Concerns about sudden increases in overutilization could be addressed by monitoring the claims. As CMS does with the AY modifier,[69] it could use existing information about the prevalence of the condition/disease being treated.

(3) Update the adjustment amount annually by either the market basket or by the appropriate pharmaceutical proxy, just as CMS separately updates the home dialysis training add-on annually but on a non-budget neutral basis.

Because this method for calculating the adjustment is based on the average patient using the product, it is still appropriate to apply the outlier policy to these drugs or biologicals. The Proposed Rule does not indicate whether the outlier policy would apply to the products under the post-TDAPA add-on adjustment. We suggest that it should.

However, as we have noted in the past and most recently in response to the 2022 RFI, the outlier policy is not sufficient alone to address the cost of adding new products to the bundle. Rather, it is designed to address the significantly higher costs of those patients whose medical needs require the administration of certain products. If the outlier pool were used instead of an add-on adjustment, the proportion of the outlier payments associated with patients receiving any new drug would likely increase so substantially that the current base rate would be eroded. Based on its analysis of the inclusion of the first new drugs into the bundle, The Moran Company found that many patients whose treatments historically qualified for outlier payments would no longer qualify under the current policy due to the significant increase in the outlier threshold. Any new product that qualifies for the outlier pool and has a significant cost associated with it will lead to higher threshold amounts. This result will make it more difficult for the outlier pool to support the costs associated with other products, because those costs alone may no longer meet the higher threshold. This situation could lead to the outlier pool being primarily consumed by a single group of services. The problem would be substantially worse if there were no adjustment to the rate to cover the cost of the average

[69] 77 *Fed. Reg.* 67450, 67453 (Nov. 9, 2012) ("In this rule, we reiterate the purpose of the AY modifier and emphasize that we are continuing our monitoring efforts. We also indicate that we may consider eliminating the AY modifier in future rulemaking if we believe that the AY modifier is not being used for the purpose intended." To date, the monitoring has worked and the AY modifier continues to be in place.)

patients receiving the new drug or biological. Those patients the outlier pool was designed to protect would be left behind. Additionally, because the outlier policy is budget neutral, the average dialysis patient would also be harmed because the dollars intended to cover the cost of their treatments would necessarily be cut. Because the overwhelming majority of individuals who rely upon dialysis are from communities of color who already experienced severe inequities in the delivery of their health care, it is important that Medicare's reimbursement policies are not contorted to exacerbate this problem. Relying on the outlier policy to cover the cost of new products entering the bundle would expand the inequities in the delivery of health care that the Biden-Harris Administration otherwise seeks to eliminate. We appreciate that CMS recognized these concerns in the preamble of the Proposed Rule[70] and reiterate our comments in this letter to support that conclusion.

b. CMS Should Apply Its Goal of Paying More Accurately to the Post-TDAPA Payment Add-On Adjustment for Functional Category Drugs.

As noted in our response to the RFI in 2022, KCP agrees that CMS should "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."[71] Other commenters agreed with this suggestion as CMS notes in the preamble.[72] However, KCP's support was based on options in the RFI that considered the reconciliation to be linked to (1) "any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products";[73] (2) "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";[74] or (3) "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," as determined by CMS.[75] As the preamble notes, CMS did not include a blanket 35 percent cut as an option in the RFI.[76] It also notes that, "[C]ommenters expressed support for establishing a methodology that would consider the decline in estimated expenditures for

[70]Display Copy 91. ("We recognize that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries.)

[71]Display Copy 87.

[72]Display Copy 101.

[73]Display Copy 87.

[74]Display Copy 87.

[75]Display Copy 88.

[76]KCP recognizes that MedPAC made this recommendation, but it is important to distinguish the policies that the vast majority of commenters supported and the comments of a single entity.

drugs that are clinically or empirically related to the new renal dialysis drug or biological product."[77]

It is important to be as accurate as possible in the payment to avoid ESRD facilities, which are already struggling to address substantial, yet unrecognized, increases in the cost of labor from being incentivized to avoid treating costlier beneficiaries.[78] CMS should appropriately account for the funds in the base rate attributed for drugs or biologics in the same functional category when establishing the post-TDAPA payment amount. The use of an arbitrary 35 percent discount abdicates CMS' responsibility to provide adequate payment to support use of innovative products that improve quality of care, beneficiary health outcomes, and reduce costs.

KCP also supports ensuring efficiency and competition among products which a bundled system creates,[79] as well as CMS' often stated desire to refine the payment system so that it pays more accurately. "We are striving for payment accuracy, which is achieved when relative Medicare payments are proportional to relative costs." [80] KCP members and others in the kidney care community are concerned that it is not necessarily true that every existing functional category has sufficient funding in the current base rate to support the adoption of an innovative product with a 35 percent cut. Moreover, we disagree that a 35 percent cut is more transparent[81] than the options about which CMS requested comment or commenters recommended. CMS already calculated such an offset under the TPNIES policy for certain home dialysis equipment.[82] It also makes even more complex calculations to adjust the hospital inpatient and outpatient PPS bundles/packages. KCP is confident that CMS could provide accurate and transparent calculations.

A more tailored approach is needed for the ESRD PPS to address the inequities dialysis patients face when it comes to the development, adoption, and use of innovative treatment options. Any challenges the agency may experience are minimal compared to the negative impact on patients that the continuation of a payment structure that fails to adequately incentivize innovative treatment options for beneficiaries who are primarily people of color, in medically underserved areas, and low-income. Thus, we ask that CMS evaluate drugs and biologicals on a case-by-case basis rather than apply a blanket policy. We oppose adopting an

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[77]Display Copy 101.

[78]*See* Display Copy 91 (In a similar situation, CMS recognizes if the payment system does not recognize additional resources facilities require to treat more costly patients, then facilities are incentivized not to treat them. "We recognize that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries.")

[79]Display Copy 93.

[80]Display Copy 66.

[81]Display Copy 101.

[82]Display copy 33.

arbitrary reduction of 35 percent and recommend that CMS adopt an offset policy that avoids payment duplication.

It is incorrect to assume that the current bundled payment amount accounts[83] for all innovative products developed and implemented well after the base rate was established in the same way. We know from prior analyses of CMS data by The Moran Company that when CMS structured the bundle, it did not incorporate equal funding for all functional categories.

2017 Utilization by Facilities Priced at ASP+6

Functional Category	Avg. MAP per Tx
Bone and Mineral Metabolism	$ 1.09
Cellular management	$ 0.02
Access Management	$ 0.18
Anti-infective	$ 0.12
Other injectables	$ 1.37

Because CMS recognized the unique costs associated when it created the bundled rate for drugs, it should continue to recognize those differences when it establishes the offset for calculating the post-TDAPA payment add-on adjustment.

In addition, it is not appropriate to apply a policy designed in relationship to MAC-determined pricing for equipment and supplies to drugs and biologicals for which there is a market-based calculation based on ASP. The current TDAPA policy already discounts the reimbursement to facilities by using ASP+0 percent instead of the ASP+6 percent used in other payment systems. Given that ASP by definition is an average, we know that at least half of the facilities who provide a product at ASP+0 percent will be reimbursed less than actual costs. To add another 35 percent reduction is simply not appropriate. We understand that a 35 percent reduction is applied in the inpatient hospital NTAP context. The hospital payment system, however, differs in many ways from the ESRD payment system. Most notably, it has multiple bundles tied to patient-needs rather than a one-bundle-fits-all approach. It also can adjust DRG payment rates as new technologies enter the market to allow the DRG rates to reflect the cost of providing services more accurately, which the ESRD PPS cannot currently do. As a result, historically, hospital patients have enjoyed access to cutting edge technologies and drugs and biologicals, while ESRD patients have not. The ongoing inequities experienced by dialysis

[83] Display Copy 85-86 ("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. We stated that under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and that there would be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. We noted that a central objective of the ESRD PPS and of prospective payment systems in general is for ESRD facilities to be efficient in their resource use.")

patients provides ample justification to treat innovative ESRD drugs and biologicals different than devices and drugs in other health care settings.

Moreover, it is not accurate to conclude that the 35 percent cut "would have the same general effect of accounting for declines in other drug expenditures,"[84] The case-study of Korsuva, the only drug potentially eligible for this adjustment, demonstrates the problem. CMS' own data show that there is essentially no money in the anti-pruritic functional category. Under a more tailored offset, the per treatment amount would have an offset of pennies at most. However, under the CMS proposal the adjustment would be cut by 35 percent. The two policy options do not remotely have the same general effect.

CMS' concern about a future possibility of having to calculate multiple offset adjustments in the event that there could be multiple new renal dialysis drugs or biological products[85] is misplaced at this time. To date, there are only a handful of potential drugs in the pipeline. Only two have been approved by the FDA and only one has been awarded a TDAPA. We understand that there is the potential for additional products that could be in the same functional category to be approved, but if that were to occur, CMS would be able to consider any post-TDAPA payment add-on adjustment for purposes of the offset as well. Given the lack of innovative treatment options available to dialysis patients, CMS should be encouraging and supporting additional treatment options and competition. It should not be using the potential for such improvements as a reason to adopt a policy that has a high probability of stifling future innovation.

Consistent with CMS' request for comments on alternative methods for calculating an offset for this adjustment, KCP recommends, as we did in the RFI, that CMS offset the amount of the add-on adjustment by an amount that corresponds with the reduction in expenditures for other formerly separately billed renal dialysis drugs that were caused by the inclusion of the new product.

- The reduction in utilization of a product should be based on objective, clear, transparent data from available public claims data. This aspect of the recommendation would address CMS' stated concerns about transparency.

- The attribution of the reduction to a specific product(s) should be determined by reference to a predictable, objective, and transparent source, such as the FDA approved indication for each product expressly listing the same primary indication. This aspect of the recommendation would support transparency and reduce the challenges and burdens CMS believes it would incur by making such determinations.

[84]Display Copy 102.

[85]Display Copy 103.

- The offset should be linked using empirical (meaning observation or experiential) data that the change in expenditures is directly attributable to the adoption of the new product. CMS should be able to identify the offset in existing drugs, items, or services based on claims data. If it believed existing data were not available to identify such changes from the claims, CMS could rely upon clinical practice information that links the product to other items or services.

As The Moran Company has been able to demonstrate, CMS has previously released sufficient information to assess the dollars in the base rate for drugs and biologicals. CMS proposes to collect additional data as part of this rule to better understand the use or former-composite rate items and services. Thus, the data exist and can be made publicly available to undertake this process.

In response to CMS' request for suggested guardrails, KCP believes that the following policies function as appropriate and effective guardrails to "ensure any growth in post-TDAPA add-on payment adjustment amounts is reasonable."[86] These include:

- Limiting TDAPA to drugs and biologicals with certain FDA NDA types.

- Setting the per treatment payment amount based on TDAPA cost and utilization and inflating it annually using price proxies rather than simply paying it based on a quarterly ASP amount.

- Eliminating double payments by adopting an offset policy linked to the impact of the new product on existing items and services.

- Monitoring utilization over time, as it does with the AY Modifier for drugs paid outside of the bundle, to deter overutilization.

Using these guardrails will incentivize the development, use, and long-term adoption of innovative drugs and biologicals for a patient population that has not had the same access to innovation that patients with other acute and chronic diseases and conditions have been able to experience.

c. CMS Should Avoid a Policy that Establishes another Payment Cliff to Provide Sustainable Support for Innovation and Eliminate Existing Inequities in Treatment Options.

The Proposed Rule states that CMS would "calculate the post-TDAPA add-on payment adjustment annually, based on the latest available full calendar quarter of average sales price

[86]Display Copy 103.

(ASP) data."[87] However, it also states "that for each of the 3 years for which this proposed post-TDAPA add-on payment adjustment would be paid, we would update the amount of the post-TDAPA add-on payment adjustment by the ESRD PPS market basket update to account for estimated future input price changes faced by ESRD facilities."[88] It is not clear to our members if this means that the adjustment will be recalculated each year with the most recent ASP and utilization data, or if the initial calculation will be updated by the market basket or if both will occur. We ask that CMS clarify this proposal in the final rule.

However, regardless of that clarification, KCP believes it is essential to incorporate new money into the payment amount for innovative drugs and biologicals for which the amount calculated for the adjustment after the offset is greater than zero. As we have noted in previous comments, the community continues to believe that the purpose of TDAPA for functional category drugs, like that for drugs outside of functional categories, is to allow for a period during which CMS can collect data about price and utilization. Once it has sufficient data, CMS should assess whether there are sufficient funds within the payment amount to support ongoing access to the product. As KCP proposes the calculation of the post-TDAPA payment add-on adjustment, if CMS were to determine an adjustment is warranted, it means that the current bundled data at the end of the TDAPA period for the product is not sufficient to support patient access to the product. As such, the adjustment should be provided when a facility provides access to the drug to a specific patient. As noted above, this policy would be similar to the complexity adjustment used in the HOPPS. CMS does not have to adopt all of the aspects of the HOPPS payment system to support a similar policy. The modifications KCP recommends to the proposed post-TDAPA payment add-on adjustment would allow the ESRD PPS to function in a similar manner by promoting innovation, tailoring payments more accurately and closely to costs, and reduce health care inequities.

Thus, we support updating the adjustment annually using either the market basket or the appropriate pharmaceutical proxy. We note that the latter proxy would be more appropriate given that the adjustment is related to pharmaceuticals rather than all of the cost centers within the full market basket update mechanism. We do not, however, support CMS sunsetting the adjustment after three years. Such a limited time might address practice change and similar issues CMS highlights in the preamble;[89] however, just as "a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products,"[90] the sudden end of the post-TDAPA payment add-on adjustment will also likely result in a decrease in access to such products especially when the post-TDAPA analysis has shown that the entire cost of the product is not

[87]Display Copy 103.

[88]Display Copy 104; *see also* Display Copy 106 ("We are proposing that payment of the post-TDAPA add-on payment adjustment would end no later than 12 calendar quarters after the end of the TDAPA payment period for the new renal dialysis drug or biological product.")

[89]*See* Display Copy pages 92, 96-97.

[90]Display Copy page 93.

offset by existing items or services in the bundle. This would be especially true for products that address gaps in treatment and that do not reduce the need for other items or services in the bundle. We recommend CMS make the adjustment permanent to support patient access to innovative products.

6. These Recommendations Can Be Finalized for CY 2024 because They Constitute a Logical Outgrowth of the Proposed Rule.

KCP believes the recommendations outlined above would be a logical outgrowth of both the RFI which included options that align with KCP's recommendations and the current Proposed Rule request for comments on these issues. As with the forecast errors above, case law supports CMS making these modifications between proposed and final rule.

As a reminder, KCP makes three policy recommendations. First, KCP recommends that CMS calculate the adjustment amount using the number of treatments with claims for the TDAPA drug as the denominator and applying the add-on payment amount only to claims for patients who receive the product, especially when a small portion of the ESRD population medically requires the drug. Second, KCP recommends that CMS calculate the offset to the add-on amount that accounts for products in the drug's functional category that are directly impacted by the innovative product to address the situation when there is little to no money in the current payment amount to support a product. Third, KCP recommends that the adjustment extend beyond the proposed three-year sunset to ensure the long-term patient access to the drug or biological by providing facilities with long-term certainty on payment policies.

The information in the Proposed Rule is sufficient for CMS to adopt the KCP recommended methodology because the "affected parties should have anticipated that the relevant modification was possible." Along with its proposed policies, CMS also raises the alternatives that KCP and other stakeholders have recommended and sought comments on alternative methodologies to the one being proposed.[91]

This Proposed Rule differs from the final rule the Supreme Court struck down in *Allina* because CMS has clearly indicated to stakeholders that the policy is open for discussion, which was not clear in *Allina*. If CMS were to adopt these recommendations, the agency's possible course of action was "reasonably foreseeable," consistent with the standard relied upon by the court in *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). "[A] final rule is a 'logical outgrowth' of a proposed rule only if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-

[91] *Allina Health Services v. Sebelius*, 746 F.3d 1102, 1107 (D.C. Cir. 2014) (citing *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1080 (D.C. Cir. 2009) (citations omitted)). *Id.* at 1108.

comment period."[92] The purpose of the comment period is to allow stakeholders to offer alternatives that CMS could adopt a final rule. Given the recommendations can be anticipated as potential outcomes in the final rule, stakeholder could reasonably anticipate that they would be adopted.

In adopting the recommendations outlined above, CMS would also be aligned with the ruling in *Brennan v. Dickson*.[93] As noted previously, the court upheld a final rule that implemented a policy that it had specifically rejected in the proposed rule.[94] The D.C. Circuit concluded that this change from proposed to final rule "was no surprise."[95] The agency had requested comment on whether two measures should be adopted and finalized one of the measures in the end. The court concluded that the plaintiff had notice of, and opportunity to comment on, the measurement that was rejected in the proposed rule.[96] Even if CMS had not raised the options, courts have upheld different outcomes between proposed and final rules when an agency adopted a "last-minute proposal" from interested stakeholders "too late for adverse comment."[97]

Thus, CMS would be well withing the scope of the logical outgrowth doctrine to adopt the modifications to the proposed post-TDAPA payment add-on adjustment that KCP recommends in this letter.

C. The Case-Study of Korsuva Demonstrates the Importance of Adoption the KCP Recommendations.

Korsuva is the first and only FDA-approved drug to receive the functional category TDAPA under the ESRD PPS. It is also the first and only drug approved to treat CKD-aP for hemodialysis patients with moderate to severe pruritus. Approximately 35% of ESRD patients have moderate to severe pruritus.[98] Prior to Korsuva's approval, physicians had no effective

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[92] *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007).

[93] 45 F.4th 48 (D.C. Cir. 2022).

[94] In *Brennan*, the preamble to the proposed rule at issue stated:

The FAA considered and rejected a requirement to indicate the control station's geometric altitude. . . . Barometric pressure altitude is a more precise measurement than geometric altitude and is the standard altitude reference for aviation.

84 Fed. Reg. 72438, 72473 (Dec. 31, 2019) (emphasis added). However, in the final rule, the FAA abandoned the barometric pressure altitude measurement and instead implemented the geometric altitude measurement it specifically rejected in the proposed rule.

[95] 45 F.4th at 69.

[96] *Id.* at 69-70.

[97] *Great Lakes Communication Corp. v. FCC,* 3 F.4th 470 (D.C. Cir. 2021).

[98] Sukul N, Karaboyas A, Csomor PA, Schaufler T, Wen W, Menzaghi F, Rayner HC, Hasegawa T, Al Salmi I, Al-Ghamdi SMG, Guebre-Egziabher F, Ureña-Torres PA, Pisoni RL. Self-reported Pruritus and Clinical, Dialysis-Related, and Patient-Reported Outcomes in Hemodialysis Patients. Kidney Med. 2020 Nov 21;3(1):42-53.e1. doi: 10.1016/j.xkme.2020.08.011. PMID: 33604539; PMCID: PMC7873756.

treatment options for CKD-aP. Patients with CKD-aP were often given anti-histamines (like Benadryl) or corticosteroids, neither of which stopped the itch. Many patients with this condition report having given up hope for an effective treatment. Some suffer from open wounds from the scratching, leading to serious infections.[99]

CMS granted Korsuva pass-through status under the existing TDAPA framework beginning in April 2022. Importantly, Korsuva's TDAPA period is under a payment system policy that will not adjust the payment amount when Korsuva's TDAPA period ends in April 2024. As a result of this policy, KCP members, especially physicians, report that despite the effectiveness of the product for the minority of patients who would medically benefit from it, they have not prescribed Korsuva because they do not want to be in the position of stopping the prescription when the TDAPA period ends. The assumptions that physicians do not allow payment policy to affect their prescribing behavior are false. As noted above, CMS has recognized that payment drives practice in many instances. The underlying premise of payment practices is to impact utilization. Most notably, it was a foundational reason why the agency eliminated the SNF RUGs payment system and adopted the SNF PDPM only a few years ago. In that case, higher payment rates drove an increase in therapy prescriptions and a sharp decrease in the services that complex patients required.

> Moreover, we do believe that there is clear evidence that PDPM alone is impacting certain aspects of SNF patient classification and care provision. For example, through FY 2019, the average number of therapy minutes SNF patients received per day was approximately 91 minutes. Beginning almost immediately with PDPM implementation (and well before the onset of the pandemic), the average number of therapy minutes SNF patients received per day dropped to approximately 62, a decrease of over 30 percent. Given both the immediacy and ubiquity of this change in the SNF data, without any concurrent change in the SNF population, it is clear that this overall decrease in the amount of therapy services provided to SNF patients is a result of PDPM implementation and not other factors.[100]

Based on the statements from physicians across the country and the utilization seen to date, we believe that CMS's post-TDAPA "no new money" policy has resulted in severe access problems for dialysis patients with CKD-aP. To date, a very small percentage of hemodialysis patients (less than 1%) have been treated with Korsuva despite all credible data describing the prevalence of the condition at approximately 35% of hemodialysis patients.

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[99]Ramakrishnan K, et al. Int J Nephrol Renovasc Dis. 2014;7:1-12.

[100]86 *Fed. Reg.* 19954, 19986. We recognize that there may be concerns about an adjustment leading to overutilization of a particular product. We discuss the guardrails that CMS could use to avoid this scenario below.

KCP is pleased that CMS proposes to add a non-budget neutral post-TDAPA add-on adjustment. However, the proposed design of the adjustment fails to address some of the most critical barriers the current payment system creates for Korsuva. Three aspects of the policy inappropriately impact patient access to Korsuva and create barriers for other new, innovative products.

Because the proposed policy fails to direct the money to the patients who need it. CMS's example of the proposed post-TDAPA add-on payment adjustment set forth in the Proposed Rule demonstrates the problem clearly as it provides a mere 9 cents for Korsuva.[101]

In essence, CMS' proposed policy will simply perpetuate the problem that it proports to address. The proposed post-TDAPA payment policy does not provide facilities with adequate payment to support long-term budgeting and planning, hinder uptake and use of innovative therapies. It will stop dialysis patients – a majority of whom are black, in medically underserved areas, and low-income – from having access to the only effective treatment option for a serious disease that not only impact patient quality of life, and cause other serious, downstream consequences.

The proposed one-size-fits-all 35% adjustment is arbitrary and would result in offsets that are not in line with cost realities and will create inappropriate incentives that fail to further CMS's goal of accurate payment. In the Korsuva example, it is accepted that virtually no money was included in the bundle and virtually no money is currently spent managing chronic kidney disease associated pruritus. A 35% offset where no money is currently being spent is an inevitable financial disincentive to utilize Korsuva. Conversely, this one-size-fits-all approach would under adjust drugs where a more one-to-one substitution of costs is occurring and would result in the sort of windfall CMS and MedPAC hope to avoid.

A more balanced, patient-centered approach would create a drug specific offset. This recommendation is consistent with one of the options CMS included in the RFI, which received broad support across the kidney care community. In this methodology, CMS would use the data gathered during the new drug's TDAPA period to compare the relative per treatment cost of other drugs in the same functional category when the TDAPA drug was used versus when it was not used. This delta would form the basis for an accurate, drug-specific offset to the add on payment. Examples of this methodology are provided in the attached appendix. This methodology will properly account for monies in the bundle attributed to drugs in the same functional category, ensuring CMS is maintaining its fiduciary responsibility to taxpayers while supporting beneficiary's access to innovative therapies.

[101] Display Copy 107.

The final step would be to apply this adjustment only to future claims that include the HCPCS code for Korsuva without sunsetting the adjustment. This money following the patient approach would promote the right patient getting the right treatment at the right time.

As described in detail above, this modified approach does not re-instate the separately billed drug policy of the past because it uses the average cost per treatment as defined by the TDAPA utilization and the most recent ASP. It is also comparable to the HOPPS complexity adjustment which similarly directs dollars to patients who medically need them.

Without the modifications suggested, CMS's proposed policy continues to disincentivize the use of the product, while the kidney care community's proposal creates a patient-centered approach that balances the incentivize to administer innovative treatment options while reducing the potential for unnecessary expenditures. Moreover, it puts the choice of using the product in the hands of patients and physicians. As noted above, only a small percentage of ESRD patients do not already have wrap-around coverage of some type to offset the co-payment amount according to MedPAC. For patients with CKD-aP who have been living with this devastating disease without an effective treatment option, they should have the choice of using the product. In the case of Korsuva, very few patients would be required to pay the copayment because of their access to secondary coverage or Medicaid status. For those who do, the copayment amount would likely be minimal.

Unfortunately, as the TDAPA period has demonstrated, access to a product is positively or negatively affected by the payment policies CMS adopts. Without the modifications KCP suggests, the proposed post-TDAPA adjustment policy will not "support ESRD facilities in providing the new renal dialysis drug or biological product to all beneficiaries for whom it is reasonable and medically necessary."[102] We add that it would not support physicians prescribing Korsuva either.

Once the adjustment amount is determined, it should remain in place permanently and be updated annually. The proposal to end the post-TDAPA payment add-on adjustment after three years only creates another cliff that will not support continued use of the product, which the example of the post-TDAPA no new money policy during Korsuva's TDAPA period has shown to be a legitimate challenge and concern. Just as with the HOPPS complexity adjustments, CMS should apply the adjustment specific to those patients who medically require the product to ensure its continue use and address the inequities this population faces.

In the preamble, CMS raises the concern of having to apply multiple post-TDAPA payment add-on adjustments if more than one product qualifies for the adjustment. This issue is not exclusive to a permanent adjustment because the situation could also occur during the proposed three-year period before the adjustment sunsets. However, a tailored offset policy

[102] Display Copy 108.

would address this concern. If a new anti-pruritic would come to market at some point in the future, CMS would be able to use the more accurate per-treatment adjustment amount to offset the cost of the new product. Having the competition between two products, as CMS notes in the preamble,[103] would create a balance that would help limit expenditures. Moreover, if such a situation were to occur, CMS could address in future rulemaking how to appropriately adjust the post-TDAPA adjustment to account for multiple products. However, as CMS recognizes, this is only a hypothetical situation currently and the need to protect patient access to an existing treatment option to support health care equity should not be sacrificed for a hypothetical situation.

In the case of Korsuva in particular, KCP supports extending the TDAPA period for an additional two years. The current TDAPA period will expire in April 2024, and during this period the CMS policy has been not to provide new money for the product once the TDAPA period ends. This policy has severely depressed utilization such that both the utilization and the ASP amount do not reflect what the actual utilization and cost of the product would have been if providers understood new money would be added after the TDAPA period. CMS recognizes that the TDAPA period for new drugs or biologicals outside of an existing functional category "is paid until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years."[104] Given the negative impact the post-TDAPA no new money policy has had and continues to have on Korsuva adoption, CMS should collect two full years of data under the appropriate post-TDAPA funding landscape. It is imperative that utilization and ASP be established in the proper context and with the knowledge and understanding of the post-TDAPA funding before creating the post-TDAPA add-on payment adjustment for Korsuva.

D. To Support All Medicare ESRD Beneficiaries, CMS Should Align Medicare Advantage Policy with the Post-TDAPA Add-On Adjustment for Functional Category Drug Policy.

While KCP understands that Medicare Advantage (MA) program policies are beyond the scope of the Proposed Rule, we nevertheless encourage CMS to breakdown the silos between the traditional Medicare program and the MA program to support innovation for ESRD beneficiaries regardless of the program they have selected. Eliminating the inequities dialysis patients face in terms of access to innovative treatment options means supporting the long-term adoption of innovative treatment options and ensuring that MA plans recognize these adjustments. It would be tragic for prevent federal dollars meant to help dialysis patients not being spent on patient care for those patients who enrolled in MA plans and expect to receive access to the same items and services that individuals enrolled in traditional Medicare receive. We ask CMS to support KCP's efforts with the Congress to provide clear authority for CMS to

[103] Display Copy page 85.

[104] Display Copy page 96.

act to address the inequities some MA plans perpetuate by not recognizing TDAPA and, we fear, that might not recognize the post-TDAPA payment add-on adjustment CMS proposes.

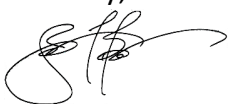
E. Conclusion

KCP supports CMS' recognition of the community's concerns and has proposed to add new money through the adoption of an add-on adjustment for TDAPA products once their TDAPA period ends,[105] but strongly encourages the agency to adopt the modifications outlined in this section of the KCP comment letter to address inequities in accessing innovative treatment options that dialysis patients continue to experience as a result of the structure of the payment system. We believe that the post-TDAPA payment add-on adjustment modified as KCP suggests would be more "in line with CMS's commitment to advance health equity by supporting access to renal dialysis services"[106] than the policy as proposed.

III. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. Our counsel in Washington, Kathy Lester, will be reaching out to schedule a meeting, but please do not hesitate to reach out to her if you have any questions in the meantime. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

cc: Meena Seshamani, MD, PhD, Deputy Administrator and Director
Elizabeth Richter, Deputy Director
Jason Bennett, Director, Technology, Coding, and Pricing Group
Ing Jye Cheng, Director, Chronic Care Policy Group

[105] Display Copy 93.

[106] Display Copy 100.

Appendix A: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Dialysis Care Center
Dialysis Patient Citizens
DialyzeDirect
Dialysis Vascular Access Coalition
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Unicycive

Appendix B: Illustrative Examples of Post-TDAPA Methodologies

Overview

- The Post-TDAPA Add-on Payment Adjustment capitated per treatment amount for the new product would be calculated based on the products ASP x Utilization.
    - The ASP would be the most recent quarter ASP at the end of the TDAPA period.
    - The utilization would be the utilization for the most recent 12-month period.
    - The per treatment amount would be determined by dividing the numerator (ASP x utilization) by the total number of dialysis treatments when the product was used. (This differs from the CMS proposal to use all dialysis treatments regardless of their including the drug/biological on the claim).
- The offset would be determined as follows:
    - Using the FDA labels and other relevant clinical information, CMS would identify drugs/biologicals that are clinically related to the TDAPA drug/biological and already in the functional category that were previously separately billable.
    - Using the most recently available claims data, CMS could determine the dollars per treatment for such clinically related drug(s)/biological.
    - The per treatment amount would be determined by dividing the numerator (ASP x utilization) by the total number of dialysis treatments when the product was used.
- Because the final adjustment is a capitation rate it would be updated by an appropriate proxy amount (most logically the appropriate pharmaceutical proxy) annually.

Rationale

- Protects patient access to innovative treatments.
    - Address the problem with the proposed methodology, especially for mid-sized dialysis facilities that would have to treat more patients than they may actually serve to support one patient receiving the product.
    - CMS would make sure that the new money added to the system would be directed to improvements in patient access or patient outcomes
- CMS would ensure that facilities receive the adjustment when the product is actually provided to the patient.
    - This avoids paying for the product when it is not provided.
    - CMS could monitor the utilization to guard against unnecessary utilization, as it does with the AY modifier. . If the utilization appears to exceed the known prevalence for the condition the drug/biological is treating, then CMS could audit the questionable claims. This monitoring is similar to how CMS has ensured that the AY modifier has not resulted in an overuse of certain drugs/biologicals that can sometimes be used for purposes other than the treatment of ESRD.
- CMS would control cost under this policy since the adjustment is a capitated amount that is not tied to a quarterly change in the ASP.

    - This approach of using a capitated adjustment aligns with how CMS uses capitated payments throughout the program.
    - Yet, because the adjustment is available only when the drug/biological is administered it promotes patient access to the product which is balanced by the monitoring to prevent unnecessary utilization.
- Tailoring the offset to the actual expenditures aligns with CMS's stated desire to pay facilities more accurately.
    - CMS offers this rationale to justify the request for facilities to report time on machine data in the Proposed Rule.
    - This approach would also avoid CMS paying twice for any new drug coming into the bundle.
    - Additionally, it would eliminate paying for a drug/biological that is not used.
- Limiting the offset to previously separately billed drugs/biologicals (including drugs/biologicals that received TDAPA) would be appropriate because the amount in the bundle for composite rate drugs is negligible.
    - The Moran Company has determined that the dollars in the current bundled amount <u>for former composite rate drugs</u> are negligible.
    - Trying to establish an offset for these products, especially since the claims and cost reports do not currently include the information necessary to calculate an offset.
    - Given The Moran Company's analysis, if a calculation for composite rate drugs were possible, the offset amount would like be essentially a "rounding error" and not worth the administrative effort to make the calculation given that it is unlikely to result in a meaningful amount to warrant and offset.
- A tailored offset would avoid potential underpayments and overpayments if a second similar product would come to market.
    - Because the first TDAPA drug/biological would be within the functional category, the per treatment amount of any additional new product that would be offset to ensure that there is no double payment.
- CMS could reassess overtime to adjust to changes in utilization or ASP the same way other adjusters are adjusted periodically.

Example calculation 1

Product Medically Needed by Small Percentage of Patients[107]

This example demonstrates that the KCP recommended policy protects patient access to a drug that is not used by the average patient while continuing to leverage the benefits of a capitated payment structure to avoid excessive expenditures. It would also address the problem with the proposed methodology, especially for mid-sized dialysis facilities that would have to treat more patients than they may actually serve to support one patient receiving the product.

A. Calculation of the post-TDAPA amount using the KCP recommended methodology

TDAPA Drug Per Treatment Adjustment Amount (before offset)

TDAPA drug ASP	$100
TDAPA drug utilization	100,000 doses
Total dialysis treatments when used	100,000 treatments
TDAPA per Treatment Cost	*$100/treatment*

Offset amount

Clinically related product in the functional category was a composite rate drug
Offset = $0

Total TDAPA Adjustment Amount (with offset)

$100-$0 = $100

This result is extremely different than the CMS calculation below. The system would create the perverse incentive not to use the innovative product. Thus, CMS would have infused new money into the system, but have no improvement in access or patient outcomes.

B. Calculation of the post-TDAPA amount using the CMS recommended methodology

TDAPA Drug Per Treatment Adjustment Amount (before offset)

TDAPA drug ASP	$100
TDAPA drug utilization	100,000 doses
Total dialysis treatments	19,500,000 treatments

[107]To simplify the calculation, the other adjusters, such as case-mix, that would apply to the calculation have not been included, but we anticipate they would be and would likely modify the final adjustment amount.

TDAPA per Treatment Cost	*$0.50/treatment*

Offset amount

The 65% risk-sharing adjustment is applied.

Total TDAPA Adjustment Amount (with offset)

(0.5) x (0.65) = $0.33

A facility would receive $0.33 for providing a $100 drug. This methodology creates the perverse incentive not to use the innovative product. This problem is particularly difficult for mid-sized dialysis facilities that would have to treat more patients than they may actually serve to support one patient receiving the product. Thus, CMS would have infused new money into the system, but have no improvement in access or patient outcomes.

Example calculation 2 – Product Medically Needed by Most Patients[108]

This example demonstrates that the KCP recommended policy protects patient access to a drug that is used by the average patient and avoids excessive CMS expenditures.

A. Calculation of the post-TDAPA amount using the KCP recommended methodology

TDAPA Drug Per Treatment Adjustment Amount (before offset)

TDAPA drug ASP	$100
TDAPA drug utilization	19,500,000 doses
Total dialysis treatments when used	19,500,000 treatments
TDAPA per Treatment Cost	*$100/treatment*

Offset amount

Clinically related product in the functional category was a separately billed drugs. Claims data with utilization multiplied by the most recent quarter of ASP+6 percent, which is publicly available, (since that is the rate at which separately billed drugs were added to the base rate). Assume that the total amount of spending calculated using the most recent ASP+6% x the utilization of the clinically related formerly separately billed drugs is $50.

[108]To simplify the calculation, the other adjusters, such as case-mix, that would apply to the calculation have not been included, but we anticipate they would be and would likely modify the final adjustment amount.

Total TDAPA Adjustment Amount (with offset)

$100-$50 = $50

B. Calculation of the post-TDAPA amount using the CMS recommended methodology

TDAPA Drug Per Treatment Adjustment Amount (before offset)

TDAPA drug ASP	$100
TDAPA drug utilization	19,500,000 doses
Total dialysis treatments when used	19,500,000 treatments
TDAPA per Treatment Cost	*$100/treatment*

Offset amount

The 65% risk-sharing adjustment is applied.

Total TDAPA Adjustment Amount (with offset)

(100) x (0.65) = $65

In this case, CMS would be overpaying for the drug..

As these examples demonstrate, CMS's methodology, if finalized, will result in the payment system dis-incentivizing the adoption and administration of innovative products, especially for patients with less prevalent conditions. This result is inconsistent with the goals and principles CMS has repeatedly indicated it wishes to achieve for individuals who rely on Medicare for coverage for kidney failure.