CY 2022 ESRD PPS Final Rule - Medicare Program; End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury: Summary of Comments in Response to Requests for Information

In the CY 2022 ESRD PPS proposed rule (CMS-1749-P; 86 FR 36322), CMS included a request for information (RFI) on several topics in order to inform payment reform under the ESRD PPS. As discussed in the CY 2022 ESRD PPS final rule (CMS-1749-F; 86 FR 61996), we noted that we would provide more detailed information about the commenters' recommendations in a future posting on the CMS website. Accordingly, the comments of the respondents are summarized below in this document. The RFI was issued for information and planning purposes. We encourage stakeholders to continue dialogue with CMS as we aim to better align resource use with payment.

Informing Payment Reform under the ESRD PPS

Over the last several years, CMS, in conjunction with its contractor, has been conducting research, including holding three technical expert panels (TEPs), to explore possible improvements to the ESRD payment model. We utilized the information from the TEPs to formulate ideas for alternative approaches and potential methodological refinements to enhance the ESRD PPS. In order to obtain additional feedback from as wide of an audience as possible, we presented the ideas and solicited comments from the public through the CY 2022 ESRD PPS proposed rule. The comments and recommended approaches will assist CMS in making refinements to the ESRD PPS through future rulemaking.

The CY 2022 ESRD PPS proposed rule RFI provided information from our previously held TEPs[1] and solicited specific feedback on the following topics: low-volume payment adjustment (LVPA), calculations for case-mix adjustment, the calculation for the outlier payment adjustment, the current pediatric dialysis payment model, recommendations for ESRD PPS and

[1] The materials from the TEPs and summary reports can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

hospital cost report modifications, recommendations for modifying the pediatric cost report, and home dialysis for Medicare beneficiaries with acute kidney injury (AKI). The background and comments received on the specific topics are summarized below. Please consult the actual RFI that is found in the CY 2022 ESRD PPS proposed rule (CMS-1749-P; 86 FR 36322), and the comments to the RFI, for further details.[2]

Calculation of the Low-Volume Payment Adjustment (LVPA) under the ESRD PPS

Background on the LVPA for the ESRD PPS

Section 1881(b)(14)(D)(iii) of the Social Security Act (the Act) provides that the ESRD PPS "shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services…" The definition of low-volume is codified at 42 CFR § 413.232(b). In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume and to determine the treatment threshold for those facilities identified.

Suggested Approaches for Calculating of the LVPA under the ESRD PPS

CMS is considering alternative approaches to the LVPA methodology. One methodology discussed utilized census tracts to identify geographic areas with low demand, which suggested increased beneficiary access by incentivizing dialysis organizations to continue operating facilities in otherwise non-viable locations. We requested responses regarding the census tract methodology. Specifically, we wanted to know 1) whether a distinction other than census tract

[2] A link to CY 2022 ESRD PPS proposed rule (CMS-1749-P) can be found on Federal Register website: https://www.federalregister.gov/documents/2021/07/09/2021-14250/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis. Comments regarding the CY 2022 ESRD PPS proposed rule (CMS-1749-P) can be found at Regulations.gov: https://www.regulations.gov/document/CMS-2021-0114-0002/comment

information should be considered; and 2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility.

Another area we explored was a low-volume and isolated (LVI) adjustment. In its June 2020 report to Congress, MedPAC recommended that the Secretary replace the LVPA and rural adjustment under the ESRD PPS with a single payment adjustment, LVI adjustment, in an effort to better protect isolated, low-volume ESRD facilities that are critical to ensure beneficiary access. A determination that a facility is low volume and isolated would be based on that facility's distance from the nearest facility and its total treatment volume. This methodology would be accomplished via a single facility-level regression approach instead of the current two-regression approach utilized by CMS. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural adjustment should be maintained.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for LVPA

All of the fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural adjustment. One small dialysis organization within a large non-profit health system responded that they are reliant upon the LVPA and the rural adjustment, and support both adjustments, albeit with modifications.

MedPAC renewed their support for the LVI. MedPAC maintained that, as the LVI has three tiers, there is reduced incentivization for gaming the payment system. Additionally, MedPAC stated their view that payment problems are a result of CMS' failure to provide clear and timely criterion for facility eligibility. MedPAC noted that CMS must ensure the LVPA methodology is transparent, including specification of the model and the results being made

publicly available. They think that this combined adjuster would distribute payments properly to LVPA facilities and would subsequently mitigate the "cliff" effect by targeting facilities more than five miles from the nearest facility, regardless of ownership.

In concurrence with MedPAC, a coalition of dialysis organizations commented that the rural adjustment should be eliminated and the LVI methodology should be adopted, as they considered the census tract methodology to be both complicated and not transparent. Three large dialysis organizations (LDOs), a non-profit kidney organization and a provider advocacy organization also supported MedPAC's LVI recommendation. One was in favor of a calculation that avoids a single cut point. Several commenters concurred with the reference to the "cliff effect" of the current LVPA policy and advocated for the retirement of the rural adjuster and allocation of payments to facilities where higher treatment costs are acquired. A network of dialysis organizations renewed their request to discontinue the rural adjustment and provide those funds to a tiered LVPA for facilities that are operating at a loss. They concurred with MedPAC that the combined adjuster would target 5 miles from the nearest facility regardless of ownership, redistributing the payments to isolated facilities and mitigating the "cliff effect." Another LDO commended the data contractor for their work during the TEP on this topic. They maintained that while the proposed LVI adjustment does not entirely remove the gaming incentive or "cliff effects" seen under the current LVPA, the tiered nature of the LVI mitigates them.

A non-profit kidney organization commented in support of replacing the current LVPA and rural adjustments with a single low-volume facility adjuster that has two tiers. The first tier would be for facilities providing less than 4,000 treatments per year while the second tear would be for facilities providing over 4,000 but less than 6000 treatments per year. They believed this system would prevent gaming and better target facilities that provide care to a vulnerable population.

A provider advocacy organization suggested that both adjustments be restructured to appropriately target independent and small facilities providing care to beneficiaries in rural areas by limiting payment of the adjustments to small and independent facilities. They suggested that the rural adjustment be limited to a smaller subset of facilities, as the cost incurred per treatment in rural facilities are lower than their urban counterparts. The organization noted that 85 percent of facilities in rural areas are owned by LDOs and further noted their view that these LDOs are able to absorb a lower rural adjustment.

A small dialysis organization within a large non-profit system commented in support of expansion of the rural adjustment to include the entire rural metropolitan statistical area and modification of the LVPA where geographic location is utilized to determine facility eligibility and the volume threshold is raised to 5,000. They maintain that adopting these measures will adequately target facilities that are in need.

Another small dialysis organization relies on the current LVPA and rural adjustment; therefore, they supported both the LVPA and rural adjustments. They expressed their view that the tiered methodology lacked common sense, and was arbitrary in nature. Instead, they supported a system similar to Critical Access Hospital programs where facilities are paid based on actual treatment costs per patient. They believed their proposal will eliminate the "cliff" effect.

Two LDOs, a provider advocacy organization, two non-profit kidney organizations and a small dialysis organization opposed the census tract methodology for the LVPA, as it contains parameters which may be difficult to quantify, including patient's willingness to travel. In addition, they believed it is complicated, lacks transparency and will not adequately target low volume facilities. One small dialysis organization stated that the eligibility for the census tract methodology is based on low population density or lack of providers. One LDO stated that the census tract methodology would mirror the same inefficiencies noted on the current LVPA

methodology, and believed it will attenuate the cliff effect and gaming incentivization. One non-profit kidney organization maintained that the proposed census tract methodology presents legitimate equity issues. The organization noted that they are "very concerned that a methodology that relies upon 'driving time' does not accurately represent the socioeconomic status and transportation needs of [their] patient population and, by extension, disregards and may exacerbate health inequities for underserved communities."

Calculation of the Case-Mix Adjustments under the ESRD PPS

Background on the Case-Mix Adjustments under the ESRD PPS

Section 1881(b)(14)(D)(i) of the Act mandates that the single payment system under the ESRD PPS implemented by the Secretary "shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors." The ESRD PPS includes facility-level and patient-level adjustments to the base rate associated with resource utilization and the cost of providing dialysis treatment. The ESRD PPS is a case-mix adjusted, bundled payment model intended to reflect total treatment costs, which consist of formerly separately billable costs and composite rate costs (75 FR 49032). The goal of case-mix adjustment is to ensure that payment for a dialysis treatment reflects expected resource use.

Current Case-Mix Methodology under the ESRD PPS

The current model uses two equations, including a patient-level equation for formerly separately billable costs and a facility-level equation for composite rate costs (75 FR 49083 through 49127). Formerly separately billable services are itemized on the ESRD facility claim, (Type of Bill: 72x) and include injectable drugs and their oral equivalents plus certain laboratory tests and supplies. Composite rate services, which are captured on the cost report, constitute approximately 90 percent of a treatment's cost, and include capital, labor, and administrative

costs plus certain drugs, laboratory tests, and supplies (75 FR 49036; 84 FR 38396). Case-mix factors in the current model include age categories, body surface area (BSA), low body mass index (BMI) indicator, onset status, and comorbidities (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome) (80 FR 68989 through 68992). Facility adjusters include wage index, low volume status, and rural status (80 FR 68972 and 69001).

Suggestions for Modifying Case-Mix Adjusters and for Allocating Composite Rate Costs in the ESRD PPS

CMS has been carefully studying MedPAC's suggestion to base the ESRD PPS on a "one-equation model" (i.e., a patient-data focused model) that accounts for variation in the cost of providing the full PPS payment bundle. CMS is not currently able to implement this recommendation for the ESRD PPS because we do not have data on the charges associated with the components of dialysis treatment costs that vary across patients in the use of the formerly composite rate services.

We solicited comments on the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim. Questions posed included which of the five composite rate cost components (i.e., age, BSA, BMI, onset of dialysis, comorbidities) are most likely to vary with treatment duration. In addition, respondents were asked if new information for these cost components should be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration. Discussions regarding the collection of duration of treatment were followed by examining the advantages, disadvantages and challenges of obtaining treatment duration information from blood urea nitrogen time on dialysis through the End Stage Renal Disease

Quality Reporting System (EQRS) (our new system that has replaced the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb)), versus collecting treatment duration through new fields on claims. The RFI also solicited input on alternative proxies for resource utilization that can be reported at the patient /treatment level.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for Case Mix Methodology

Dialysis organizations have commented over the years that CMS should remove the co-morbidities, revise the age adjustments, and revise the weight-based adjustments (BSA and BMI). In response to the CY 2022 ESRD PPS RFI, one coalition of dialysis organizations pointed out that the TEP panelists and observers have been virtually unanimous in their comments that pursuing these data elements would not identify high-cost patients, and what little variation might be identified would not be worth the burden of collecting the information. The one exception is related to weight (BSA specifically), which the coalition supported as a case-mix adjuster. They explained that using BSA as an adjuster is clinically sound, because patients who weigh more require more time to dialyze. Simply weighing each patient, which is the standard of care today, provides the necessary data to evaluate the appropriateness of this adjuster. The coalition stated that the information to claim this adjuster is also straight-forward to obtain and easy to verify.

Most stakeholders, including the national LDO organizations and independent dialysis facilities did not support the collection of time on machine data. One coalition of dialysis organizations stated they do not believe that treatment duration is necessary to establish appropriate adjusters for this population. They pointed out that the TEP (December 2019) participants and observers were virtually unanimous in their comments that pursuing this data element would be burdensome and complex, would not identify high-cost patients, and what little variation might be identified would not be worth the burden of collecting the information.

They noted that some machines may track the time, but others do not, and that requiring another obligation on dialysis professionals when the outcome is unlikely to produce a meaningfully better result is not worth the cost and time away from patients. They stated that requiring home dialysis patients, who do not have machines that record their time, to keep treatment logs is also unnecessarily burdensome and intrusive. In addition, these commenters stated that dialysis facilities staffing is based on prescribed time, not on the actual time a patient is on the machine. They stated that the prescription approach is the most rational way to determine staffing levels, because dialysis facilities do not have time on machine in advance. According to these commenters, facilities thus would only have the prescribing physician's prescription to use.

Respondents also recommended removal of the comorbidity adjustments, because they report the adjustments are not utilized. They recommended CMS refine the age and weight (BSA and BMI) adjusters to better capture and designate higher cost patients. They supported the onset of dialysis adjuster without recommending modifications. Other dialysis organizations made the same recommendations including other LDOs, a network of dialysis organizations and MedPAC. An LDO and a provider advocacy organization recommended CMS eliminate the remaining comorbidity adjustments. A small dialysis organization within a large non-profit health system commented that in their experience, BMI and some comorbidities such as heart failure and fluid overload result in longer dialysis times and that the other case-mix adjustment factors do not normally result in additional dialysis time. They stated that the current method of case-mix adjustment is objective as information comes from the patient's chart and the filed claim.

MedPAC also recommended that CMS develop a one-equation regression model, consider removing the comorbidity adjustments and revise the body size adjustment. They recommended that CMS address the inherent correlation between BSA and BMI by jointly estimating the association of BSA and BMI with treatment cost. Both BSA and BMI are

calculated based on patient height and weight. The Commission's analyses have found that their values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented.

A non-profit dialysis association agreed with MedPAC and recommended that CMS minimize resources devoted to adjusters, providing only the minimum needed to deliver quality patient care, to restore significant funding to the base rate for the benefit and care of all beneficiaries, and to focus retained adjusters only on those that are clearly linked to patient cost of care or clear barriers to access. Specifically, they recommended that: CMS retire the remaining comorbid case mix adjusters; revise the weight adjusters to maintain a low-BMI adjuster; create a high-BMI adjuster; eliminate the BSA adjuster; retire the age adjuster (which they believe is not methodologically sound and does not resonate with clinician or dialysis facility experience of care); maintain the adjuster for low volume facilities; consider expanding the adjuster to a second tier of facilities providing fewer than 6,000 treatments per year; eliminate the rural adjuster; and maintain the onset of dialysis adjuster to support the resource intensive needs of patients starting dialysis. They also recommended that CMS provide greater data and methodology transparency to ensure an ability for independent replication of ESRD PPS policies. They suggested CMS update the budget neutrality standardization factor every year by examining the actual value for the most recently available data associated with retained adjusters, as well as the prevalence of those adjusters within the Medicare dialysis population.

One commenter stated that work needs to be done to address the short-comings with the age and weight adjusters, as they believe there is no clinical reason to support the continuation of the comorbid case-mix adjusters. They stated that age and weight are not necessarily drivers of patient care needs; therefore, the comorbid adjusters should be eliminated for CY 2022.

A network of dialysis organizations expressed their longstanding concern that the case-

mix adjusters are not serving their intended policy purposes, particularly the comorbidity adjusters. The network noted that it is extremely time consuming for facility staff to obtain the diagnostic information needed to report the adjusters. While they believe it would be too preliminary to eliminate the case-mix adjusters wholesale, they recommended that CMS initiate a discussion of the adjusters that are true drivers of high costs and how the use of adjusters can be operationalized for practical purposes. They stated that the outlier pool is an important tool for supporting the treatment of high-cost patients and that questioning the extent to which the outlier pool and case-mix adjusters are redundant is reasonable.

One payment adjustment that was universally supported by commenters was the onset adjustment. However, commenters were generally less supportive of collecting information on treatment duration. A coalition of dialysis organizations did not believe that new cost components should be collected on cost reports to infer composite rate costs associated with treatment duration. They believed there is very little variation in the basic composite rate items and services across patients. In addition, cost reports focus on facility-level costs, not patient-level costs, and are not appropriate data sources for collecting data to establish patient-level measures. They stated that a cost report-based patient metric offers too much opportunity for noise rather than actual cost difference to be measured. They also found no advantage to obtaining treatment duration information from the EQRS versus through claims reporting. Because they believe there is no meaningful variation in time on machine other than perhaps when it comes to patients who weigh more, they did not think requiring time on machine to be reported is helpful or necessary to refining the ESRD PPS case-mix adjusters.

A provider advocacy organization opposed the use of dialysis treatment duration for purposes of ESRD PPS primarily because certain patients benefit from shorter, more frequent dialysis such as patients with catheter-related access issues, non-compliant patients, patients with chronic pain or diarrhea, patients suffering from certain comorbidities. They expressed

significant concern that use of dialysis treatment duration for differentiating treatment cost variability creates inappropriate incentives for certain providers to unfortunately game the system by: (1) putting patients on dialysis longer than necessary; or (2) placing patients on the cheapest dialyzer and keep them on it for all five possible hours of dialysis. Another small dialysis organization agreed, pointing out that most dialysis treatments, regardless of time, will have similar composite rate costs. In other words, they asserted that if a treatment is 3.5 hours compared to 5 hours, the composite rate costs for those treatments will be very similar. The only difference in cost between those two treatments would be 1.5 hours more use of utilities, dialysate and bicarbonate solution, machine depreciation, and a small amount of labor to check on the patient. The vast majority of labor for dialysis treatments is putting the patient on and taking the patient off of dialysis. Therefore, in both of the above scenarios, that cost will remain the same. Further, they point out that some patients will not remain for their full dialysis treatment, and short of using restraints, there is nothing that can be done to force a patient to remain for their full prescribed treatment time. Therefore, in their view, using actual treatment time for cost allocation is not realistic.

A small dialysis organization within a large non-profit health system commented that reporting treatment times will be difficult and confusing and identified many factors that would need to be outlined by CMS including: When does dialysis time start; what happens when a patient chooses to discontinue their treatment early, or has complications resulting in reduced treatment time; what happens when a facility inadvertently does not track time for a treatment; how does this information get included on a claim; and facilities would need to train staff on how to count and track time. They expressed concern about the reporting of time on machine creating opportunities for facilities to game the system by having the dialysis run an extra few minutes to move into the next highest level. For this reason, they recommended that CMS develop units of time instead of tracking the specific minutes associated with every treatment. Due to these

concerns, the small dialysis organization did not support incorporating treatment duration into the case-mix adjustment factors.

Calculation of the Outlier Payment Adjustment Under the ESRD PPS

Background on the Outlier Payment Adjustment Under the ESRD PPS

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis-stimulating agents (ESAs) necessary for anemia management. The current outlier policy was implemented in the CY 2011 ESRD PPS final rule (75 FR 49134 through 49145) and codified at § 413.237. Under § 413.237, an ESRD facility will receive an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the FDL amount, set each year by CMS.[3]

The predicted outlier MAP amounts and FDLs create thresholds where, if the outlier MAP amount per treatment on the claim is above the threshold, there will be a per-treatment outlier payment equal to 80 percent of the amount exceeding the threshold. The loss-sharing percentage was set at 80 percent in the CY 2011 ESRD PPS final rule (75 FR 49144) to make it consistent with the loss-sharing percentages in other Medicare payment systems.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to

[3] The FDL amount is the amount by which an ESRD facility's per-treatment Medicare allowable payment amount for furnishing ESRD outlier services to an adult/pediatric beneficiary must exceed the adult/pediatric predicted ESRD outlier services Medicare allowable payment amount to be eligible for an outlier payment.

account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143).

The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundled payment: (1) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (4) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (5) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended. Beginning January 1, 2021, calcimimetics became outlier services (85 FR 71405).

Suggestions for the Calculation of the Outlier Payment Adjustment under the ESRD PPS

As the outlier payments have consistently landed below the targeted 1.0 percent of total ESRD PPS payment threshold, commenters have noted that the methodology currently used to calculate the outlier results in underpayment to the providers, as money was removed from the base rate to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). Therefore, they have urged us to adopt an alternative modeling approach, one that accounts for declining trends in outlier-eligible items and services spending over time.

Over the years, CMS has received several suggested techniques that could be employed to reach the 1.0 percent target more predictably.

One of these suggestions is a calculation of "after the fact" FDLs that would achieve the 1.0 percent outlier target for each year included in the FDL calculation. This has been referred to as the retrospective FDL, which would be lower than the FDLs published in the final rule for each corresponding year. This calculation would be used for future outlier calculations.

Another suggestion included using the three most recent years to simulate FDLs and outlier payments for 2020 resulted in a simulated outlier percentage for 2020 of 0.8 percent. The actual outlier payment percentage made for 2020 claims was 0.6 percent; therefore, the alternative methodology results in an outlier percentage that is closer to the 1.0 percent target in the adult population.

CMS is considering potential revisions to the calculation of the outlier threshold to address stakeholder concerns, and issued an RFI both to seek feedback on the approach suggested above, and to solicit information that will better inform future modifications to the methodology. The RFI asked respondents to comment on how many years of data should be included in the calculation of a retrospective FDL trend to best capture changes in treatment patterns. We asked for input regarding the factors that affect the use of ESRD outlier services over time, and to what extent CMS should try to forecast the effect of these factors. The RFI also noted that ESRD beneficiaries can now choose to enroll in Medicare Advantage, and CMS requested descriptions of any anticipated effects of this enrollment change on the use of ESRD outlier services in the ESRD PPS. We also posed the issue that adoption of the suggested methodology may account for systematic changes in the use of high cost outlier items, but that inherently unpredictable changes may still push the outlier payment off the 1.0 percent target. Therefore, we requested comment on the acceptability of three possible payment adjustment methods. These include the following 1) payment reconciliation, whereby an add-on payment adjustment or a payment reduction might be necessary to bring payments in line with the 1 percent target; 2) an add-on payment adjustment that would be distributed after sufficient data

reveal the magnitude of the deviation (1 year after the end of the payment year). The distribution of these monies could be done via a lump sum or via a per-treatment payment add-on effective for 1 year. This add-on payment adjustment would be paid irrespective of the outlier claim status in that year; and 3) a payment reduction could take the form of a reduction in the base rate, also to be applied 1 year after the end of the payment year.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for Calculation of Outlier Payments

For years, commenters have expressed concern that the outlier target has not been achieved and urged us to reduce the percentage and increase the base rate to account for the difference between estimated actual outlier payments and the amount targeted. For the CY 2022 ESRD PPS RFI on outlier payment, we received comments from major national patient and provider organizations. The commenters pointed out that outlier payments under the ESRD PPS have not achieved the 1 percent target since the system was implemented. They suggested various strategies for addressing the outlier policy including: reducing the outlier target percentage to 0.5 or 0.6 percent and factoring in the difference between the targeted amount and estimated actual amount into a subsequent year's withhold amount and a grant program to support provider activities aimed at reducing health disparities. One LDO suggested that we reduce the withhold amount from 1.0 percent to an amount that equals the amount paid out in the prior year and reduce a subsequent year's withhold amount by the difference between the targeted amount and estimated actual amount.

A non-profit dialysis association pointed out that including the transitional drug add-on payment adjustment (TDAPA) payment for calcimimetics in the calculation for the outlier pool will result in CMS withholding an even greater amount of dollars from the ESRD PPS that, based on the long history of poor performance in the outlier pool, will not be paid out to facilities. They stated that because drugs paid through the TDAPA (including calcimimetics)

and devices paid through the proposed transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) are *not eligible* for the outlier pool, any increase in the withhold for the outlier pool because of the TDAPA or TPNIES will have no correlation to utilization of the outlier pool. Suggestions included excluding TDAPA and TPNIES payments in the outlier calculation methodology. Commenters also recommended that a mechanism should be established to return unpaid outlier amounts to the ESRD PPS.

While some organizations agreed using a retrospective FDL trend determined with historical utilization data would yield outlier thresholds that achieve the 1.0 percent outlier target, they remained concerned that changes in utilization or price increases for new and innovative products could move the thresholds in directions not anticipated when the withhold is calculated. MedPAC suggested that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend in spending over time for items in the ESRD bundle that were separately billable prior to 2011.

The RFI also solicited comments on any anticipated effects enrollment changes in Medicare Advantage (MA) plans might have on the use of ESRD outlier services. A coalition of dialysis organizations pointed out that to the extent that MA plans are not permitted to systematically include healthier ESRD patients and exclude costly patients, there would seem to be little impact on the outlier pool from the shifting of patients between fee-for-service to MA. However, they expressed concern that the decision to modify network adequacy standards that apply to nephrology care and eliminate network adequacy rules designed to protect patients' access to dialysis facilities will discourage many patients from enrolling in MA plans, especially those that might need more specialized treatment or require additional medications. To the extent this scenario was to occur, it could result in “outlier” patients remaining in traditional Medicare and the healthier patients enrolling in MA plans.

Calculation of the Pediatric Dialysis Payment Adjustment Under the ESRD PPS

Background on the Pediatric Dialysis Payment Adjustment under the ESRD PPS

Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment for pediatric providers of services and renal dialysis facilities. In the CY 2022 ESRD PPS RFI, we discussed the current ESRD PPS regarding ESRD facilities that furnish renal dialysis services to pediatric patients, and requested information on specific approaches as well as other topics related to developing a pediatric payment adjustment under the ESRD PPS.

Current Pediatric Dialysis Payment under the ESRD PPS

In the CY 2016 ESRD PPS final rule (80 FR 68968), we refined the ESRD PPS in accordance with section 632(c) of ATRA, which required CMS to conduct an analysis and make appropriate revisions to the case mix payment adjustments. We analyzed the case-mix payment adjustments under the ESRD PPS and revised the payment adjusters using CYs 2012 and 2013 ESRD claims and cost report data. For pediatric dialysis, we used the same methodology that was used for the CY 2011 ESRD PPS final rule, except for the use of more recent data years (2012 through 2013) and in the method of obtaining payment data. Specifically, we used the projected MAP based on 2013 claims to calculate the ratio of pediatric total MAP per session to adult total MAP per session. The resulting adjustment factors reflected an 8.21 percent increase to account for the overall difference in average payments per treatment for pediatric patients. The pediatric adjusters that were finalized for CY 2016 and are currently in effect are:

<13 peritoneal dialysis =1.063

<13 hemodialysis =1.306

13-17 peritoneal dialysis = 1.102

13-17 hemodialysis = 1.327

Suggestions for the Calculation of the Pediatric Dialysis Adjustment under the ESRD PPS

Since 2015, we have continued to hear from organizations associated with pediatric dialysis about their views that Medicare undervalues pediatric ESRD care, which requires significantly different staffing and supply needs from those required to deliver ESRD care to adults. Stakeholders have expressed concern that costs unique to pediatric dialysis are not adequately captured in current cost reports or claims and suggested that an alternative payment methodology be considered. During the December 2020 TEP, three approaches were discussed that could potentially lead to a more accurate estimate of pediatric dialysis costs under a revised payment model: (1) the addition of pediatric-specific case-mix adjustment multipliers; (2) the creation of a separate payment bundle for pediatric ESRD treatment costs; and (3) revisions to current data collection practices.

To illustrate how the refined model would incorporate the pediatric population, the contractor applied the model using each of the two current age groupings, resulting in an increased effect of age on costs, with multipliers of 1.61 and 1.74 for age <13 years and age 13 to 17 years, respectively, compared to the reference adult population.

Request for Information on the Calculation of the Pediatric Dialysis Adjustment under the ESRD PPS

The RFI solicited information regarding specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations. Other questions we asked were whether the magnitude of total costs and pediatric multipliers reflect ESRD facilities' actual incurred costs, and if not, what specific costs are not being reported on claims and/or cost reports. We sought input on whether there were specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations. We also asked if there is sufficient variation in composite rate costs among pediatric patients to justify use of a proxy to distribute facility-level composite rate costs to individual treatments. We requested information regarding alternate proxies to consider if

duration of treatment is not a valid proxy for composite rate costs per treatment. We requested input on the issues facing pediatric billing and accounting staff with regard to completion of claims and cost reports, and information on how these problems can be remedied. We asked if there are additional cost factors for pediatric patients that are not adequately captured on the 72X claim.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for Pediatric Dialysis Payment Adjustment

In the CY 2022 ESRD PPS RFI responses for calculation of pediatric dialysis payment adjustment, all the commenters agreed that the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD bundled payment and existing pediatric multipliers. A few commenters recommended streamlining the reporting for claims and cost reports. A physician association stated that hospitals often triage their cost reporting obligations focusing on those that affect reimbursement over those that do not. The association further stated that this fact is true when it comes to pediatric dialysis costs as well, noting that despite efforts to educate reporting and billing staff, many hospitals have often made an administrative decision that the burden and complexity of reporting outweighs any revenue generated. As a result, the commenter asserted that hospitals expend very few facility resources on collecting these data and recommended that we streamline the reporting required and make it more consistent with reporting required from the state Medicaid programs or the private payers.

The commenters, including a coalition of dialysis organizations, a professional organization of pediatric nephrologists, a professional organization of nephrologists, a national organization of patients and kidney health care professionals, a non-profit dialysis association and a network of dialysis organizations, do not believe that using duration of treatment is a valid proxy for composite rate costs. The commenters stated that there is no meaningful variation in

time on machine other than perhaps when it comes to patients who weigh more. In addition, they expressed concern that collecting time on machine is that it will be extremely burdensome to providers and patients. In addition, they stated that for patients at home it is intrusive to ask them to record their time on machine. Commenters expressed that the requirement to fill out logs (paper or electronic) fosters a level of frustration and implies a culture of mistrust.

Alternatively, a professional organization of pediatric nephrologists and a national organization of patients and kidney health care professionals recommended that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs for pediatric patients. They provided the following list of pediatric comorbidities for CMS: failure to thrive/feeding disorders, noting that 80 percent of children under 6 years of age require a G-tube and feeding pump for management of oral aversion or supplemental enteral nutrition to promote growth and ensure appropriate cognitive development; congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal); congenital bladder/urinary tract anomalies; non-kidney solid organ or stem cell transplant; neurocognitive impairment; global developmental delay; cerebral palsy; seizure disorder; chronic lung disease (including dependency on CPAP and ventilators); and, inability to ambulate or transfer.

Both organizations also suggested that the costs of pediatric care can be broken down into the following age groups: <6 years old, 6-11 years old, and 12-18 years old. They stated that treating a young child of small size usually requires more staff resources and specialized equipment than treating the typical older and larger pediatric dialysis patient and that, generally, care becomes less resource-intensive as the child becomes older, more cognitively mature, and approaches adult body size. A provider advocacy organization, a professional organization of nephrologists and a coalition of dialysis organizations, and a non-profit kidney organization also expressed support for the suggested age groups.

In addition, a professional organization of pediatric nephrologists also agreed that given the extremely small number of pediatric patients contributing to the entire data pool by which multipliers would be calculated, any multiplier derived with combined pediatric and adult data would essentially only reflect the adult population.

One non-profit dialysis association stated that other payment mechanisms, such as Medicare Advantage, have adjusters that aim to target high cost patients and do not require providers to report burdensome information for all treatments to deliver care. They believe these are superior models than the current ESRD PPS adjusters that they believe either randomize payment or cause funds to leak from the ESRD PPS because payment adjusters often go unreported.

Modifying the Cost Report for Pediatric and Adult Dialysis under the ESRD PPS

Background on Cost Reporting for Pediatric and Adult Dialysis Under the ESRD PPS

Since January 1, 2011, Medicare has paid for renal dialysis services under a single prospective payment system bundle. The ESRD PPS bundle has two components. They are the composite rate services and the separately billable services. The composite rate services are those directly related to the dialysis treatment, such as labor, equipment and supplies; the separately billable services include Part B drugs and biologicals. CMS implemented the "fully case-mix adjusted" ESRD PPS. The ESRD PPS base rate was adjusted to reflect patient and facility characteristics that contribute to higher per treatment costs. The payment adjusters for the ESRD PPS are derived from both the Medicare cost reports and the 72x dialysis claims data. The level of payment each adjuster receives is determined by a two-equation, regression-based model. By law, the ESRD PPS base rate is adjusted annually by an ESRD market basket increase factor reduced by the productivity adjustment.

Pediatric composite rate costs are not differentiated from adult costs on hospital cost reports; however, some pediatric-specific costs are itemized on the existing free-standing cost report. Our research has shown, pediatric treatments are more expensive to administer than adult treatments (e.g., pediatric dialysis supplies than for adult supplies). Further analysis, however, revealed that a substantial portion of facilities do not differentiate between adult and pediatric costs in their cost report accounting. Overall, we found that 13 percent of facilities that treat both pediatric and adult dialysis patients do not differentiate costs between the two age groups.

Current Cost Reporting for Pediatric and Adult Dialysis Payment under the ESRD PPS

Currently, six component costs of dialysis treatment are recorded in the cost report. They are capital, direct patient care labor, administrative, drugs, laboratory tests, and supplies. Composite rate costs constitute 89 percent of total treatment costs, while formerly separately billable costs, mostly drug costs, but also including some lab tests and a small portion of

supplies, comprise the remaining 11 percent. The bundle of essential services included in the composite rate are not itemized on the 72x claim. These costs can only be determined from the cost report. Differentiating how these costs vary at the patient level is essential to the efforts to develop a more refined payment model.

Request for Information on the Modifications of Cost Reports for Pediatric and Adult Dialysis Under the ESRD PPS

We solicited recommendations for modifying the cost report information pertaining to pediatric patients, along with the ESRD PPS and the hospital cost report, to allow for differentiation between the primary cost drivers of labor, capital and supplies by different dialysis modalities or by adult and pediatric dialysis. We want to obtain more precise information on the allocation of dollars in the base rate, including the components of the composite rate, to refine the ESRD PPS.

We asked for recommendations for cost report modifications pertaining to pediatric patients, including what degree of specificity is needed in the reporting of pediatric dialysis costs. We requested specific input as to whether there are dialysis supply costs associated with the treatment of pediatric patients that cannot be reported currently on the cost reports. We inquired whether ESRD facilities that administer dialysis to both adult and pediatric patients could differentiate dialysis supply costs for adult versus pediatric patients, and if so, what specific high-cost supplies unique to the treatment of pediatric patients could be used to isolate additional costs related to pediatric dialysis. We asked if ESRD facilities would prefer that the cost reports include additional specific items for pediatric supplies or a separate section for supply costs associated with pediatric dialysis. We requested input regarding the differentiation of dialysis labor costs for adult versus pediatric patients, and potential cost report revisions to identify costs unique to the pediatric population (for example, revisions to items and services being reported; format revisions to help facilitate reporting on pediatric costs). We asked about

obstacles ESRD facilities face in reporting pediatric specific costs of dialysis treatment and suggestions for overcoming them. Since pediatric dialysis patients comprise a small number of patients in ESRD facilities other than children's hospitals or medical centers we asked for suggestions on reporting pediatric dialysis costs in nonspecialized ESRD facilities that predominantly serve adult patients without undue burden on the provider.

In addition, the RFI discussed potential revisions to the Independent Dialysis Facility Cost Report (CMS Form 265– 11). These include changes in the reporting of composite rate components: 1) capital costs for dialysis machines and related equipment; 2) stratification of direct patient labor costs; 3) differentiation of administrative and managerial costs; and, 4) differentiation of separately billable from composite rate laboratory and supply costs. Regarding costs for capital-related assets that are dialysis machines, the RFI queries included improved cost report instructions for purchased equipment, including purchase price, depreciation, maintenance, repair, insurance and replacement. We also requested information on cost stratification of capital-equipment by setting and modality.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for Modification of Cost Reports for Pediatric and Adult Dialysis under the ESRD PPS

In the current responses to CY 2022 ESRD PPS RFI for modifying the cost report information pertaining to pediatric patients, commenters support updating the cost report to allow facilities to include costs that cannot be currently reported on the cost report. Specific recommendations included breakdown of patient age groups, pediatric-specific dialysis supplies, additional overhead at hospital outpatient dialysis facilities, psychosocial support, specialized pharmacy needs and costs unique to the pediatric population for home dialysis.

With regard to the cost reporting questions and approach, a professional association of pediatric nephrologists and other respondents suggested the following changes be made to the cost reports to better capture pediatric-specific costs.

- Include Breakdown of Patient Age Groups (page 2, line 3)- This would include the following: less than 6 years old; 6 to 11 years old; 12 to 18 years old; 19 to 25 years old (includes addition to adult care); and, 26 years of older, if neuro-cognitive challenges or other medical challenges that require specialized care at the pediatric center.
- Pediatric-specific Supplies (page 4, line 9)- Respondents agreed and noted that while most supplies needed in pediatric ESRD care are also used in adult dialysis, pediatric facilities need to be stocked with a wider array of equipment and supplies to care for patients who range in size from infants to fully-grown adolescents of adult size. Categories of supplies for which there is a significantly increased cost for the pediatric population include: pediatric dialyzers and special lines (pediatric, neonatal), catheter kits, fistula needles, saline flushes, monitors for vitals, blood pressure cuffs and CritLine supplies for safe fluid removal. A unique pediatric supply cost includes items, like books and crafts, used to occupy and gain cooperation of children throughout the dialysis session.
- Facility Employees (page 2, lines 21-31)- Commenters to the RFI noted that while adult and pediatric centers employ many of the same categories of employees, staff who treat children must have specialized training in pediatric care. Additionally, adult units rely heavily on dialysis technicians, whereas technicians are rarer in pediatric facilities due to the complexity of care. The specialization of staff reduces the potential pool of qualified individuals and increases personnel costs. The concern being that the expense to hire and retain such staff in pediatric dialysis facilities and the cost of retaining these resources is not currently captured by claims or cost reports. Another staffing issue noted by was that the ratio of staff used to dialyze pediatric patients (1:1 or 1:2) differed significantly from adult units (1:4 to 1:6). It was suggested that CMS add the following categories: registered nurses with pediatric experience; pediatric dieticians; child life specialists.

The TEP considered adding certain staff categories to CMS Form 265-11, Worksheet S-1, Lines 21-31(Renal Dialysis Facility—Number of Employees (Full Time Equivalents)). A provider advocacy group suggested the form should account for the cost differences by identifying costs for the following: psychosocial supports including child life specialists; creative arts therapists; psychologists; school liaisons; pediatric dietitians (with frequent evaluation to assess and promote caloric intake and growth); nursing personnel; and clinician personnel, including highly skilled pediatric nephrologists and pediatric nephology nurse practitioners. Additional recommendations included pediatric-specific lines in the cost report for administration, management and other unique pediatric costs.

The professional association pointed out that in facilities that typically serve adults, there are already greater resources devoted to filing the cost report than in children's hospitals, and the extremely small number of children requiring this data from any single non-pediatric dialysis unit should make the likelihood of undue burden very small. In a unit that almost exclusively dialyzes adults, it should also be easier to break down pertinent costs for outliers such as pediatric supplies. Moreover, since many of these adult facilities do not have pediatric specific services but attempt to fit their pediatric patients into their usual adult care structure, there may be limited pediatric-specific costs to report in the first place.

A coalition of dialysis organization and a non-profit dialysis association supported these recommendations related to cost report changes related to pediatric patients. They stated that CMS should not consider a requirement reporting on all labor categories by adult and pediatric populations because this level of granularity is excessive. One non-profit dialysis association stated that they are sympathetic to the fact that pediatric patients are few and the costs associated with their care can be greater than and more variable than the adult dialysis population. They were supportive of CMS identifying these pediatric costs and ensuring that adequate costs are conveyed to providers to deliver quality pediatric dialysis care. They stated that it is likely that

these costs were never captured accurately in the ESRD PPS. They believed the base rate has historically been underfunded for adults and stated that we should make any such changes in a manner that is *not* budget neutral and should add funds, as needed, to ensure appropriate care for children with kidney failure.

One provider advocacy organization stated that a significant amount of the costs incurred by outpatient hospital-based pediatric dialysis units do not vary at the patient level but rather vary at the facility level. Specifically, higher overhead costs, psychosocial support, a higher nurse-to-patient ratio with more registered nurses than technicians and other highly skilled pediatric nephrologists and pediatric nephology nurse practitioners, unique and specialized pharmacy needs not covered by Medicare, including electrolytes supplements and others. The organization stated that the costs of delivering high-quality care to pediatric patients are distinct and separate from the cost of care delivery for adult patients. Therefore, they suggested that the cost report information pertaining to pediatric patients should account for the cost differences by identifying costs for the aforementioned categories. The organization also stated that home dialysis is the primary modality for pediatric patients and the current Medicare payment system does not adequately cover the equipment, supplies, training, and nursing costs necessary for pediatric home dialysis.

The professional association stated that freestanding children's hospitals generate limited revenue from this population and do not have other Medicare patients outside of the ESRD population so they may lack resources and expertise with Medicare cost reporting.

Despite best efforts to educate reporting and billing staff, several commenters noted that hospitals often triage their cost reporting obligations, focusing on those that affect payment over those that do not; they stated that this is particularly true with pediatric dialysis costs. In order to improve reporting, the commenters recommended streamlining the reporting required and making it more consistent with reporting required from the state Medicaid programs or the

private payers.

In the current responses to RFI for modifying the ESRD PPS and Hospital Cost Reports for non-pediatric patients, we received input from ten stakeholders consisting of large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; an independent commenter; and MedPAC suggesting revisions. All the commenters expressed support for making improvements to the cost report that will improve accuracy of information collected that informs payment policy. Additionally, commenters recommended CMS consider modifying hospital cost report reporting instructions to ensure complete, consistent, and accurate data reporting as well as make timely updates to reflect policy changes like TDAPA and TPNIES. Commenters overwhelmingly cautioned CMS that prior to making changes, it should weigh the burden of data collection against the benefit to the system in collecting it.

Modifying Payment Methodology and Site of Services Provided to Medicare Beneficiaries with Acute Kidney Injury (AKI)

Background on Medicare Payment for AKI

On June 29, 2015, the Trade Preferences Extension Act (TPEA) was enacted. In the TPEA, Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and may be adjusted by the Secretary on a budget neutral basis for payments under section 1834(r) of the Act by any other adjustment factor under section 1881(b)(14)(D) of the Act. In CY 2017 ESRD PPS final rule (81 FR 77870 through 77872), we finalized the AKI

dialysis payment rate.

Current AKI Payment Methodology under the ESRD PPS

Dialysis treatments furnished to AKI patients in outpatient dialysis facilities are paid by Medicare under the ESRD PPS according to the following formula: Payment = ESRD PPS Base Rate * [Labor Share*Hospital Wage Index + (1-Labor Share)]. Payments for AKI treatments do not include ESRD adjustments/add-ons for case-mix, low-volume status, rural status, outlier, TDAPA, TPNIES, and self-dialysis training. Currently, there is no payment for AKI patients for home dialysis.

Although Medicare does not limit the number of paid treatments for AKI, as is done for ESRD treatments, the treatment patterns for AKI-D and ESRD do not noticeably differ from each other, as the average number of treatments per week for each population are all in the range of 2.68 to 2.85.

Request for Information on Calculating the AKI under the ESRD PPS and for Modifying the Site of Services Provided to Medicare Beneficiaries with AKI

During previous rulemaking cycles, we received several comments, including concerns from ESRD facilities; national renal groups, nephrologists, and patient organizations; patients and care partners; manufacturers; health care systems; and, nurses regarding the site of renal dialysis services for Medicare beneficiaries with AKI. CMS solicited feedback from the public on the differences in care for patients with AKI versus patients with ESRD and whether it has bearing on the ability of patients with AKI to perform home dialysis safely. We request any additional comments regarding potentially modifying site of renal dialysis services and inclusion of payment for AKI in the home setting.

Public Comments Received in Response to the CY 2022 ESRD PPS RFI for AKI

The current responses to the RFI for modifying site of service provided to Medicare beneficiaries included numerous requests to allow payment for home dialysis for patients with

AKI. Of the 16 total comments received on this topic, 15 discussed modification of the site of service requirements, to include payment for AKI patients to receive home dialysis, with commenters supporting payment for AKI patients receiving dialysis at homes, including skilled nursing facilities. Two LDOs, two provider advocacy organizations, two small dialysis organizations, national organization of patients and kidney health care professionals, provider coalition, a non-profit dialysis association, a non-profit organization of ESRD networks, a kidney disease patient organization, a professional association, a device manufacturer, a home dialysis alliance, and a home dialysis services organization favored modification of site of service requirements to include payment of home dialysis for AKI patients when deemed appropriate by the beneficiary's physician. The not-for-profit dialysis organization believed allowing AKI patients to dialyze at home allows for greater freedom and improved quality of life for beneficiaries.

A home dialysis services organization, which provides staff-assisted home dialysis to hundreds of SNF residents in several states, commented that AKI patients in SNFs should have access to onsite home dialysis. A small dialysis organization within a large non-profit health system stated that home should be defined as the patients' skilled nursing home; the organization provides dialysis services to skilled nursing facility patients through their home care programs. A home dialysis stakeholder alliance stated that AKI patients should be afforded the opportunity to dialyze at home, including payment for SNFs as a site of care for home dialysis.

An LDO and a non-profit dialysis association recommended that a new AKI modifier be identified for laboratory tests and pharmaceuticals used by AKI patients. A distinct AKI modifier would allow CMS and providers to track utilization of key products and services by AKI patients to better inform policy in future rulemaking. They asked that such modifiers be appropriately flagged in rate setting and standard analytic data files to ensure transparency to the public for the

purpose of analysis. They stated that the "AY" modifier should not be used on AKI claims. In addition, they also recommend modifying the dialysis facility cost reports to more accurately capture data related to AKI. Specifically, new rows should be added to Worksheet D for AKI hemodialysis treatments and peritoneal dialysis treatments. The instructions should explain that AKI treatments are to be reported separately from all other ESRD dialysis treatments. The Network Fee should not be removed from the AKI payments. The Networks are charged with focusing on patients with ESRD, and as noted above, should not be applied to AKI payments. Thus, payment rates should be reported without a reduction for the Network Fee.

In addition, the non-profit dialysis association stated that physicians agree that greater monitoring of individuals with AKI receiving dialysis is necessary. Thus, the frequency with which some lab tests are provided, and the amount of labor involved in monitoring patients may be significantly different than what we know about individuals with ESRD. The association appreciated that CMS has indicated a forthcoming monitoring program for AKI patients, and would like to work with CMS to develop parameters for such a program. The association, two LDOs and a coalition of dialysis organizations also requested CMS make publicly available data on AKI patients treated in outpatient settings via the AKI monitoring system to allow better understanding of AKI patients.

Several commenters, including a home dialysis stakeholder alliance, an LDO and a national organization of patients and kidney health care professionals noted the importance of appropriate training and Medicare payment for AKI home dialysis via the addition of training codes (CPT 90989 and 90933) being added to the telehealth list. In addition, a small dialysis organization within a large non-profit health system, a coalition of dialysis organizations and a professional association requested payment for training AKI patients for home dialysis. A device manufacturer requested home training payment for hospital and ESRD facilities treating

AKI patients. A professional association noted that nephrology nurses can treat this population in their own homes with proper payment.

A policy and legal advocacy coalition of industry stakeholders campaigned for utilization of digital health tools for AKI patients.