CY 2024 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 Regarding the ESRD PPS Low Volume Payment Adjustment

In the CY 2024 ESRD PPS proposed rule (88 FR 42430), CMS included a request for information (RFI) on several topics in order to inform payment reform under the ESRD PPS. In the CY 2024 ESRD PPS final rule (CMS-1782-F), 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. The comments and recommended approaches may assist CMS in making refinements to the ESRD PPS through future rulemaking, though CMS will not be responding to the information provided by the commenters in response to the RFI. We encourage interested parties 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 2024 ESRD PPS proposed rule. The comments and recommended approaches will assist CMS in making refinements to the ESRD PPS through future rulemaking. The CY 2024 ESRD PPS proposed rule RFI provided information from our previously held

TEPs[1] and solicited specific feedback on the potential improvements to the low-volume payment adjustment (LVPA). The background and comments received on the specific topics are summarized below. For more background on the LVPA and additional details of the potential alternative approaches, please consult the actual RFI that is found in the CY 2024 ESRD PPS proposed rule (88 FR 42430)[2] and the actual comments in response to the RFI.[3]

Calculation of the (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). The current amount of the LVPA is 23.9 percent.

Summary of Current Issues and Concerns:

MedPAC, the GAO and other interested parties have expressed their concern that the treatment count threshold introduces a cliff effect, incentivizing ESRD facilities to restrict their patient count to below 4,000 treatments per year in order to receive the payment adjustment. As a result, these interested parties have requested that CMS consider geographic isolation of ESRD facilities as part of the determination of LVPA eligibility. Interested parties have also criticized LVPA eligibility criteria as too rigid and suggested flexibility would be appropriate in certain circumstances. Some even suggested that

[1] The materials from the TEPs and summary reports can be found at https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-reports-and-educational-resources

[2] The CY 2024 ESRD PPS Proposed Rule can be found at https://www.federalregister.gov/documents/2023/06/30/2023-13748/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis.

[3] Public Submission Document metadata can be found at http://www.regulations.gov.

the attestation process is too burdensome and may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.

CMS explained that because our analysis showed that isolated low volume facilities do not face higher costs as compared to other low volume facilities, and CMS is statutorily limited to the language included in Section 1881(b)(14)(D)(iii) of the Act, commenter concerns must be addressed via a separate payment adjustment than the LVPA. Possible refinements were discussed during previous TEPs held by CMS. CMS also requested information in the CY 2022 ESRD PPS proposed rule to inform future LVPA payment reform.

Suggested Approaches for Calculation of the LVPA under the ESRD PPS:

CMS is considering alternative approaches to the LVPA that include an additional payment adjustment for isolated and low demand facilities that would reduce burden, eliminate negative incentives, and target ESRD facilities critical for beneficiary access. CMS solicited comments in the CY 24 ESRD PPS notice of proposed rulemaking (NPRM) regarding several possible modifications to the LVPA methodology. CMS provided commenters the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function.

The first methodology discussed the possibility of maintaining a single threshold for the LVPA, where ESRD facilities that fall below the treatment threshold would continue to receive payment, and payments would not be adjusted for those ESRD facilities above the threshold. We suggested that the 4,000-treatment threshold could be maintained and recalibrated to 17.6 percent using the latest available cost and claims data, or the treatment threshold could be reduced to 3,750 treatments to maintain the 23.9 percent payment adjuster. The second methodology discussed potentially creating a tiered payment adjustment that would include multiple thresholds, with separate adjustments calibrated so that ESRD facilities in tiers with the lowest treatment volume would receive the highest payment adjustment, and vice versa. We suggested possible structures for these tiers, including four-tier and eight-tier systems (see

figures below) that either reduced the ESRD PPS base rate to maintain budget neutrality, or adjusted the thresholds in order to maintain LVPA payments at the current level. The third and final potential methodology discussed establishing a continuous function to adjust LVPA payments, under which ESRD facilities with the lowest treatment volume would receive the highest payment adjustment, and the payment adjustment would decrease continuously as volume increases. We suggested that this function could include a calibration point at which the payment adjustment becomes zero to correspond with the existing 4,000 treatment upper bound, or that a new upper bound is established based on a regression analysis. We requested responses regarding the single threshold, tiered approaches, and the continuous function methodologies described above. Specifically, CMS sought input on the following:

- Regarding concerns about a payment cliff in the existing LVPA, we are considering implementing payment tiers or a continuous adjustment, based on treatment volume, in place of the current single tiered adjustment.
    - Please comment on which payment structure would be more appropriate: single threshold as currently employed, tiered structure, or continuous function, and provide the reasoning behind your recommendation.
    - Please also comment on which option would be most effective in removing gaming incentives, and which option would bring greater congruence between cost of providing renal dialysis services and payment.
- Using the alternative methodology described above, under a tiered or continuous payment adjustment, the treatment threshold for eligibility would be determined based on the median treatment count among all ESRD facilities (approximately eight thousand treatments per year). The resulting tiers and incremental payment adjustments between tiers could follow several different configurations.

- What factors should be evaluated to best determine the treatment count threshold, as well as the tiering structure? Specifically, comment on the treatment volume beneath which per-treatment costs begin to increase.
- Please enumerate any concerns you might have should the implementation of a tiered or continuous adjustment result in an expanded set of eligible ESRD facilities, and payment redistribution.

- Interested parties have voiced concern regarding the administrative burden involved in the current LVPA attestation process. As such, we are considering potentially decreasing the number of years of attestation data needed to determine LVPA eligibility.
  - Please comment on the extent to which this change would alleviate burden, and if there are other administrative changes that could be made to simplify this process.
  - Please describe any anticipated effects of decreasing the amount of treatment volume data used to determine LVPA eligibility. Please describe the ways that simplifying the attestation process could help ESRD facilities with fewer resources to promote health equity by improving their ability to serve vulnerable and underserved communities.

LVPA Adjustment with 4 Tiers

Tier	LVPA Adjusters (without Scaling)	LVPA Adjusters (with Scaling)	Number of Eligible CCNs
Tier 1 (less than 5,000)	13.7%	5.8%	767
Tier 2 (5,000 – 5,999)	8.4%	3.6%	331
Tier 3 (6,000 – 6,999)	4.7%	2.0%	332
Tier 4 (7,000 – 7,999)	1.9%	0.8%	318

LVPA Adjustment with 8 Tiers

Tier	LVPA Adjusters (without Scaling)	LVPA Adjusters (with Scaling)	Number of Eligible CCNs
Tier 1 (less than 1,000)	123%	40.5%	22
Tier 2 (1,000 – 1,999)	57.6%	19%	69
Tier 3 (2,000 – 2,999)	33.9%	11.2%	137
Tier 4 (3,000 – 3,999)	21.4%	7.1%	250
Tier 5 (4,000 – 4,999)	13.7%	4.5%	290
Tier 6 (5,000 – 5,999)	8.4%	2.8%	331
Tier 7 (6,000 – 6,999)	4.7%	1.5%	332
Tier 8 (7,000 – 7,999)	1.9%	0.6%	318

Another area we explored was a new payment adjustment that accounts for isolation, rurality, and other geographical factors. The new geographically based payment adjustment could possibly consider local dialysis need (LDN) instead of basing payment strictly upon a rural designation, as set forth in § 413.233 and 413.231(b)(2). The methodology suggested utilization of census tracts to identify geographic areas with low demand, then calculating latent demand by multiplying the number of beneficiaries near ("near" is defined by driving time to ESRD facilities) an ESRD facility by the average number of treatments for ESRD beneficiaries. The threshold could then be applied by determining the threshold of adjusted latent demand. The ESRD facilities which fall below the threshold would be eligible. Specifically, we requested input on the following:

- What factors should be considered in formulating a payment adjustment for ESRD facilities in isolated geographical areas or areas for which there is a low need for renal dialysis services?
- What are the best ways to incentivize renal dialysis service provision in isolated geographic areas?
- Our analysis of the LDN methodology has shown that low LDN census tracts intersect with areas designated as HPSAs. What impact would a payment adjustment based on geographic isolation have on the ability of ESRD facilities in isolated areas to recruit and retain health care professionals?
- Please comment on the appropriateness of maintaining the rural facility adjustment under § 413.233, if we were to establish an LDN payment adjustment in conjunction with a modified LVPA.
- Please comment on the relationship between geographic isolation and cost.
- Please provide any data that could further inform CMS's understanding of the relationship between geographic isolation and cost for low volume facilities. Please comment on the appropriateness of utilizing driving time between current beneficiary address and treatment location as the appropriate metric for travel time.
- Are there ways in which the suggested methodology for this potential payment adjustment could fail in targeting isolated ESRD facilities, or ESRD facilities in areas with low LDN?
- Are there ways in which the determination of LDN might be subject to gaming?
- Would a payment adjustment for ESRD facilities in areas with low LDN improve health equity? Are there specific recommendations to change the LDN methodology described above to promote quality access to care for all ESRD beneficiaries?

- Please comment on the favorability of CMS's implementation of a new payment adjustment for ESRD facilities in areas with low LDN as described above.
- Are there any other considerations we should keep in mind when considering proposing a new payment adjustment based on an LDN methodology?

Public Comments Received in Response to the CY 2024 ESRD PPS RFI for the LVPA by Topic:

Payment Adjustment Options:

Seventeen interested parties provided feedback on CMS's RFI on possible modifications to the LVPA. Regarding the potential single threshold, multi-tier, or continuous adjustment methodologies presented in the RFI, the single threshold methodology received only tepid endorsement from one ESRD facility. This party noted that a single tier may be acceptable if the LVPA adjustment percentage were recomputed using the most recently available data and did not exceed 23.9 percent in order to maintain the base rate. Nearly every other commenter indicated that this option would be an ineffective refinement because it does not address the issue of payment cliffs.

Many commenters advocated for a tiered methodology but did not find the tiered options presented in the RFI acceptable for various reasons. Support for a tiered methodology was split amongst two closely related methodologies: MedPAC's proposed low-volume and isolated (LVI) adjustment, and another approach suggested by a coalition of dialysis organizations. MedPAC's LVI methodology, as published in their 2020 Letter to Congress, calls for the removal of the rural adjustment and features three tiers consisting of facilities that furnish less than 4,000, 5,000, and 6,000 treatments, respectively, in each of the three years preceding the payment year. This methodology was explicitly supported by four other commenters, including a small dialysis organization within a large non-profit health system, a non-profit dialysis organization, a provider advocacy organization, and a large dialysis organization (LDO). Similarly, the coalition of dialysis organizations suggested a two-tiered approach that also entails eliminating the rural adjustment, and where the first tier includes facilities with less than 4,000 treatments

per year, while the second tier includes those that furnished 4,001 – 6,000 treatments per year. The commenters suggested that the payment percentage for facilities in tier one should not exceed 23.9 percent and that the payment percentage for tier two should not exceed the value of the current rural adjuster. The coalition of dialysis organizations noted that the second tier in their methodology is intended to be a transitional tier, allowing low-volume facilities that experience marginal increases in patient count to not lose the entire adjustment. This methodology was explicitly supported by two additional commenters including a non-profit kidney organization and a small dialysis organization within a large non-profit health system. Several commenters, including a network of dialysis organizations and regional offices, a not-for-profit dialysis organization, and a non-profit kidney care alliance expressed general support for a tiered methodology but did not concur with the ideas outlined by CMS, MedPAC, or the coalition of dialysis organizations. They agreed that the tiered approaches are transparent and straightforward, allowing for providers to predict their Medicare payment rates more easily. They conceded that these approaches do not eliminate the issue of payment cliffs, though they thought it could significantly attenuate the one present in the current LVPA policy.

Other than the eleven commenters who supported some form of tiered methodology, the remainder of commenters generally did not support the tiered approaches. Some commenters, including an LDO and a non-profit organization of ESRD networks, believed that the 4-tier system CMS detailed would still feature significant payment bumps and would fail to discourage gaming. They explained that although a higher number of tiers lessens the magnitude of payment cliffs, an 8-tiered system could be overly expansive, and possibly award the LVPA to facilities that were not in need of the adjustment. Additionally, they believed that payment adjustments under the 8–tiered system could result in excessive changes in payment for facilities close to the lower bound and miniscule adjustments for those close to the upper bound. They thought this, in turn, could result in an administrative expense for attestation that might exceed the actual adjustment. Several interested parties opposed expanding the value of the LVPA adjustment due to the effects this could have on the base rate.

In terms of the continuous adjustment, several commenters noted that the use of a continuous function with 4,000 treatments as the upper bound could be acceptable, noting that this could allow for facilities with the lowest volume to receive the highest adjustment, potentially eliminate payment cliffs completely, and has the potential to align resource use with payment at a higher degree of accuracy than the tiered or single threshold options. While MedPAC favored their LVI approach, they also were open to considering a continuous adjustment, if that adjustment (1) retained current isolation criteria (no other facilities within five miles) and (2) was calculated using a single factor (where the single factor was derived from facility cost regressed on facility size in the 0-6,000 range) and multiplied by facility treatment volume below a given threshold (e.g., factor × [6,000 – facility volume]). MedPAC cautioned that the continuous adjustment might be more challenging to administer than a categorical approach. Specifically, to determine the value of a facility's continuous adjustment, the facility would need to attest to whether the number of treatments provided in each of the three preceding years was lower than the 7,000-treatment threshold. For example, before the payment year, facilities would also need to provide CMS an estimate of the average annual number of treatments provided across the three years preceding the payment year (i.e., average of actual treatment volume for the first two years of this period and the projected treatment volume for the third year still in progress) and multiply that number by the continuous adjustment factor. However, other commenters, including a coalition of dialysis organizations and a non-profit organization of ESRD networks were concerned that a continuous option could dilute the impact of the adjustment and potentially lack transparency and predictability. Those most vehemently opposed, including an ESRD facility and a small dialysis organization within a large non-profit health system, noted their preference to maintain the status quo instead of the options outlined in the RFI.

Factors to Consider when Determining Tiered Structure:

Commenters also provided feedback regarding important factors to consider in determining treatment thresholds for a tiered structure. A coalition of dialysis organizations and an ESRD facility claimed that use of the median treatment count is an unreasonable benchmark for LVPA eligibility

because an award provided to approximately half of all facilities could entail a dramatic reduction in the amount of the payment adjustment and further incentivize gaming. The ESRD facility also suggested that CMS instead evaluate the 25th-30th percentile; however, more details about this suggestion were not provided. Additionally, several commenters identified cost per treatment as an essential metric in determining eligibility, since the facilities that should be targeted to receive the adjustment are those whose patient counts produce revenue that is too low to cover costs and could result in negative and unsustainable profit margins. As such, they urged CMS to consider use of per-treatment costs and facility Medicare margins to identify cutoffs below which keeping facilities open would be infeasible. Another ESRD facility suggested that CMS use Medicare volume (as opposed to total treatment volume) in order to make determinations of LVPA eligibility. This, they claim, could obviate the need for attestation and better allocate Medicare funds to Medicare beneficiaries.

Attestation Process:

Commenters were also divided in their thoughts on possible changes to the attestation process. One coalition of dialysis organizations thought that it was important that CMS maintain the three-year attestation to determine eligibility for the LVPA, as it is an important safeguard against gaming. On the other hand, an LDO supported the use of only one year of data, noting that this method could correctly identify low-volume facilities while alleviating administrative burden. Commenters also provided several suggestions to simplify the attestation process. A coalition of dialysis organizations suggested that CMS calculate facility treatment volume and notify facilities of their LVPA status, rather than facilities completing attestation. Under this method, facilities deemed ineligible by CMS could be given the opportunity to appeal CMS's determination. One LDO suggested that providers be able to submit a single attestation for all facilities to each Medicare Administrative Contractor (MAC), rather than separate attestations for each facility. They also suggested that CMS change the timing of attestation, as the November 1st deadline causes discrepancies in forecasting treatments in November and December. Alternatively, they suggested that CMS could also provide an allowable variance in end-of-year treatment

counts, such that clinics with forecasted treatments slightly above 4,000 treatments could be included. The LDO further suggested that if in January, dialysis facilities still surpass variance thresholds, MACs could exclude them from receiving the LVPA. Lastly, the LDO asked that CMS consider changing the current attestation process in the case of acquisitions. Currently, if a facility acquisition closes after the November 1st deadline, the closing facility is required to attest beforehand, although they have no incentive to do so. The LDO suggested that CMS allow a process change such that either the acquiring entity or the entity being acquired can submit an attestation.

General Comments Regarding LDN Methodology:

Commenters were generally opposed to the prospect of an LDN methodology. Many of the concerns voiced during the 2020 TEP were reiterated by the commenters. Commenters found this method to be overly complicated and were concerned with the possible lack of transparency. A coalition of dialysis organizations voiced the concern that the LDN method would take away providers' ability to make financial decisions about their operations, since they would not be able to predict their eligibility for the LDN payment adjustment nor the amount they would receive. The coalition of dialysis organizations also maintained that the LDN may not target the appropriate facilities and could provide opportunity for gaming. They claimed that the central issue faced by these facilities is low patient count, which they think the LDN methodology does not recognize, and thus the adjustment may be provided to facilities that are isolated, but have high patient counts, and are not in need of an additional payment adjustment. The coalition of dialysis organizations and a non-profit kidney organization both felt that the current LVPA requirement of the distance between a facility receiving adjustment and the next facility under common ownership be at least 5 miles apart is an important feature that discourages gaming, one that is not included in the LDN methodology. Furthermore, the coalition of dialysis organization thought that the LDN method would lack stability, given that patient location varies over time. However, one rural and isolated ESRD facility voiced support for the LDN, noting that it would be a significant help to facilities to continue providing care for underserved populations. MedPAC suggested that if the LDN were

adopted, CMS should ensure that the methodology is transparent; for example, making the specifications and results for the regression equation that adjusts for differences between hypothetical and latent demand available on CMS' website and on the Federal Register. In addition, the commission stated that CMS should note how often the model would be updated, discuss how census tract populations changing over time would affect the stability of the adjustment, and how the approach would address the anticipated increase in home dialysis use.

Health Equity:

Several commenters, including a coalition of dialysis organizations and a non-profit organization of ESRD networks, were concerned that the LDN approach had negative ramifications for health equity. They noted that possible decreased payment adjustment percentages may have disproportionate and negative effects on facilities where access to healthcare services is already limited, such as in rural areas. Additionally, a non-profit kidney care alliance and a coalition of dialysis organizations found driving time to be an inappropriate metric to introduce into the methodology, as it is complex and has limited application for some patient populations. More specifically, the commenters asserted that most patients have cars and can rely upon vehicles to travel to dialysis centers may reinforce structures of inequality that exist in urban areas, since drive times are relatively short, but is not the mode of transportation used by most patients.

Relationship Between Geographic Isolation and Costs:

One ESRD facility described the variety of challenges and unique costs that geographically isolated facilities face. These include difficulty in recruiting and retaining staff, necessitating bonus incentives in some cases. Furthermore, the commenter explained that rural and isolated facilities may only be open part time, which also inhibits hiring as potential candidates generally prefer full–time work. Isolated facilities also face operational challenges including delays in laboratory processing, supply chain shortages, and increased cost of deliveries. Lastly, they note that lack of patient access to care in these regions creates unique financial difficulty, because negative patient outcomes seen at these facilities

impact Medicare reimbursement via lower Quality Incentive Program (QIP) scores. A coalition of dialysis organizations also pointed out that MedPAC reported in their 2020 report to Congress that half of all rural facilities are high volume. They suggested that facilities deserving of further subsidy are not those that are simply rural or geographically isolated, rather those whose per-treatment costs would be higher when spread over a smaller volume of patients.

Maintenance of the Rural Adjuster:

Commenters varied in their opinion of the rural adjuster. Several commenters, including a non-profit dialysis association, a coalition of dialysis organizations, and a non-profit kidney organization felt that the rural adjuster should be removed, and its funds incorporated into one of the tiered LVPA methodologies proposed by MedPAC and the coalition of dialysis organizations described above. They also noted that an LVPA, a rural adjuster, and a possible LDN adjustment would be redundant. A coalition of dialysis organizations bolstered this claim by noting that CMS' reliance on ZIP codes to identify rural facilities is no longer an adequate proxy for facilities in need, and cited MedPAC and a health care research company to claim that many rural facilities enjoy a large patient count and positive profit margins. Other commenters were in support of the rural adjuster, explaining that it was especially appropriate in conjunction with a modified LVPA methodology, since under the options presented by CMS in the RFI, many facilities would experience significant decreases in payment. The additional funds provided by the rural adjustment would protect against the closure of rural facilities.

With any change, commenters asked that CMS assess the impacts of closures on access to care for surrounding beneficiaries. Additionally, they ask that CMS continue to monitor patient health outcomes as changes to payment policies are implemented.