CMS-1768-F: CY 2023 Final Rule Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Summary of Comments in Response to Request for Information on Health Equity Issues Within the ESRD PPS With a Focus on the Pediatric Payment

In the CY 2023 ESRD PPS proposed rule (87 FR 38464), we requested information on advancing health equity under the ESRD PPS, including an additional request focused on health disparities faced by pediatric ESRD patients within the ESRD PPS payment program. As discussed in the CY 2023 ESRD PPS final rule, 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. Please note that this is only a summary and for a more complete and accurate understanding, please refer to the comments themselves which may be found at https://www.regulations.gov/search/comment?filter=CMS-1768-P. 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. Please send additional input regarding health equity and pediatric dialysis in the ESRD PPS to the ESRD PPS team at the following address: ESRDPAYMENT@cms.hhs.gov.

Health Equity Issues Within the ESRD PPS

CMS is committed to achieving equity in health care for our beneficiaries by recognizing and working to redress inequities in our policies and programs that serve as barriers to access to care and quality health outcomes. CMS policy objectives also reflect the goals of the Biden

administration, as stated in Executive Order 13985.[1] In this final rule, "health equity means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."[2]

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the Federal Poverty Level, are factors frequently associated with worse health outcomes.[3,4,5,6,7,8,9,10] Numerous studies have shown that among Medicare beneficiaries, individuals belonging to a racial or ethnic minority group often experience delays in care, receive lower quality of care, report dissatisfactory experiences of care, and experience more frequent hospital readmissions and procedural

[1] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government
[2] https://www.cms.gov/pillar/health-equity
[3] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675-681.
[4] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.
[5]Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298-2308.
[6] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID-19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307-316.
[7] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf
[8] https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf
[9] www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm
[10] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327

complications than white patients and patients with a higher levels of income. [11,12,13,14,15,16] When compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis services are disproportionately young, male, disabled, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting.[17]

Underserved Communities in the ESRD Medicare Population

CMS's ESRD data contractor has provided data stratified by the following factors in order to identify subpopulations for which health disparities may exist among the ESRD population: sex, age, race/ethnicity, urban/rural residence, socioeconomic status proxy (combines both dual eligibility and receipt of premium subsidy for Part D), original reason for Medicare entitlement, and the Area Deprivation Index (ADI) for the beneficiary's residence (which also serves as a proxy for socioeconomic status). Definitions for these categories as well as relevant results, based on enrollment numbers in January 2020, are detailed below.

- Sex[18] - The ESRD PPS population was 58.7 percent male compared to 46.9 percent male in the non-ESRD Medicare population.

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[11] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[12] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf

[13] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107-15.

[14] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672-1679.

[15] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675-681

[16] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086-1090.

[17] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

[18] Sex is derived from the Enrollment Database (EDB), and is categorized into male and female. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

- Age[19] - The ESRD PPS population was younger than the non-ESRD Medicare population, in part because ESRD is a qualifying condition for Medicare, regardless of age, if the individual otherwise meets Social Security benefit qualifications.[20] Approximately 40 percent of the ESRD PPS beneficiary population was younger than 60 compared to 10 percent in the non-ESRD Medicare population.

- Original Reason for Medicare Entitlement - The ESRD Medicare population had a higher proportion of beneficiaries entitled to Medicare due to disability compared to the non-ESRD population. Forty-seven percent of the ESRD population was originally eligible for Medicare due to disability (with or without ESRD), compared to 21 percent for the non-ESRD Medicare population.[21]

- Race and Ethnicity[22] - Members of racial or ethnic minority groups comprised a larger proportion of the ESRD Medicare population compared to the non-ESRD Medicare population. This was especially true among Blacks/African-Americans who comprised 34.5 percent of the ESRD population, compared to 8.9 percent of the non-ESRD Medicare population.

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[19] Beneficiary age (in years) is measured at the beginning of each month, and is obtained from the Medicare beneficiary birth date variable in the EDB Record Identification Code (RIC) A Table. The following seven age groups are used for all relevant data presentation for this TEP: less than 12, 13-17, 18-44, 45-59, 60-69, 70-79, and 80. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

[20] Section 226A of the Act; 42 C.F.R. § 406.13.

[21] ESRD beneficiaries are stratified into four mutually exclusive categories based on their original Medicare entitlement: 1) less than 65 years of age and had both ESRD and disability at time of enrollment; 2) less than 65 years of age and had ESRD at time of enrollment; 3) less than 65 years of age and were disabled at time of enrollment; and 4) those who aged into Medicare (and were diagnosed with ESRD after turning 65). See: https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf

[22] Beneficiary race and ethnicity information is derived from the Research Triangle Institute (RTI) race algorithm, as obtained from CMS Common Medicare Environment (CME) data. This data provides seven mutually exclusive categories: Non-Hispanic White, Black/African American, Asian or Pacific Islander, Hispanic, American Indian or Alaska Native, and Other/Unknown. See: https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf

- Urban and Rural Residency[23] - ESRD Medicare beneficiaries were more likely to reside in urban areas than the non-ESRD Medicare population. Approximately 84 percent of ESRD beneficiaries lived in urban areas, while approximately 79.6 percent of the non-ESRD Medicare population lived in urban areas.

- Socioeconomic status proxy[24] - 42.5 percent of the ESRD Medicare population was dually eligible for Medicare and Medicaid as compared to 15.4 percent of the non-ESRD Medicare population. As compared to the non-ESRD Medicare population, ESRD Medicare beneficiaries were more likely to be enrolled in Medicare Part D (73 percent ESRD PPS as compared to 61 percent of non-ESRD Medicare beneficiaries). Among ESRD Medicare beneficiaries, Non-Hispanic White beneficiaries are less likely to be enrolled in Medicare Part D (70.0 percent Part D enrollment) compared to other groups (ranging from 72.3 to 77.2 percent enrolled in Part D).[25]

- ADI[26] - ESRD Medicare beneficiaries were more likely to be living in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare

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[23] The Core-Based Statistical Area (CBSA) designations are used to determine urban or rural residency status. Beneficiaries whose county of residence is located within a CBSA are deemed urban residents. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.

[24] Among Medicare Part D enrollees, Medicare benefit status was derived from monthly enrollment status and low-income status in EDB. Both the beneficiary's dual eligibility status (whether the beneficiary was eligible for both Medicare and Medicaid in a given month) and Premium Subsidy status (whether the beneficiary was receiving any level of premium subsidy in a given month) were considered in determining the beneficiary's Medicare benefit status. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

[25] This result is believed to be due to the fact non-white beneficiaries are more often dually eligible for Medicare and Medicaid compared to White beneficiaries. The low-income subsidies provided to dually eligible beneficiaries gives them the means to enroll in Part D, which is likely why this percentage is slightly higher for non-whites.

[26] ADI is a measure constructed by the Health Resources and Services Administration, and has been validated, refined and adapted by researchers at the University of Wisconsin, Madison, to rank neighborhoods (geographically localized communities within a larger cities, towns, suburbs or rural areas) by socioeconomic disadvantage, specifically factoring in income, education, employment, and housing quality. From these percentile rankings, six mutually exclusive categories of ADI Rankings are constructed with the 1st to 5th percentile being the least disadvantaged and 95th to 100th percentile being most disadvantaged.

beneficiaries, approximately 29 percent of the ESRD PPS population resided in the most disadvantaged ADI percentiles (76th to 100th percentile) compared to 19.2 percent of non-ESRD Medicare beneficiaries. ESRD beneficiaries who were socioeconomically disadvantaged were more likely to be enrolled in Medicare Part D than those less disadvantaged.

Based on the demographics of the Medicare ESRD beneficiaries, this population represents many individuals who belong to underserved communities for which health disparities may exist..

CMS Activities to Advance Health Equity

The CMS Framework for Health Equity outlines a path to advance health equity that aims to support Quality Improvement Network Quality Improvement Organizations; federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other interested parties in activities to advance health equity.[27] The CMS Framework for Health Equity focuses on five core priority areas which inform our policies and programs: (1) Expand the collection, reporting, and analysis of standardized data; (2) Assess causes of disparities within CMS programs and address inequities in policies and operations to close gaps; (3) Build capacity of health care organizations and the workforce to reduce health and health care disparities; (4) Advance language access, health literacy, and the provision of culturally tailored services and, (5) Increase all forms of accessibility to health

https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

[27] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Framework for Health Equity 2022-2032. Available at: https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf

care services and coverage.[28] The CMS Quality Strategy[29] and Meaningful Measures Framework[30] also include elimination of disparities as central principles.

CMS also requested information in a previous rulemaking, in the CY 2022 ESRD PPS proposed rule, on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for ESRD facilities, providers, and patients (86 FR 36362 through 36368). We refer readers to the summary of this previous information request as presented in the CY 2022 ESRD PPS final rule (86 FR 61996 through 61197).

CMS's efforts aimed at advancing health equity to date have included providing transparency of health disparities, supporting health care providers and health officials with evidence-informed solutions to address social determinants of health and advance health equity, and reporting to providers on gaps in quality. Some of those efforts are:

- The *CMS Mapping Medicare Disparities Tool,* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[31]

[28] Centers for Medicare & Medicaid Services Office of Minority Health. Framework for Health Equity 2022-2032. Available at: https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf

[29] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf

[30] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page

[31] https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities

- The *Rural-Urban Disparities in Health Care in Medicare Report*, which details rural-urban differences in health care experiences and clinical care.[32]
- *The CMS Innovation Center's Accountable Health Communities Model*, which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities,* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[33]
- The *Chronic Kidney Disease Disparities: Educational Guide for Primary Care*, which is intended to foster the development of primary care practice teams in order to enhance care for patients who are medically underserved with chronic kidney disease and are at risk of progression of disease or complications. The guide provides information about disparities in the care of patients with chronic kidney disease, presents potential actions that may improve care and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[34]

These efforts are informed by reports by the National Academies of Science, Engineering and Medicine and the Office of the Assistant Secretary for Planning and Evaluation, which have examined the influence of social risk factors on several of our programs.

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[32] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf

[33] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf

[34] CMS. Chronic Kidney Disease Disparities: Educational Guide for Primary Care. February 2020. Available at: https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf

Technical Expert Panel (TEP) Focused on Health Disparities Represented in the ESRD PPS

CMS continues to work with federal and private entities to better collect and leverage data on social determinants of health to improve our understanding of how these factors can be better measured in order to reduce health disparities and advance health equity. We continue to work to improve our understanding of this important issue and to identify policy solutions that achieve the goal of attaining health equity for all patients. One of the efforts demonstrating our ongoing commitment to uncover hidden disparities within the ESRD PPS includes the recently held December 2021 TEP focused on improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services.

Over the last several years, CMS has been working towards a potential refinement of the ESRD PPS. This effort has included focused data analysis by CMS and included input of interested parties. Four contractor-led TEPs, each with a focus on different aspects of the ESRD PPS, have been convened. The specific objective for the latest TEP (December 2021) was to gather input from diverse interested parties on health disparities arising among patients who are historically medically underserved and are represented in the ESRD PPS patient populations. The TEP included 16 panelists representing ESRD facilities, nephrologists, patient advocates, and representatives from professional associations and industry groups. The contractor presented results of analysis of health disparities that can be measured by currently collected data. Panelists responded with their interpretations of these results and provided their insights about what they thought were hidden disparities not currently measured. Ideas and suggestions for potential changes to data collection for the ESRD PPS to better measure and potentially reduce health disparities were offered. The TEP did not provide formal recommendations, but provided discussion items and suggestions in a

subsequent report (https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf). All TEP presentation materials and summary reports can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

TEP Discussion and Comments from Interested Parties

During the 2021 ESRD PPS TEP, panelists discussed various topics, including the types of direct patient care labor used in renal dialysis care, the case-mix payment adjustment model, subpopulations at risk of health disparities and for whom data are not currently available, and the special case of pediatric patients receiving renal dialysis services. The following is a synopsis of the 2021 TEP discussion topics. For a more complete summary, please review the December 2021 TEP Summary Report.[35]

Direct Patient Care Labor Categories in Dialysis Care

CMS's contractor explained that direct patient care labor categories under the ESRD PPS include social workers, nutritionists, and other staff, but does not include nephrologists, as they are paid separately for their services to dialysis patients. The ESRD facility cost report includes lines for administrative and managerial staff. The base rate can be broken down into a direct patient care labor-related portion and a non-direct patient care labor-related portion, and that the direct patient care labor-related portion is multiplied by the facilities' CBSA wage index for the included job categories. In areas of the country with high wages, the wage index value usually exceeds one, increasing the labor-related portion of the base rate. The current wage index for the

[35] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf[36] Pre-reclassified wage index in ESRD PPS means that wages for all hospital registered nurses are combined to obtain the CBSA-specific wages for RNs in ESRD facilities.

ESRD PPS is based on a pre-reclassified acute care hospital wage index and is not derived specifically from ESRD facility cost reports.[36] Panelists and other interested parties have commented that actual direct patient care labor costs associated with providing renal dialysis services are not currently being accurately captured and additional direct patient care labor categories should be explored.

Case-Mix Model

The goal of case mix adjustment is to ensure payment accuracy, meaning payment for a treatment corresponds with expected resource use and cost for that treatment. As noted in the CY 2011 ESRD PPS final rule (75 FR 49034), resources required to furnish routine renal dialysis services such as staff and equipment time vary by patient. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria. To that end, the goal is to protect access to care for the least healthy and most costly beneficiaries..

The ESRD PPS also includes facility level adjustments designed to align ESRD facility resource use with payment. Facility level adjustments account for additional costs that facilities incur resulting from treatment volume, location, and proportion of high cost treatments

[36] Pre-reclassified wage index in ESRD PPS means that wages for all hospital registered nurses are combined to obtain the CBSA-specific wages for RNs in ESRD facilities.

(75 FR 49116 through 49127). Panelists also suggested that CMS identify ESRD facilities located in areas with low physician to patient ratios and in disadvantaged areas and study health outcomes for patients in those areas.

Patient Characteristics and Comorbidities

Patient characteristics and comorbidities that best predicted variation in renal dialysis service costs were introduced in the CY 2011 ESRD PPS final rule (75 FR 49034) and revised in the CY 2016 PPS final rule (80 FR 68974 through 68979). The four case-mix adjusters are patient age, body surface area (BSA), low body mass index (BMI) and comorbidities (hereditary hemolytic or sickle cell anemia, myelodysplastic syndromes, gastrointestinal (GI) tract bleeding with hemorrhage, and pericarditis). During the December 2021 TEP, panelists noted that BSA and BMI are often correlated. They stated that there were other factors they believe were important to include in the case mix adjustment and suggested replacing the current comorbidities, which panelists noted have a low incidence in the ESRD patient population, with others. One panelist suggested that upper GI bleeds be removed from the present list of comorbidities in favor of coronary artery disease history, diabetes history, and hypertension. Another panelist offered that respiratory failures should be considered, due to the frequency of this comorbidity they see in their practice. Finally, panelists stressed the importance of accurately assessing the factors associated with increased treatment costs for high-risk and vulnerable patient populations, and strongly urged CMS to collect standardized information regarding the direct use of social determinants of health (SDOH) and incorporate that information in the case-mix adjustment within the ESRD PPS.

Subpopulations with Observable Disparities in Treatment or Outcomes Related to ESRD

Panelists noted the existence of patient sub-populations for whom data are not currently available that likely experience health disparities with regard to their treatment of ESRD. These include beneficiaries at ESRD facilities with low physician to patient ratios, as a lack of sufficient physician staffing could lead to poor access to care. Panelists also suggested that patients who are experiencing homelessness, with undocumented status, have limited English proficiency, and those that have mental health issues, should be considered subgroups at risk as well. They noted that many patients fit into more than one of these high-risk subgroups. Medicare and Medicaid benefit status and ADI serve as proxies for socioeconomic status in the absence of patient-specific income data. The ADI is a measure constructed by the Health Resources and Services Administration. It has been validated, refined, and adapted by researchers at the University of Wisconsin, Madison, to rank neighborhoods (geographically localized communities within larger cities, towns, suburbs, or rural areas) by socioeconomic disadvantage, specifically factoring in income, education, employment, and housing quality. From these percentile rankings, five mutually exclusive categories of ADI rankings are constructed. ESRD beneficiaries were more likely to live in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare beneficiaries. Approximately 29 percent of the ESRD PPS population resides in the most disadvantaged ADI percentiles (76th to 100th percentile) compared to 19.2 percent of non-ESRD Medicare beneficiaries. Some panelists questioned whether the ADI was the best measure of neighborhood disadvantage as it does not consider availability of health resources within neighborhood groupings; however, they did not offer suggestions for any alternative measures.

Payment Accuracy

Payment accuracy, for the purposes of the TEP discussion, was defined as how well ESRD PPS payments are aligned with observed costs for providing dialysis treatment. Panelists largely agreed that there was general alignment of costs and payments through the ESRD PPS, but they noted that there were patient groups and provider types for which payments were inadequate. The focus of these analyses was to explore potential disparities in payment accuracy among patient groups and provider types that might exacerbate health disparities. CMS's contractor presented information on payment accuracy across patient demographic subgroups (including age, sex, race/ethnicity), and facility types (including rural, low volume and geographically isolated facilities; and wage index and facility ownership type.) The panelists discussed at length the relationship between geographic isolation, patient access to care, and resulting costs. Panel members suggested that access to public transportation may be a relatively accurate marker of geographic isolation (defined as the distance between ESRD facilities) in urban areas. They also noted that geographic isolated communities were likely to have few primary care facilities and are also more likely to be "food deserts." The panelists suggested that beneficiaries residing in these areas also experience difficulties in obtaining timely care for other medical conditions, such as diabetes, hypertension, and cardiovascular disease. They further noted that geographic isolation and difficulties in gaining access to care often results in a renal dialysis patient population with a greater burden of disease. Finally, panelists observed that patients in geographically isolated areas often turned to the renal dialysis facility for their unmet medical care needs. The panelists urged CMS to consider an upward payment adjustment for isolated facilities in areas where low income and low resources drive up the costs of providing care.

The panel focused much of their discussion around patient populations that faced special challenges in access to renal dialysis services and for whom the cost of care was likely higher, but who were not accounted for in current data collection activities under the ESRD PPS. The panel identified some of these patient subgroups to include: patients with housing insecurity as they are ineligible for both organ transplantation and home renal dialysis and thus dialyze in-center indefinitely; patients that are disabled or amputees who may require transfer assistance or extensive wound care; patients in hospice; patients who are not treatment compliant due to factors such as limited English proficiency, or low health literacy. In addition, behavioral or mental health disorders may require additional resources such as psychiatric intervention during dialysis, or engagement of the ESRD network to find a facility best-suited for the patient with a psychological or psychiatric illnesses.

Incorporation of ESRD PPS Payment Adjustments Based on Social Determinants of Health

Discussions during the December 2021 TEP on SDOH were based on the definition of SDOH referring to non-biological factors that affect health status in a population.[37] The TEP members suggested making greater use of SDOH in the case-mix payment adjustment to help address additional costs associated with caring for patients with underlying social and economic risk factors (including, for example, housing insecurity, language barriers, lack of transportation, etc.) that make getting to and adhering to renal dialysis treatment more difficult and costlier for health care providers.

There are many factors that can contribute to increased costs. One panelist noted that their ESRD facility caseload included patients with undocumented status, experiencing

[37] https://academic.oup.com/ije/article/35/4/1111/686451
A reference for social determinants of health can be found at the following website: https://health.gov/healthypeople/priority-areas/social-determinants-health.

homelessness, and had mental health issues; the panelist noted that these types of issues should be considered in payment models. Panelists strongly suggested that in order to better characterize the factors associated with increased treatment costs for these medically vulnerable and historically underserved patients who are at high-risk for adverse health outcomes, efforts should be made to standardize the collection of SDOH data among patients enrolled in the ESRD PPS. They suggested several means of collecting this information including making more extensive use of the SDOH on the 2728 ESRD Medical Evidence Report Form (which is completed at the initiation of renal dialysis services); using SDOH screening tools and embedding them in patient enrollment materials; and using validated third-party patient experience surveys. The panelists also suggested that this information be collected using Z codes in Medicare claims so that it could be updated on a regular basis, but cautioned that this would increase reporting burden on the facilities. The panelists also suggested that placing a modifier on claims to indicate the need for intensive resource utilization during renal dialysis services (for example, for amputees) may help better identify these costly patients. Another panelist suggested the focus should be on acting on the data already available instead of collecting more data.

Following the presentation on differences in treatment patterns among subgroups of the ESRD patient population, the panelist discussion focused on the following topics: home renal dialysis services, additional data elements that should be collected, potential payment changes to address disparities, and transportation. Panelists discussed potential reasons for differential use of home renal dialysis modalities and the need to track preventive care measures delivered through the more advanced stages of Chronic Kidney Disease (CKD). They also stated that better data on such patient characteristics as health literacy, English language proficiency, and

transportation availability for treatment will help policymakers better understand treatment choices and treatment adherence.

Panelists also discussed treatment frequency and missed treatments in response to data presented by the contractor. While treatment frequencies did not vary significantly across patient race/ethnicity or proxies for income status, we found that the percent of monthly missed treatments varied noticeably for the following groups: American Indian/Alaska Native (30 percent) and Black/African American beneficiaries (27 percent), beneficiaries with proxies (Medicare and Medicaid benefits, and ADI ranking) indicating lower socioeconomic status (27 percent compared to higher income of 20 to 22 percent, and beneficiaries living in urban areas compared to rural (25 percent compared to 22 percent).[38] Some panelists suggested that missed treatments be incorporated into the case-mix adjustment; however, it was noted that the overall number of missed treatments is very small, across facility types. CMS data indicated on average, only one tenth of one percent of treatments are missed.

Summary of Request for Information on Advancing Health Equity under the ESRD PPS

In response to the efforts described above and the information we received from TEP panelists and other interested parties associated with the TEPs, we sought additional information from the public in the form of a request for information (RFI). In the CY 2023 ESRD PPS proposed rule, we requested information on advancing health equity under the ESRD PPS (87 FR 38527 through 38528). We received comments from 16 interested parties, with 3 additional interested parties who submitted health equity comments pertaining only to pediatric patients, which are addressed separately in this summary report on page X. We note that 5 of the comment letters in response to this RFI came from organizations and interested parties that were

[38] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2021.pdf; slides 77,78, 80, and 81.

represented by the 16 panelists from the December 2021 TEP. Below we provide a synopsis and highlights from the comments, for each of the RFI questions raised in the CY 2023 ESRD PPS proposed rule. Please note that this is only a summary and for a more complete and accurate understanding, please refer to the comments themselves which may be found at https://www.regulations.gov/search/comment?filter=CMS-1768-P. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments.

Potential Refinements to Mitigate Health Disparities

CMS requested information on what kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity. In response, many commenters expressed support for CMS's efforts to reduce disparities and improve equity in the delivery of ESRD care. MedPAC, a federal advisory agency, noted that traditional incentives for providers and payers to deliver high quality care efficiently may require change so that incentives are applied fairly and do not undermine access to care. Commenters offered a number of suggestions. One non-profit treatment and research center and one professional association of social workers recommended the establishment of add-on payments and other adjustments to the facility payor mix to provide for social work staffing and complex care coordination. A national organization of patients and kidney health care professionals suggested add-on payments for higher percentages of dual eligible home dialysis patients and patients with housing or food insecurities. A small dialysis organization within a large non-profit health system wrote in favor of patient-level adjusters for patients with high resource needs. A large dialysis organization recommended an extension of Kidney Disease Education (KDE) benefits to Medicare beneficiaries are who not yet on dialysis but who have Stage V

CKD as well as to those within the first 6 months of ESRD. One national organization of patients and kidney care health professionals and one non-profit treatment and research center supported the adoption of a payment model similar to the CMS's ESRD Treatment Choices (ETC) Model to improve health equity. A large dialysis organization and a coalition of dialysis organizations advocated for allowing facility-employed social workers, dieticians, and others to work with physicians to provide KDE services to beneficiaries. A provider advocacy organization suggested that CMS expand equitable access to life-saving dialysis care by issuing guidance to all states to encourage the expansion of Emergency Medicaid to undocumented people with kidney failure.

Comorbidities

CMS asked whether specific comorbidities should be examined when calculating the case-mix adjustment that will help better represent the ESRD population and help address health disparities. Several commenters provided feedback on the role of comorbidities on the health outcomes of ESRD patients and recommendations around the use of comorbidities in the ESRD PPS. Several commenters opined that the current comorbidity case mix adjusters are methodologically unsound and should be eliminated from the ESRD PPS. One non-profit dialysis association explained that its analysis showed effects of comorbidities on resource utilization for separately billable items, independent of the onset of dialysis, and noted that costs are higher for patients with comorbidities during the first 4 months of treatment. A coalition of dialysis organizations noted that obese individuals require longer dialysis sessions, which affects their cardiovascular system and quality of life. A small dialysis organization within a large non-profit health system suggested development of patient-level adjusters to account for patients with left ventricular assist device, tracheostomy,

cardiomyopathy with ejection fraction at or under 20, significant mental health conditions, non-weight bearing transfers, and patients who chose to skip >50 percent of treatments in a given month. A few commenters, including a non-profit health care organization, remarked upon the role of mental health and neurological conditions (e.g., cognitive impairment), noting that such conditions affect patients' ability to function and adhere to care regimens. A coalition of dialysis organizations and a non-profit dialysis association referenced research produced by MedPAC and The Moran Company as resources to inform CMS policy on comorbidities and claims adjustment.

Subpopulations

CMS requested comment about whether there are specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy and which should be evaluated for potential health disparities. Several commenters, including a coalition of dialysis organizations, remarked on the large percentage of ESRD patients who are dual eligible and who have higher costs of care despite similar utilization. A coalition of dialysis organizations and a device manufacturer spoke to the lack of caregiver support, the burden of caregiver fatigue, and concerns about storage and supplies management as factors contributing to health disparities, including the lack of access to home dialysis. A large dialysis organization noted the lack of health literacy as a contributing factor to disparities. A non-profit treatment and research center cited the lack of high-speed internet as a contributor to disparities in telehealth access and thus in access to home dialysis.

CMS also asked how existing data sources could be used to better identify unmet needs among specific subpopulations that could result in health disparities. In response, a non-profit health care organization noted that mental health conditions are coded using ICD-

10 codes and should be available in claims data. The same commenter also suggested that CMS develop and use Z codes to track SDOH, but recommended that CMS might instead use dual eligible status or Area Deprivation Index (ADI) and Social Vulnerability Index (SVI) at the 9-digit ZIP code level until Z codes are operational. The commenter noted that frequent address changes in CMS claims for a given patient might indicate housing instability. A provider advocacy organization and a large dialysis organization recommended screening for CKD using the CMS-2728 patient registration form.

Demographic Information and Social Determinants of Health

CMS asked for comments suggesting ways to address, define, collect, and use accurate and standardized, self-identified demographic information (including information on race and ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would mitigate disparities and refine ESRD PPS payment policy. In response, commenters indicated support for collecting SDOH also cautioned against the accompanying increased administrative burden on staff. A provider advocacy organization suggested working with facilities already tracking SDOH through electronic medical records and then engaging vendors to extract the data. A large dialysis organization and a drug manufacturer advocated for voluntary pilot studies to test out best practices. For example, a pilot program could (1) study the uniform collection and analysis of patient-level SDOH data and (2) test interventions. A few commenters, including a provider advocacy organization and a coalition of dialysis organizations, suggested the use of Z codes to collect data on common SDOH such as housing and food insecurity and minimal caregiver support. A non-profit health care organization recommended that CMS use the Health-Related Social Needs

(HRSN) screening tool and mental health variables to identify subgroups in need; the commenter also suggested looking to past studies on HRSNs from the early 1980s and how these were used to develop diagnosis-related groups for data on empirical estimates of the additional costs from HRSNs. The same commenter noted its own success with SDOH collection and suggested that CMS look to the standardized data collection methods described in the 2009 Institute of Medicine reporting on standardized collection of race, ethnicity, and language data.

Revisions to Case-mix Categories in the ESRD PPS

CMS sought comment on what revisions to case-mix categories in the ESRD PPS could be made to better represent underserved populations. A provider advocacy organization recommended that CMS adopt a payment adjustment for ESRD facilities treating a large proportion of patients with SDOH challenges that would be similar to the Disproportionate Share Hospital (DSH) payment available to hospitals under the Inpatient Prospective Payment System (IPPS). A non-profit health care organization suggested CMS use the Complication or Comorbidity (CC) or a Major Complication or Comorbidity approach, as used in IPPS. That is, the existing categories could be modified to include two or three levels of HRSNs as modifiers, with higher levels of HRSNs being associated with higher payments. The commenter noted that this approach would leave the basic case-mix system unchanged but would add a HRSN concept exactly analogous to the CC modifier – an additional, orthogonal factor that contributes to cost and can contribute to payment.

Mitigating Bias in Renal Dialysis Technologies, Treatments, and Clinical Tools

CMS asked for comment regarding what actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies,

treatments, or clinical tools that rely on clinical algorithms. A coalition of dialysis organizations suggested that CMS work with the Office for Civil Rights to address health literacy issues and improve education materials. A large dialysis organization suggested that CMS incorporate the use of peer mentors and navigators to assist in education of ESRD patients as well as to help with minority recruitment into primary care settings and nephrology training. Similarly, a professional association of nurses suggested that CMS incentivize medical students to pursue nephrology. A non-profit dialysis center discouraged CMS from over-adjusting for SDOH in a way that would move the payment system away from bundled payments and towards an FFS approach that would, in the commenter's view, undermine the ESRD PPS.

Summary of Responses from the Requests for Information on Health Equity Issues within the ESRD PPS with a Focus on the Pediatric Payment

Background and Pediatric Dialysis Overview[39]

Compared to the Medicare dialysis adult population, the Medicare dialysis pediatric population is much smaller, comprising approximately 0.14 percent of the total ESRD patient population in 2019. Consequently, only 1.4 percent of ESRD facilities that furnish treatment in 2019 were pediatric facilities,[40] where "pediatric facilities" is defined as those providing at least 100 pediatric dialysis treatments in 2019. These facilities are mostly located in urban areas and typically based in a children's hospital or major medical center. Pediatric facilities are also either very small (furnishing less than 4,000 treatments per year) or very large

[39] ESRD TEP Summary Report of TEP held on December 10-11, 2020, p. 18-19. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf

[40] As per the 2020 TEP, 1.4 percent of all ESRD facilities were designated pediatrics, when defining pediatrics as >100 treatments/yr in 2019. See: https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf

(furnishing at least 10,000 treatments per year). Pediatric facilities also have higher direct patient care labor expenditures than adult facilities.

CMS continues to hear concerns from organizations associated with pediatric dialysis about underpayment of pediatric renal dialysis services under the current ESRD PPS payment model. These organizations emphasize that pediatric renal dialysis services require significantly different staffing and supply needs from those of adults. Most of these organizations agree there is a need for more finely tuned cost data for pediatric dialysis. Many organizations support CMS efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients.

RFI

CMS published an RFI in the CY 2023 ESRD PPS proposed rule to solicit input on topics such as circumstances and health inequities unique to the pediatric dialysis population, possible refinements to the ESRD PPS payment policy to mitigate health disparities for this population, the possible inclusion of a specific payment modifier on the claim indicating pediatric dialysis, and putting more emphasis on pediatric comorbidities. Specifically, we solicited public comment on the following:

- Please provide any information and supporting documentation about whether there are health disparities in this sub-population.
- How could refinements to the ESRD PPS payment policy mitigate health disparities in the pediatric population?

- Should a pediatric dialysis payment include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options (for example, age related or comorbidity related)?
- Are there specific comorbidities that should be examined when calculating the case mix adjuster that will help better represent the pediatric ESRD population and help address health inequities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such conditions.
- Are there other direct patient care labor categories that should be considered when determining the cost to provide renal dialysis services to pediatric patients, and if so, which ones?
- How should CMS revise case-mix categories in the ESRD PPS to better represent the pediatric population?
- Are there SDOH that are specific to the pediatric ESRD population?

We received comments on these issues from approximately 10 interested parties that directly and indirectly addressed the RFI topics stated above. We note that 2 of these commenters were representatives at the December 2021 TEP. Below we provide a summary of the comments for topics discussed in the CY 2023 ESRD PPS proposed rule. Please note that this is only a summary and for a more complete and accurate understanding, please refer to the comments themselves which may be found at https://www.regulations.gov/search/comment?filter=CMS-1768-P. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments.

General Comments

Commenters appreciated that CMS acknowledges the unique and complex care needs of the pediatric dialysis patient population, which typically requires a much higher intensity of labor-related services and additional supplies. These factors contribute to the higher cost of pediatric ESRD and CKD care. Some commenters, including a professional organization of pediatric nephrologists, thanked CMS for its continued engagement with them regarding this specialized population.

All commenters agreed that pediatric patients receiving dialysis face different health disparities than those that adults receiving dialysis face. Some commenters, including a renal physicians association, a national organization of patients and kidney health care professionals, and a coalition of dialysis organizations, discussed the health disparities faced by Black pediatric dialysis patients, noting that Black pediatric patients are disproportionally impacted by CKD overall. Commenters pointed to data showing that in comparison to White children receiving dialysis, Black children receiving dialysis are more likely to be on hemodialysis, wait longer for a kidney transplant, and are ultimately less likely to receive such a transplant. Commenters noted that these differences are significant since home dialysis, and ultimately transplant, are the preferred treatments for ESRD in the pediatric population. While outside the scope of the RFI, a few commenters expressed concern with the algorithms used to match kidneys of deceased donors to pediatric kidney transplant recipients, noting that the current inclusion of race as a factor in these algorithms may negatively impact overall access to transplantation for children. Commenters also pointed to socioeconomic and demographic factors that contribute to the disparity of Black children receiving transplants.

Factors Affecting the Cost of Pediatric Dialysis Treatment and the Need for Data Collection

Almost all commenters discussed economic and social determinants of health as factors that affect the cost of pediatric dialysis treatment. They pointed to factors such as lack of adequate housing, nutritional concerns, and transportation as problems these children face that contribute to the disparity for this sub-population. Housing insecurity was one of the main SDOH that commenters, including a coalition of dialysis organizations, a renal physicians association, a national organization of patients and kidney health care professionals, and a professional organization, identified in their comments. A few commenters recommended CMS provide housing assistance for families with children with kidney failure. They suggested this assistance could be provided to children who do not have homes, stable addresses, or are in struggling school districts. Commenters noted that without a home to support care, children receiving dialysis are more dependent on hemodialysis provided in a dialysis facility. Since pediatric dialysis facilities are rare and typically located exclusively in hospitals, many pediatric dialysis patients would have significant commutes to receive this more specialized care. This lack of nearby pediatric dialysis facilities drives many of these patients to receive hemodialysis in dialysis facilities that predominantly care for adults and, consequently, may not have the proper staff, resources, and equipment to meet the unique needs of pediatric dialysis patients.

Nutritional concerns were another topic of discussion by several commenters, including a renal physicians association, a coalition of dialysis organizations, and a national organization of patients and kidney health care professionals. Some commenters highlighted the need to address food insecurity and access to nutritional foods to address disparities and advance health equity. Commenters noted that access to proper foods impacts proper growth

and development and therefore has a different impact on children than adults. Further, commenters stated that for pediatric patients living in families that are impacted by SDOH, the food required to adhere to a renal diet may include items that a family cannot afford. A national organization of patients and kidney health care professionals recommended that CMS expand access to food programs and make sure those programs cover the nutritional supplements that children with kidney disease need. In particular this national organization mentioned the need to cover access to foods with appropriate potassium and sodium levels and certain nutritional supplements or interdialytic parental nutrition in the Special Supplemental Nutrition Program for Women, Infants, and Children; the Supplemental Nutrition Assistance Program; and any other nutrition assistance programs. This national organization further stated the issue of infant formulas was also a concern as programs may not cover specialized formulas or more than one formula that may need to be mixed with another. Other commenters supported this view and expressed similar ideas about the need to expand access to food programs. Social determinants of health are not currently collected as part in the ESRD PPS case mix adjustment model, but commenters noted their value in assessing the care needs of the pediatric dialysis population.

In addition to discussions of SDOH, interested parties expressed concern that there is other information not currently collected that affects the true costs of pediatric dialysis treatment within the ESRD PPS. For example, other existing medical conditions are not factored into case-mix adjustment for pediatric patients, nor are the costs associated with the type of specialized treatment required by the youngest patients and those with developmental and other disabilities and special needs. All the commenters suggested factors to consider for the patient level case-mix adjuster. Three interested parties supported the professional

organization of pediatric nephrologists' recommendation and ideas on how age, weight, and pediatric specific comorbidities could be used as a proxy for composite rate costs. One specific recommendation supported by a national organization of patients and kidney health care professionals, a professional organization of pediatric nephrologists, and a coalition of dialysis organizations was that the costs of pediatric care be broken down into the following age groups: less than 6 years old, 6-11 years old, and 12-18 years old. A provider advocacy organization suggested CMS consider introducing an age category for newborn to 3 years old as these children require additional specialist and psychosocial supports.

Other commenters noted specific comorbidity factors. For example, one provider advocacy organization asked CMS to consider conditions such as cardiac disease, seizure disorders, congenital abnormalities, cardiac malfunction, as well as the numerous lung diseases that are frequently seen among infants born prematurely. Additionally, commenters provided CMS with a list of comorbidities to consider. A professional organization of pediatric nephrologists provided a list of pediatric comorbidities, for which two other commenters expressed support. The comorbidity list was similar to the one noted in the CY 2023 ESRD PPS proposed rule (87 FR 38529). The list included conditions such as failure to thrive/feeding disorders, feeding pump, congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal), specific congenital disorders, seizure disorder and the inability to ambulate or transfer. Beyond these physical conditions, commenters noted that pediatric patients often experience severe neurological conditions as well as psychological disorders and challenges, which should be considered in case-mix adjustment.

Commenters, including one Large Dialysis Organization (LDO), requested that CMS consider the additional unreported expenses for the key support personnel responsible for

addressing the unique challenges related to cognitive, physical, and developmental disabilities in these patients. They expressed that these staff challenges contribute to the higher cost of pediatric ESRD and CKD care and should be accounted for in the case mix. The commenters further explained that pediatric interdisciplinary team members all require specific pediatric training, and advised that these costs could be accurately captured by pediatric specific direct patient care labor categories. Additionally, commenters advocated for Medicare payment for care coordinators for the pediatric population. An LDO expressed that having a consistent staffing model for pediatric care delivery requires different staffing ratios. According to this commenter, the staffing needs of one dialysis patient that is 5 years of age or younger are equal to the staffing needs of 2 adult patients; the needs of a patient 6 to 15 years of age are equal to 1.5 adult patients; and the needs of a patient 15 years of age are equal to 1 adult patient. Some commenters also requested that CMS change its payment policies to better support pediatric nephrologists, as they assert more are needed in the field. Commenters suggested that CMS help get additional residency slots, provide medical students with incentives for pursuing nephrology, and encourage medical schools to dedicate more time to ESRD related curriculum. A coalition of dialysis organizations also encouraged CMS to enhance telehealth payments to help address the shortages of pediatric nephrologists. In addition to labor related cost, a provider advocacy organization suggested that CMS also consider the addition costs related to overhead, psychosocial supports, specialized pharmacy needs, and home dialysis for this pediatric dialysis population.

In the CY 2023 ESRD PPS proposed rule, CMS requested comments about whether a pediatric dialysis payment should include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-

options. Commenters, including a professional organization of nephrologists and a renal physicians group, supported the inclusion of a modifier. A few commenters, including one LDO, suggested that CMS create a non-budget-neutral payment associated with a pediatric specific modifier. These commenters suggested the pediatric base rate should account for the unique specialization and costs associated with pediatric care and that the adjustments should not be made in a budget neutral manner and "new money" should be incorporated into the system to account for the needed modifications. Another commenter suggested CMS develop a Pediatric ESRD PPS defined by actual costs of care that would be separate from the current ESRD PPS and outlier payment policy. A device manufacturer advocated for CMS to create a separate bundled payment with patient adjusters unique to this population's psychosocial developmental, nutritional, and family needs, as well as a unique pediatric facility adjuster, in addition to rural and low-volume adjusters. This commenter stated their belief that this would incentivize providers to develop pediatric specific clinics, encourage home dialysis, invest in pediatric supplies and acquire specially trained staff. Some commenters' responses to this RFI expressed ideas similar to those expressed in some of the comments from the CY 2020 ESRD PPS final rule (84 FR 60648). In that rule, commenters highlighted that pediatric dialysis facilities are a special case, that a pediatric case mix adjuster is warranted, and that revisions to cost reports should be made to allow for facilities to adequately report the true cost of providing care to this special population. In response to this RFI, only one commenter addressed the Medicare cost report directly. That commenter reiterated comments that were already provided to CMS ultimately asking that CMS give ample lead time to make any changes to the Medicare cost report and recommending implementation no sooner than January 1, 2023.

We appreciate all of the comments and the interest in this topic. We believe that this input is very valuable in the continuing development of our ESRD payment policy as we work to address health disparities in the pediatric population. We will continue to take the comments into account as we work on improving CMS's ability to detect and reduce health disparities within the ESRD PPS payment program for pediatric patients receiving renal dialysis services. While we did not respond to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development.