



August 25, 2022

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

RE: CMS-1770-P: “CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts” (Proposed Rule)

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the “CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts”¹ (Proposed Rule). We applaud CMS for expanding access to dental services for individuals with kidney failure seeking transplant and request that CMS further expand dental services for all beneficiaries who require dialysis services. We also ask CMS to reconsider the policies related to the split-shared services. Finally, KCP reiterates our concern about the ongoing cuts to vascular access reimbursement codes that disproportionately affect individuals who are Black and Brown.

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

¹87 Fed. Reg. 45860 (July 29, 2022).

I. KCP Supports Expanding Access to Dental Services for Individuals with Kidney Failure Seeking Transplant or Receiving Immunosuppressant Medications, as well as to All Individuals Receiving Dialysis.

Researchers have long demonstrated that “[o]ral health represents a potential determinant of health outcomes in patients with end-stage renal diseases (ESRD).”² Studies show that adults with ESRD have more severe oral disease than the general population, which can lead to increased mortality.³ As CMS recognizes in the preamble to the Proposed Rule, oral infections can threaten transplants as well. KCP is pleased that CMS has worked closely with the kidney care community to identify opportunities to expand access to dental services for individuals living with kidney failure. Access to dental services not only is important for dialysis patients as part of their ability to access kidney transplants, but also to access cardiovascular procedures given that many dialysis patients also live with serious, chronic cardiovascular conditions, and to reduce the risk of systemic infections developing from an oral source. We strongly encourage CMS to finalize the proposals outlined in the Proposed Rule that include:

- Clarifying that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, an otherwise covered medical service, including dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery, as well as for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, use of an operating room, other facility services, regardless of whether the services are furnished in an inpatient or outpatient setting.⁴
- Expanding payment under Medicare Parts A and B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not subject to the exclusion under the Social Security Act (SSA), including the dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure; and (2) the necessary dental treatments and diagnostics to eliminate the oral or dental infections found during a dental or oral examination as part of a comprehensive workup prior to an organ transplant, as well as for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room, regardless of whether the services are furnished in an inpatient or outpatient setting.⁵

²Costantinides F, Castronovo G, Vettori E, Frattini C, Artero ML, Bevilacqua L, Berton F, Nicolin V, Di Lenarda R. Dental Care for Patients with End-Stage Renal Disease and Undergoing Hemodialysis. *Int J Dent*. 2018 Nov 13;2018:9610892. doi: 10.1155/2018/9610892. PMID: 30538746; PMCID: PMC6258100.

³*Id.*

⁴*See 87 Fed. Reg.* at 46037.

⁵*See id.* at 46038.

- Expanding payment to include dental exams and medically necessary diagnostic and treatment services prior to treatments for the initiation of immunosuppressant therapy.⁶

In addition to finalizing these policies, we ask that CMS employ its existing authority, if possible, or at least use its broad waiver authority to expand coverage and payment for ongoing dental services, such as regular dental exams and the ancillary services provided with them, to all individuals receiving dialysis under the Medicare benefit. These services are integral to the standard of care for dialysis patients and so the preclusion under the statute should not apply.⁷ Many studies have recognized oral health plays a critical role in the outcome of individuals living with kidney failure. Their oral health not only affects transplant access, but also morbidity, such as negative cardiovascular outcomes, systemic infections and peritoneal dialysis associated peritonitis,⁸ and overall mortality.⁹ CMS has rightly focused on reducing bloodstream infections (BSI) among those individuals who receive dialysis. Our clinician members report that many of these infections begin with bacteria in the mouth. Regular dental visits could have a positive impact on reducing BSI as well. Poor oral health care also affects nutrition, an area of vulnerability for many people with kidney failure, particularly those who lack the socioeconomic resources to tailor a nutritionally appropriate diet to their oral health limitations. This nutritional vulnerability, exacerbated by health equity issues, is another gap in care that MedPAC has identified. In addition, individuals with poor oral health often experience periodontal diseases and subsequent inflammation that can make managing anemia more difficult and increase the needed dose of ESAs. Without Medicare coverage, many beneficiaries may not have access to dental services. Sixty-one percent of ESRD patients are under 65 years old, but only 11 percent currently have Medigap coverage.¹⁰ Expanding regular dental services to all Medicare ESRD beneficiaries should be viewed as integral to the standard of care for dialysis patients. Given that ESRD beneficiaries make up less than one percent of the Medicare population, expanding dental coverage to those individuals who rely upon the benefit would not overwhelm the program.

⁶*See id.*

⁷*See id.* at 46040.

⁸Sirirat Purisinsith, Patnarin Kanjanabuch, Jeerath Phannajit, Bruce Robinson, Kriang Tungsanga, *et al.* "Oral Health-Related Quality of Life, A Proxy of Poor Outcomes in Patients on Peritoneal Dialysis." doi:<https://doi.org/10.1016/j.ekir.2022.07.008> (August 5, 2022).

⁹*See, e.g.,* Palmer S. C., Ruospo M., Wong G., et al. Oral-D study investigators. Dental health and mortality in people with end-stage kidney disease treated with hemodialysis: a multinational cohort study. *American Journal of Kidney Diseases*. 2015;66:666–676.

¹⁰Dialysis Patient Citizens. "DPC Report Card on Medigap Coverage for ESRD Patients Under 65 Years of Age." <https://www.dialysispatients.org/policy-issues/promote-financial-security/medigap-coverage/>. (accessed August 17, 2022).

II. KCP is concerned that the current split-shared services policy will negatively impact patient care coordination activities that are so vital to individuals receiving dialysis.

KCP joins with the Renal Physicians Association (RPA) and others in the health care professional community to ask CMS to revisit the current policy that defines the “substantive portion” solely in terms of the time spent with a patient. This policy allows only the physician or qualified health care provider (QHP) who performs more than 50 percent of the time of the total visit to bill a split or shared visit. Our members have voiced concern that the policy is drastically disrupting team-based care and interfering with the way care is delivered in the facility setting. Individuals receiving care in dialysis facilities are especially vulnerable to this problem because of the shortage of nephrologists.

Rather than create an arbitrary time criterion, we recommend that CMS establish a criterion that is based on medical decision-making. CMS could audit this criterion using the same methodology it applies to evaluation and management codes. Relying upon a time-based criterion undervalues the physician’s knowledge, judgment, and leadership role in the delivery of care. This approach is inconsistent with the implementation of the Kidney Care Choices Model as well. It ignores the critical role that nephrologists play in the patient care teams helping to coordinate the care provided and ensure that each patient’s plan of care (as required by the ESRD Conditions for Coverage) remains up-to-date and appropriate for the patient as well.

Therefore, we ask that CMS propose an alternative that relies on the medical decision-making in the CY 2023 Physician Fee Schedule proposed rule for comment.

III. KCP remains concerned about the ongoing cuts to vascular access reimbursement codes that disproportionately affect individuals who are Black and Brown.

Vascular access procedures are essential to individuals living with kidney failure. They are the life-line for those individuals who rely upon dialysis treatments in order to live. The KCP has enthusiastically supported efforts to reduce catheters and to support incentives for PD access. We are concerned that the 39 percent reduction to vascular access codes under the 2017 Physician Fee Schedule has led to a significant number of closures in office-based settings. These closures have led to a substantial impact on patients’ ability to obtain vascular access procedures. According to a 2018 survey by the American Society of Diagnostic and Interventional Nephrology (ASDIN), 50 percent of respondents indicating that their center already had closed noted that their patients would have to drive more than 30 additional miles to receive vital vascular access services.¹¹ 2021 Medicare claims data show a decrease in office-based vascular access services of

¹¹ Survey available for download here: https://7c6286a4-24ee-4fee-92b9-ed0f0d031061.filesusr.com/ugd/4d8e3a_450f824be03b407fbab027d9e60e9ff5.pdf

more than 30 percent since 2017.¹² KCP is particularly concerned about these closures because obtaining a fistula/graft or a PD access remains an important aspect of improving patient outcomes. Catheters should not be the dialysis access default to which patients have access because they cannot obtain other vascular access options. Catheters result in more blood stream infections, hospitalizations, and greater mortality for dialysis patients, and are a detriment to overall patient quality of care.¹³

The Dialysis Vascular Access Coalition has noted in its comment letter on the CY 2023 Physician Fee Schedule proposed rule that these cuts have had a disproportionate impact on patients from communities of color. Specifically, Black and Latino individuals are less likely to start dialysis with a fistula than white patients.¹⁴

Cutting payment rates for these life-sustaining procedures only makes it more difficult for those beneficiaries who require them to be able to access them. The KCP requests that CMS temporarily freeze the implementation of further policy updates that results in cuts to vascular access services. We also renew our request that CMS maintain Percutaneous Creation of an Arteriovenous Fistula and set the rates through rulemaking and not rely upon contractor pricing.

IV. Conclusion

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

Sincerely,



John Butler
Chairman

¹² MJBFBraid-Forbes Health Research, LLC, Medicare claims analysis of 36902, September 2021

¹³ Lacson E Jr., Wang W, Lazarus JM, Hakim RM. "Change in vascular access and hospitalization risk in long-term hemodialysis patients." *Clin J Am Soc Nephrol* 5: 1996–2003 (2010); Mehrotra R, Cheung AK, Meyer T, Nath KA. "Vascular access for hemodialysis and value-based purchasing for ESRD." *J Am Soc Nephrol* 28: 395–397, (2017) pmid:28143965.

¹⁴ *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. *JAMA Surg*.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287

Appendix: KCP Members

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