



September 30, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1734-P: CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma,

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the “CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy” (Proposed Rule).

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

In brief, KCP:

- Supports the proposed changes to the Monthly Capitated Payment (MCP) amounts for nephrologists that increase the value of these payment rates in light of previous changes to the Evaluation/Management (E&M) values;
- Encourages CMS to adjust the rates for home and in-center dialysis vascular access placement procedures to further incentivize the placement of peritoneal dialysis and AV fistula accesses, as well as higher rates for the home dialysis MCP to incentivize the use of home dialysis, consistent with the Administration's goals outlined in the Advancing American Kidney Health Initiative;
- Supports extending telehealth flexibilities beyond the COVID-19 public health emergency (PHE), but maintaining the requirement that physicians have at least one in-person visit each month with their patients who receive in-center dialysis;
- Recommends that CMS maintain Percutaneous Creation of an Arteriovenous Fistula (HCPCS Codes G2170 and G2171), but set the rates through rulemaking and not rely upon contractor pricing; and
- Recommends maintaining the National Coverage Determination (NCD) #110.14 Apheresis (Therapeutic Pheresis) (7/30/1992) to protect access for dialysis patients who need the therapy.

I. KCP supports the proposed changes to the Monthly Capitated Payment (MCP) amounts for nephrologists that increases the value of these payment rates in light of previous changes to the Evaluation/Management (E&M) values.

KCP encourages CMS to finalize the proposal to update the MCP codes “to more accurately account for the associated office/outpatient E&M visits.”¹ KCP agrees that “[b]y improving payment accuracy for the ESRD MCP codes, we would also be supporting broader efforts at advancing kidney health.”² The proposed change addresses the long-standing problem that the valuation of the monthly ESRD codes were based on the 2004 rulemaking cycle. While CMS applied the updated E&M values to all global surgical packages with E&M elements in 2006, it did not apply these increases to the family of ESRD MCP codes. The AMA Relative Value Update Committee (RUC) valued the codes again in 2008, which remain the basis of the codes used today. KCP supports the Renal Physician Association's recommendation to adjust the family of monthly ESRD services codes based on the increase in the underlying E&M services. We also agree with CMS that the additional

¹See, 85 Fed. Reg. 50074, 50125 (August 17, 2020).

²*Id.*

resources the updates will provide can help nephrology practices to address the rapid growth in patients living with chronic kidney disease (CKD) and help these patients better manage their disease, slow its progression, and improve their quality of life. Therefore, we urge CMS to finalize the proposed updates to these codes.

II. KCP encourages CMS to adjust the rates for home and in-center dialysis vascular access placement procedures to further incentivize the placement of peritoneal dialysis and AV fistula accesses, as well as higher rates for the home dialysis MCP to incentivize the use of home dialysis, consistent with the Administration's goals outlined in the Advancing American Kidney Health Initiative.

KCP recognizes the budget neutrality constraints under which adjusting one set of physician codes has an impact on the values of the other codes in the fee schedule. However, we encourage CMS also to take into account the impact that reducing the value of codes in certain areas can have on access to those procedures. In particular, the Administration continues to prioritize patient access to AV Fistulas (over catheters). The President's Executive Order announcing Advancing American Kidney Health focuses on increasing the number of patient who select home dialysis when their kidneys fail, as well. Lowering the value for these codes creates the opposite effect that the Administration intends. Therefore, while we reiterate that CMS should maintain the proposed values for the MCP codes, we also ask that it avoid implementing the budget neutrality requirement in a manner that reduces the payment rates for vascular and PD access placement. We also encourage CMS to take into account the need to incentivize home dialysis when it establishes the rate for the home dialysis MCP.

III. KCP supports extending telehealth flexibilities beyond the COVID-19 public health emergency (PHE), but maintaining the requirement that physicians have at least one in-person visit each month with their patients who receive in-center dialysis.

As KCP as referenced in previous letters, we agree that telehealth flexibilities enacted during the pandemic have benefited patients receiving kidney care. We support CMS's efforts to extend those flexibilities that are appropriate to make permanent. As we have noted in our letter on the ESRD Prospective Payment System (PPS) CY 2021 proposed rule, patients who receive dialysis in-center do need to have at least one in-person visit each month with their nephrologist. Thus, in response to the requested comment on whether MCP 90962 (once per month adult in an outpatient setting face-to-face visits provided) should be permitted to be provided via telehealth, the KCP recommends that CMS maintain the requirement that at least one of the MCP visits be in-patient for patients who receive in-center dialysis and not allow all of these monthly visits to be via telehealth.

IV. KCP recommends that CMS maintain Percutaneous Creation of an Arteriovenous Fistula (HCPCS Codes G2170 and G2171), but set the rates through rulemaking and not rely upon contractor pricing.

As noted already in this letter, promoting AV fistulas is a top priority of the kidney care community, as well as of the long-term and successful Fistula First program. The two codes for percutaneous creation of an AV fistula play an important role in making sure that payment policy incentivizes the procedures needed to create the fistulas for patients receiving in-center dialysis. While we are pleased that CMS agrees to maintain these codes, we are puzzled by the decision not to create certainty around them by leaving the rates at contractor pricing. We believe it is time and there is sufficient evidence for CMS to create a set fee schedule amount for these codes. Doing so will help incentivize the placement of fistulas by creating certainty and predictability. Leaving the codes to contractor discretion leads to uncertainty and confusion among providers. It is not clear how CMS setting a rate, as it does for nearly all other physicians services, places beneficiaries at risk of infection, which the preamble suggests is the reason for maintaining contractor pricing. The same standards that apply to determining when an institutional setting is required versus when an office setting is appropriate would apply regardless of whether CMS sets the rate or contractor pricing is maintained. Therefore, we encourage CMS to work with KCP and our members to establish the appropriate national rates for these codes.

V. KCP recommends maintaining the National Coverage Determination (NCD) #110.14 Apheresis (Therapeutic Pheresis) (7/30/1992) to protect access for dialysis patients who need the therapy.

KCP is troubled by the request to remove the NCD for Apheresis (Therapeutic Pheresis), because doing so will threaten access to those dialysis patients who require both hemodialysis and apheresis. Renal indications for apheresis include: Goodpasture's disease, IgA nephritis, focal segmental glomerulosclerosis, transplantation, antibody, multiple myeloma, TTP/HUS, cryoglobulinemia, Lupus Nephritis, and Sickle Cell Disease. As one set of researchers noted:

Although the various modalities of hemodialysis and hemofiltration are the most commonly used extracorporeal therapies in clinical nephrology, blood purification using other techniques have become necessary to remove pathogenic, toxic, or waste substances not easily cleared by hemodialysis or hemofiltration due to factors such as molecular size, protein binding, and lipid solubility.³

³Stegmayr B, Ramlow W, Balogun RA. Beyond dialysis: current and emerging blood purification techniques. *Semin Dial.* 2012;25(2):207-213. doi:10.1111/j.1525-139X.2011.01034.

We understand that the NCD could be improved upon, but it is important to protect coverage for those patients who need apheresis and not create the uncertainty that would certainly ensue if the NCD were eliminated and coverage were left to contractor discretion. CMS should address the concerns noted in the Proposed Rule by updating the NCD with input from the kidney care community instead. Therefore, we ask that CMS not finalize the proposal to rely upon contractor discretion to determine whether apheresis will be available to dialysis patients.

VI. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. Please feel free to contact Kathy Lester, counsel to KCP, if you have questions about our comments or would like to discuss them in further details. She can be reached at klester@lesterhealthlaw.com or 202-534-1773. Thank you again for considering our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Butler', with a long, sweeping horizontal flourish extending to the right.

John Butler
Chairman

Appendix A: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
American Society of Nephrology
AstraZeneca
Atlantic Dialysis
Baxter
BBraun
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
National Kidney Foundation
Nephrology Nursing Certification Commission
National Renal Administrators Association
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma