September 13, 2021

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

Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements [CMS-1751-P]

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to comment on the "CY 2022 Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements" proposed rule.

ASN welcomes numerous recommendations in the proposed rule and wishes to thank the Centers for Medicare & Medicaid Services (CMS) for working so closely with the medical community during the COVID-19 public health emergency (PHE). As CMS has recognized, patients with chronic kidney disease (CKD), especially those receiving kidney replacement therapy or with advanced non-dialysis CKD, are at heightened risk of hospitalization and mortality after developing COVID-19. Thus, finding ways to optimize care in the home through expanding telehealth services and enhancing access to home-based laboratory testing are important steps to reduce the risk of infection.

In addition, ASN appreciates the flexibilities CMS allowed clinicians and dialysis facilities during the PHE. Most importantly, ASN appreciates the Biden-Harris Administration's decision to allocate vaccines directly to dialysis facilities to allow them to leverage their frequent contact with patients and encourage them to be vaccinated.

Physician Fee Schedule Rates

ASN appreciates CMS's decision in last year's final PFS rule to revalue certain end-stage renal disease (ESRD) monthly capitated payment (MCP) codes, recognizing that the ESRD monthly services codes have values closely tied to the values of

office/outpatient evaluation and management (E/M) codes and that these E/M codes (99212 and 99214) have seen multiple increases over the years without commensurate increases to the ESRD MCP code family. ASN supports CMS's decision to increase the value of the ESRD MCP codes through a revaluing of the work, physician time, and clinical staff practice expense (PE) inputs factored into those codes.

However, overall, ASN is concerned that the statutory "budget neutrality" of the Medicare PFS leads to long-term erosion of Medicare physician pay. For CY 2022, CMS will adjust to account for changes in relative value units (RVUs) (required by law), and expiration of the 3.75 percent payment increase provided for CY 2021 by the Consolidated Appropriations Act, 2021 (CAA). CMS proposes a PFS conversion factor (CF) of $33.58, a decrease of $1.31 from the CY 2021 PFS conversion factor of $34.89. The PFS CF reflects the statutory update of 0.00 percent and the adjustment necessary to account for changes in relative value units and expenditures that would result from other proposed policies.

Medicare payments have been under pressure from mandated anti-inflationary payment policies for more than 20 years. While physician and non-physician provider services represent a very modest portion of the overall growth in health care costs, they are subject to perennial cuts to offset any increases elsewhere due to budget neutrality. Due to annual Congressional action, physicians and other health care providers generally avoided direct cuts to reimbursements caused by the sustainable growth rate formula (SGR), enacted in 1997 and repealed in 2015; however, Medicare provider payments have remained constrained by a budget-neutral financing system. Updates to the CF have failed to keep pace with inflation, and the result is that the CF today is only about 50% of what it would have been if it had been indexed to general inflation starting in 1998. In addition, the cost of running a medical practice has increased by 37 percent between 2001 and 2020, which equates to 1.7 percent per year when measured by the Medicare Economic Index (MEI). The startling reality is that, adjusted for inflation in practice costs, Medicare physician pay has declined 22 percent from 2001 to 2020, which equates to a 1.3% per year average reduction.

In several recent studies, financial compensation is frequently noted as a disincentive to pursuing nephrology. [i] [ii] This concern is understandable considering current US medical school graduates pursuing nephrology are carrying unstainable levels—median $225,000—in educational debt.[iii] Further erosion of nephrologist compensation will erect barriers that will impede ASN's efforts to ensure a representative workforce who can provide culturally appropriate care to the minoritized populations abjectly subjected to the burdens of kidney diseases.

These trends are unsustainable. Therefore, ASN has joined a broad coalition of medical societies urging Congress and the administration to make a critical investment in the nation's health care delivery system by maintaining the 3.75% increase to the CF through at least calendar years 2022 and 2023. ASN calls on the Biden-Harris Administration to work with the physician community and Congress to reach a long-

term, sustainable solution to the physician payment crisis. Failure to do so will deter physicians from pursuing nephrology, act to constrain the nephrology pipeline, and exacerbate the current nephrology workforce crisis evidenced by the less than half of training programs filling in the 2017–2020 Match cycles.[iv] ASN stands ready to contribute to that effort.

Split (or shared) E/M visits

CMS proposes to refine its longstanding policies for split (or shared) E/M visits to "better reflect the current practice of medicine, the evolving role of non-physician practitioners (NPPs) as members of the medical team, and to clarify conditions of payment that must be met to bill Medicare for these services." CMS proposes the following:

- Definition of split (or shared) E/M visits as evaluation and management (E/M) visits provided in the facility setting by a physician and an NPP in the same group.
- The practitioner who provides the substantive portion of the visit (more than half of the total time spent) would bill for the visit.
- Split (or shared) visits could be reported for new as well as established patients, and initial and subsequent visits, as well as prolonged services.
- Requiring reporting of a modifier on the claim to help ensure program integrity.
- Documentation in the medical record that would identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.

ASN finds these proposals reasonable, but requests CMS monitor their implementation to ensure that they do not unduly increase physician burden.

Telehealth

ASN believes that expanded telehealth services create an opportunity to expand access to care and to deliver increased patient-centered care.

Early in the COVID-19 PHE, public health officials realized that health-care delivery would need to pivot rapidly towards delivering health care via telehealth and away from in-person encounters, a strategy designed to minimize exposure to the virus for vulnerable patients and for the health-care professionals providing care. At the start of the PHE, with stay-at-home orders in place and warnings on the risk for severe illness from COVID-19, fee-for-service (FFS) in-person visits for primary care fell precipitously in March 2020. According to a report issued by HHS in April 2020, nearly one-half (43.5%) of Medicare primary care visits were provided through telehealth compared with less than one percent (0.1%) in February before the PHE began. For kidney disease patients, especially those with kidney failure travelling to an in-center dialysis facility three times a week, their health risks and needs became an immediate priority for HHS and Congress.

ASN thanks CMS and Congress for the speedy measures it took. The following represent the major categories of Medicare telehealth changes during the PHE:

- Waived geographic and site restrictions. Telehealth services were available across the country allowing originating sites to be everywhere, including the home and dialysis facilities.
- Expanded health-care professionals' responsibilities, allowing additional care team members to conduct and bill for telehealth services.
- Expanded services eligible for provision via telehealth, adding over 80 additional codes including those for home and in-center dialysis.
- Relaxed supervision and licensing requirements.
- Expanded modalities permitted for telehealth visits beyond video to include audio only (when video was unavailable).
- Established payment parity for audio only when asynchronous video/audio was not possible.
- Permitted new patients to interact with their care team via telehealth, in addition to existing patients.

The ASN believes that expanded telehealth services create an opportunity to expand access to care and to deliver patient-centered care. Going forward, ASN supports CMS' proposal to retain all services added to the Medicare telehealth services list on temporary (Category 3) basis until the end of CY 2023. ASN also urges CMS to permanently allow the supervision of professionals through real-time audio/video technology across as many services as possible; this enables greater efficiencies in medical workforce and patient safety. Due to the lack of internet bandwidth and the limited ability to use certain technologies by some individuals, ASN encourages CMS to provide ongoing access and payment parity for audio-only and two-way audio-visual telehealth.

ASN is committed to working with Congress and CMS to remove geographic and originating site restrictions for all telehealth services. ASN also encourages CMS to use the next 12 months to examine telehealth billings and independent research on telehealth safety and effectiveness to inform policies moving forward.

Modification to the Medical Nutrition Therapy (MNT) Benefit

ASN commends CMS for taking the steps to clarify "that MNT services are, and have been, paid at 100% (instead of 80%) of 85% of the PFS amount, without any cost-sharing, since CY 2011." CMS notes that while it made this change through its customary change request process, the Agency did not update this regulation when the Affordable Care Act (ACA) of 2010 amended the statute to except the coinsurance and deductible for preventive services defined under section 1861(ddd) (3) of the Act that have a grade of A or B from the United States Preventive Services Task Force and MNT services received a grade of B. ASN thanks CMS for taking these steps.

Quality Payment Program (QPP)

In 2022, the Quality Payment Program (QPP) will mark 6 years since the program began. ASN welcomes the steps proposed for moving this value-based program forward, particularly allowing clinicians to apply for hardship exemptions for 2021 due to COVID-19 from all four performance categories with one amendment. ASN does not believe it is appropriate to provide hardship exemptions on a case-by-case basis under the current conditions and urges CMS to provide the broadest possible latitude in approving these exemptions.

ASN supports the proposal to double the complex patient bonus for the 2021 Merit-based Incentive Payment System (MIPS) performance year due to concerns around treating patients during the COVID-19 PHE. These bonus points are capped at 10-points and will be added to the clinician's final score.

Last year, CMS finalized the conditions for creation of MIPS Value Pathways, an approach that will allow clinicians to report on a uniform set of measures on a particular episode or condition in order to get MIPS credit. CMS is proposing the first group of seven MVPs with a delayed start date until 2023. ASN supports this approach and is preparing a nephrology-specific MVP for CMS' consideration.

CMS is also proposing to sunset the traditional MIPS program after 2027 and fully transition to reporting through MVPs. Due to the confusion and complexity of reporting that has plagued MIPS, ASN supports and welcomes this approach.

Conclusion

The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are ASN members thank the Biden-Harris Administration for its commitment to providing a stable PFS program critical to improving kidney care for all patients. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,

Susan E. Quaggin, MD, FASN
President

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[i] Jhaveri KD, Sparks MA, Shah HH, et al. Why not nephrology? A survey of US internal medicine subspecialty fellows. Am J Kidney Dis. 2013;61(4):540-546. doi:10.1053/j.ajkd.2012.10.025

[ii] Nair, D., Pivert, K.A., Baudy, A. et al. Perceptions of nephrology among medical students and internal medicine residents: a national survey among institutions with nephrology exposure. BMC Nephrol 20, 146 (2019). https://doi.org/10.1186/s12882-019-1289-y

[iii] Pivert K, Boyle S, Chan L, McDyre K, Mehdi A, Norouzi S, Tuchman S, Waitzman J, Sozio SM. 2019 Nephrology Fellow Survey—Results and Insights. Washington, DC: ASN Alliance for Kidney Health, 2019

[iv] https://data.asn-online.org/briefs/09_ay-2021-match/