



May 29, 2024

Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-4207-NC Medicare Program; Request for Information on Medicare Advantage Data

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the more than 21,655 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), ASN thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to respond to the Request for Information (RFI) on Medicare Advantage Data.

In this letter, ASN will address the following topics in relation to Medicare Advantage Data:

- Missing data on enrollment
- Questions of transparency
- Medicare Special Needs Plans (C-SNPs)
- Network adequacy
- Equity
- Prior authorizations

Kidney Health Care

An estimated 37 million adult Americans, constituting 15% of the U.S. population, are affected by kidney diseases, with 1 in 3 U.S. adults projected to develop chronic kidney disease (CKD).ⁱ Among those, more than 800,000 US residents have advanced kidney failure and require dialysis or a kidney transplant to survive. Most Americans living with kidney failure qualify for Medicare coverage through the ESRD Program. Annually, Medicare spends \$50 billion on care for those with kidney failure and \$150 billion on care for all stages of kidney disease. Although Medicare beneficiaries with ESRD represent only 1% of total Medicare beneficiaries, their care accounts for 7% of traditional Medicare spendingⁱⁱ.

Kidney diseases exert a disproportionate burden on minority and underserved communities in the United States. Compared to White Americans, Black Americans are 3.8 times and Hispanic/Latinx Americans are 2.1 times more likely to develop kidney failureⁱⁱⁱ. One out of every eleven Black American males will require dialysis during their lifetime. Additionally, Black, Indigenous, and Latinx Americans are less likely to receive a kidney transplant or initiate home dialysis when requiring treatment for kidney failure compared to whites^{iv}.

Prior to 2021, Medicare beneficiaries with kidney failure, in general, were not allowed to enroll in MA plans. Medicare beneficiaries who were already enrolled in MA plans when they developed kidney failure were allowed to remain in that plan; however, if they left MA, they could not re-enroll. This prohibition was changed when Congress passed the 21st Century Cures Act (Cures Act; P.L. 114-225), which allowed beneficiaries with an ESRD diagnosis to enroll in MA beginning January 1, 2021.

Due to Medicare's enormous investment in kidney health, Congress mandated the United States Renal Data System (USRDS), the largest and most comprehensive national ESRD and chronic kidney disease surveillance system. Established in 1989, the USRDS has six goals: (1) to characterize the ESRD population; (2) to describe the prevalence and incidence of ESRD, along with trends in mortality and disease rates; (3) to investigate relationships among patient demographics, treatment modalities, and morbidity; (4) to identify new areas for special kidney studies and support investigator-initiated research; (5) to provide data sets and samples of national data to support research studies by the Special Studies Center; and (6) to report the costs of ESRD treatments and total burden of ESRD program in the United States.

Data for the USRDS database are supposed to be compiled from existing data sources including the ESRD Quality Reporting System (EQRS) (formerly known as CROWNWeb and, before that, the Renal Management Information System or REMIS), CMS claims data, facility survey data, CDC survey data (National Health and Nutrition Examination Survey), Standard Information Management System (SIMS), the ESRD Medical Evidence Form (CMS-2728), the ESRD Death Notification form (CMS-2746), United Network for Organ Sharing (UNOS) transplant and wait-list data, and registry data from prior Special Studies. The CMS data files are supplemented by CMS with enrollment, payer history, and other administrative data, to provide utilization and demographic information on ESRD patients.

Additionally, quality metrics for dialysis facilities, such as many of the measures used in the ESRD Quality Incentive Program (QIP), require claims data for case mix adjustment; this process becomes far less robust when a substantial proportion of beneficiaries receiving dialysis are covered by MA plans. Current workarounds require using shadow datasets limited to MA beneficiary hospitalizations, but these are

insufficiently assessed, inadequately transparent and limited to only hospital data, meaning that patients who are not hospitalized, potentially representing major successes in care, will have no available comorbidity data for these quality programs, rendering attempts at case mix adjustment highly flawed.

There is also concern that missing MA data could undermine the rich kidney data sets flowing to and from USRDS. ASN understands that MA data is now flowing to USRDS, but it is our understanding that data now has a three-year delay reaching USRDS which negatively impacts research and policy planning. ASN strongly urges the Department of Health and Human Services (HHS) to expand the purview of the USRDS contract to include data collected on patients enrolled in MA, ensuring timely access to robust data for the USRDS.

Missing Data on Enrollment

CMS originally projected that 83,000 beneficiaries with ESRD (14% of Medicare's ESRD program) would join an MA plan within two years of the 21st Century Cures Act provision^v. It is currently estimated that the proportion of ESRD beneficiaries enrolled in MA plans has increased by 51% since the implementation of the 21st Century Cures Act, which far exceeds CMS's initial expectations^{vi}. While exact data are not readily available, and if available is based on limited reports from dialysis providers, many more dialysis patients in the US now have MA than have Medicare fee-for-service (FFS). ASN urges CMS to collect and publish the annual number and percentage of ESRD enrollees who enrolled in an MA plan and the annual number and percentage of those who disenrolled.

Transparency issues

ASN has noted in previous comment letters to CMS its concern that the MA program does not provide the same level of transparency as the Medicare FFS program. As noted, the Medicare ESRD program has a strong history of providing quality data invaluable to researchers and policy makers. The Medicare Payment Advisory Commission (MedPAC) has reported that MA encounter data, while improving, remains incomplete^{vii}. ASN strongly urges CMS to require MA plans to provide ESRD enrollee data similar to the data collected for FFS beneficiaries. As more Medicare-eligible enrollees with ESRD select MA coverage, it is crucial that ESRD-related data be of the same quality for MA beneficiaries as for FFS beneficiaries, particularly given the heterogeneity of MA plans.

Medicare Special Needs Plans (C-SNPs)

Medicare Advantage Chronic Condition Special Needs Plans (C-SNPs) provide benefits and services to people with specific conditions, with certain health care needs, or who

also have Medicaid. SNPs include care coordination services and tailor their benefits, provider choices, and list of covered drugs (formularies) to best meet the specific needs of the groups they serve, such as for individuals with kidney failure.

SNPs receive risk-adjusted capitated payments and are responsible for providing services that would otherwise be covered under FFS Medicare. In addition, they are required to develop and describe specific models of care for eligible beneficiaries, including care coordination, population health management, and network and formulary design. ESRD SNPs are intended to tailor benefits and limit enrollment to beneficiaries with ESRD. Any Medicare beneficiary with ESRD may elect to enroll in an ESRD SNP if one is offered in their coverage area.

However, little is known about their impact. This is largely in part because MA data have not been made widely available to researchers and policymakers. Without these data, external evaluations on the success or limitations of these programs cannot be performed. Thus, Medicare SNPs are not subject to the same rigor of evaluation as CMS's FFS coverage.

Network Adequacy

Medicare Advantage network adequacy issues refer to the concerns regarding the sufficiency and accessibility of healthcare providers within the networks of MA plans. These issues often include limited access to certain specialists, hospitals, and other healthcare facilities - particularly in rural and underserved communities. Additionally, network adequacy problems can arise from narrow provider networks, where enrollees may face challenges finding in-network providers to meet their health care needs.

MA network adequacy issues can have significant implications for ESRD patients, who require specialized care and frequent access to health care services. ESRD patients rely on a multidisciplinary team of health care professionals, including nephrologists, dialysis centers, transplant centers, and other specialists to manage their condition effectively. Network adequacy issues, such as limited access to nephrologists and dialysis facilities within MA plan network, can severely impede ESRD patients' ability to access timely and appropriate care. Delays in care due to network adequacy can exacerbate health complications, lead to worsened outcomes, decrease access to transplantation, and increase health care costs.

While CMS requires MA plans to submit data on their provider networks, much of these data remain undisclosed to researchers and the public, limiting transparency and accountability. Without access to comprehensive data on network adequacy, beneficiaries may struggle to make informed decisions on plan selection. Researchers are also unable to conduct studies aimed at understanding the extent of network adequacy issues, their impact on health care access and outcomes, and potential

disparities among different populations, thereby further complicating the ability of decision makers to make health care policy decisions.

MedPAC has found that the maximum distances criteria for MA network adequacy for dialysis centers exceeds the typical travel distances that new ESRD beneficiaries in FFS Medicare Traveled to obtain dialysis in most counties^{viii}.

Equity

In general, MA plans disproportionately enroll beneficiaries who are Black, Hispanic, or are low income. As mentioned earlier in this comment letter, kidney diseases represent one of the most dramatic examples of racial/ethnic disparities in health care in the United States. Inadequate data flowing from MA plans can exacerbate health equity challenges, particularly for patients with kidney failure making it challenging to identify disparities in access to essential healthcare services, such as nephrology care and specific dialysis facilities, for ESRD patients. This lack of data inhibits efforts to address systemic barriers to healthcare access and may perpetuate existing health disparities among vulnerable populations. ESRD patients, who require specialized care and frequent access to healthcare services, are particularly susceptible to the negative effects of inadequate MA data and network adequacy. Therefore, improving data collection and transparency on MA coverage and enrollees are essential for promoting health equity and ensuring that ESRD patients have equitable access to high-quality health care services.

Prior authorizations

Although CMS has proposed several regulatory changes to address concerns about the use of prior authorization by MA plans, ASN remains deeply concerned that some MA plans have implanted prior authorization requirements for receiving dialysis services. HMO MA plans typically require prior authorization for out-of-network dialysis providers. ASN does not believe it is appropriate to establish prior authorization requirement for individuals to receive life-sustaining in-center hemodialysis three to four times a week or life sustaining daily peritoneal dialysis or hemodialysis at home. Even the slightest delay in dialysis treatment can have a negative impact on individuals' outcomes, quality of life, or even survival.

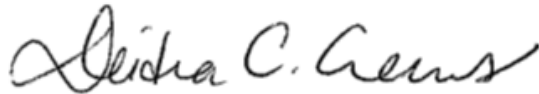
Currently, MA insurers are not required to report prior authorization requests, denials, and appeals by types of service, for specific plan within a contract, or reasons for authorization denials. Limited data on MA prior authorizations leaves researchers, policy makers, patients, and physicians alike unable to accurately assess the challenges caused by prior authorizations described above. The lack of transparency and consistency in prior authorization process due to uncollected data can exacerbate the burden on ESRD patients and their caregivers, who already navigate a complex health

care system while managing a complex chronic condition. Improving data collection and transparency regarding prior authorization in MA plans is crucial for ensuring ESRD patients receive prompt access to the care and treatments that they need to manage their condition effectively and maintain their health and quality of life.

Conclusion

ASN believes that CMS data – especially kidney data, portions of which are mandated by statute – are an invaluable resource to policy makers, health care systems, researchers, and the millions of individuals impacted by the contribution of that research through improving outcomes and saving valuable resources. That resource is jeopardized if MA data is compromised or incomplete. To discuss this letter, please contact David White, ASN Regulatory and Quality Officer, dwhite@asn-online.org.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

ⁱ [Kidney Disease: The Basics | National Kidney Foundation](#)

ⁱⁱ [Annual Data Report | USRDS \(nih.gov\)](#)

ⁱⁱⁱ Walther CP, Winkelmayr WC, Navaneethan SD. Updated US Prevalence Estimates for Chronic Kidney Disease Stage and Complications Using the New Race-Free Equation to Estimate Glomerular Filtration Rate. *JAMA Netw Open*. 2022;5(2):e220460. doi:10.1001/jamanetworkopen.2022.0460

^{iv} [Black Americans at Higher Risk for Kidney Failure as Black Health Matters, NKF Fight for Equity during National Kidney Month | National Kidney Foundation](#)

^v federal Register. Medicare and Medicaid programs: contract year 2021 and 2022 policy and technical changes to the Medicare Advantage program, Medicare Prescription Drug Benefit program, Medicaid program, Medicare Cost Plan program, and programs of all-inclusive ca

^{vi} Nguyen KH, Oh EG, Meyers DJ, Kim D, Mehrotra R, Trivedi AN. Medicare Advantage Enrollment Among Beneficiaries With End-Stage Renal Disease in the First Year of the 21st Century Cures Act. *JAMA*. 2023;329(10):810–818. doi:10.1001/jama.2023.1426

^{vii} https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf

^{viii} https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch5_MedPAC_Report_To_Congress_SEC.pdf