

June 16, 2025

The Honorable Mehmet Oz, MD, MBA Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

The Honorable Thomas Keane, MD, MBA Assistant Secretary for Technology Policy/National Coordinator for Health Information Technology 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Drs. Oz and Keane:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the request for information (RFI) from the Centers for Medicare & Medicaid Services (CMS) and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC Health IT).

In 2019, President Trump issued a sweeping and transformative executive order *Advancing American Kidney Health*. The initiative was rolled out in a public signing of an Executive Order accompanied by a white paper published by the Department of Health and Human Services (HHS) and the release of a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to create the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model)—with four additional nephrology payment models that were eventually combined into one called the Kidney Care Choices Model (KCC Model). The Executive Order (EO) established the following three objectives as official U.S. policy:

- Reduce the risk of kidney failure.
- Improve access to and quality of person-centered treatment options.
- Increase access to kidney transplants.

In the EO, the White House and HHS laid out the case for a national focus on the chronic condition of kidney disease and the urgent need to realign policies to achieve greater kidney health. "Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 (number used in 2019) have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year;

fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant" (1). (Quote from 2019)

ASN contributed to and supported this effort, writing at the time "Today was a gamechanger for people with kidney disease and for the care of these people. For the entire government and president to show this much interest in kidney disease and kidney failure is unprecedented," said ASN President Mark E. Rosenberg, MD, FASN, following the unveiling. "Having the president sign an Executive Order that increases the recognition of the value, diagnosis, development, and use of alternative dialysis therapies, and increasing the number of transplants signals to the kidney community that they are serious about changing the care of kidney patients." (Quote from 2019)

In addition to establishing the three objectives above as official policy, the Executive Order announced several kidney health action items and directs HHS and its various agencies to execute these items. These items closely mirror recommendations ASN had made to HHS over many years and, in development of this initiative, specifically over the year leading up to the release of the EO.

The ASN is appreciative of the progress made as a result of the AAKH, and there is still more to do. ASN views this RFI as an opportunity to re-engage the White House on Kidney Care issues from detecting chronic kidney disease and slowing its progression, spurring further innovations of care, to dialysis care and kidney transplantation for individuals with kidney failure, which advance the administration's stated mission of reducing the burden of chronic illness.

This RFI invited input on how best to advance a seamless, secure, and patient-centered digital health infrastructure. This RFI asked how CMS and ASTP/ONC Health IT can:

- Drive the development and adoption of digital health management and care navigation applications;
- Strengthen interoperability and secure access to health data through open, standards-based technologies;
- Identify barriers preventing the seamless exchange of health information across systems; and
- Reduce administrative burden while accelerating progress toward value-based, patient-centered care.

CMS and ASTP/ONC Health IT wish to build on the success of initiatives like Blue Button 2.0, and the CMS Interoperability and Patient Access Final Rule, all of which ASN supported in the first Trump Administration. ASN supports CMS's commitment "to ensuring that health information is not locked away in silos but rather flows securely to where it is needed most—empowering patients and providers." Also, ASN believes, like the CMS final rule indicated, patients should be able to move from doctor to doctor or to hospital and from insurer to insurer with their clinical and administrative information travelling with them – freely and easily. Kidney disease is a major public health crisis in the United States and the ninth leading cause of death. Nearly 815,000 Americans are living with End-Stage Renal Disease (ESRD), including approximately 550,000 on dialysis and 260,000 with a functioning kidney transplantⁱ. An estimated 1 in 7 adults, or about 37 million people, have chronic kidney disease (CKD), and as many as 90 percent are unaware of their conditionⁱⁱ. More than 100,000 Americans are currently on the kidney transplant waitlist, and 3,800 die each year while waitingⁱⁱⁱ. The U.S. Medicare program spends over \$150 billion annually to manage all stages of kidney disease, including \$50 billion for kidney failure alone. These figures do not include costs borne by the Veterans Affairs (VA) system or Indian Health Service, highlighting the urgent need to improve care for patients with kidney disease and reduce the overall burden on the health system.

With so many individuals unaware of their kidney disease and without prior knowledge of how to improve outcomes, the kidney care landscape is incredibly siloed. These patients may see a primary care physician, but kidney screening remains not as prevalent as it needs to be – especially for those with comorbid conditions like hypertension and diabetes. As a result, more than 125,000 Americans annually develop kidney failure, or end-stage renal disease, and need dialysis or a transplant to stay alive. The worst outcomes for patients with kidney failure occur among those who initiate dialysis in an unplanned manner—commonly known as crashing into dialysis. Crashing is not clinically defined but basically consists of a person discovering their kidneys have failed or are failing in an emergency setting like the emergency room (ER); the vast majority of these patients do not receive pre-emptive education about transplant or home dialysis options.

Approximately one in three fee-for-service Medicare beneficiaries with kidney failure crashed into dialysis during 2018–2022 based on a new measure developed by the American Institutes for Research (AIR). During the COVID-19 pandemic, a higher incidence of crash starts and increased deaths after crash dialysis occurred.^{iv} More preventive care and information are needed to prevent this crisis and to help patients and family navigate a very siloed system that needs to help people understand their disease and how to slow progression and should they reach failure, how to navigate their care through dialysis, transplant or palliative care.

The following is a list of topics covered in this letter:

- 1. Health Information Exchange (HIE)
- 2. Telehealth
- 3. Remote patient monitoring (RPM)
- 4. Dialysis and Transplant-Specific Data Standards
- 5. Interoperability and Application Programming Interfaces (APIs)
- 6. Transplant Waitlist
- 7. Data and USRDS
- 8. Medicare Advantage
- 9. Medicare Cost Reports

Health Information Exchange (HIE)

Dialysis facilities typically do not share electronic health record (EHR) systems with surrounding hospitals, skilled nursing facilities, or clinics, hindering the ability to share information in a bidirectional manner especially during transitions of care. Dialysis facilities and networks should benefit from the data collected by HIEs. Hospitalization rates for kidney failure patients can be high, with an average of about two hospital admissions per person-year, spending an average of 11.2 days in the hospital per year. Hospitalizations account for about 40% of total Medicare expenditures for ESRD patients.^v

Admission/discharge/transfer (A/D/T) feeds would be critical for individuals undergoing dialysis. A dialysis facility would be notified immediately when a patient is admitted to the hospital. Currently, dialysis facilities may receive notice of a hospitalization via fax. The information transmitted bidirectionally between the hospital and the dialysis unit includes clinical information related to medications administered during treatments, weights that inform how to manage patients' volume status, and critical treatment details.

ASN supported the interoperability standards of the first Trump Administration and remain supportive of HL7 Fast Healthcare Interoperability Resources (FHIR) standards for electronic health records (EHR) and Application Programming Interfaces (APIs).

Telehealth is increasingly used for treating people with earlier stages of kidney disease and later for those receiving in-center hemodialysis (HD) and home dialysis patients.

Telehealth use is a promising technology for individuals with chronic kidney disease (CKD) as well as those on in-center hemodialysis and home dialysis. While less than 5% of patient visits for CKD currently occur via telehealth, there is much greater potential to utilize this technology to improve access to care while maintaining quality. ASN supports continued telehealth extensions for in-center hemodialysis patients, whereby some monthly capitated payment visits can occur via telehealth. ASN also supports extensions for telehealth for home dialysis where patients can see their nephrologist monthly via telehealth with an in-person visit quarterly. This hybrid model of telemedicine and in-person care is appealing to both patients and nephrologists, and has been shown to improve outcomes.

Telehealth is particularly relevant for patients in rural and underserved areas, where access to nephrology care is often particularly challenging. Telehealth can better enable upstream management of CKD to prevent progression to ESRD, and for patients who chose home dialysis, can enable management from remote distances. The global coronavirus pandemic ^{vi} necessitated that nephrology care be delivered remotely to improve social distancing and thus, has created the need to harness the potential of using telehealth technologies.^{vii}

Patients with CKD and dialysis have high smart phone ownership and good mobile health readiness.

In December 2020, the *Clinical Journal of the American Society of Nephrology* published a survey of patients undergoing dialysis and how mobile health-ready they were. Among the 949 patients surveyed, four in five owned smartphones, 72% used the internet, and 70% had intermediate or advanced mobile health proficiency.

In addition to individuals with kidney failure, those with earlier stages of chronic kidney disease (CKD) often need to participate in complicated disease management strategies but have low levels of participation in self-management behaviors, a characteristic that links to poor outcomes. mHealth technology has the potential to improve the management of CKD by facilitating patient education, supporting behavior engagement (such as medication adherence and dietary modification), and aiding in patient-provider communication. mHealth is also an attractive option to supplement the taxed resources of health care providers, resulting, in part, from the increasing prevalence of CKD.

Remote patient monitoring (RPM) could have an important role in kidney disease given the need to monitor home weights, BP, blood sugar, etc. and sustainable reimbursement models are needed.

As stated previously, people with diabetes and hypertension are the most at risk for kidney diseases, and the development of kidney diseases in these patients increases their risk of morbidity and mortality. Advancements in RPM have demonstrated efficacy in managing both diabetes and hypertension, which, in turn, can slow the progression of kidney diseases to kidney failure.

Currently, endocrinologists, cardiologists, and other specialists involved in the care of these complex patients are able to prescribe RPM and receive coverage through Medicare Part B on patients with dialysis. However, if a nephrologist orders RPM for the same exact patient, Medicare will bill RPM under the Monthly Capitation Payment (MCP) within the ESRD bundle, effectively limiting the utilization of this important technology in the ESRD patient population. ASN urges the Trump Administration to work with Congress to move coverage of RPM outside of the MCP when ordered by a nephrologist to ensure that patients can access the best-possible management of their complex and comorbid conditions.

The Need for Dialysis and Transplant-Specific Data Standards to Enable Innovation

Current health data standards such as SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms), LOINC (Logical Observation Identifiers Names and Codes), and ICD (International Statistical Classification of Diseases and Related Health Problems) are insufficient to fully represent the clinical, operational, and logistical information relevant to dialysis and transplantation, limiting our ability to generate true interoperability. These gaps impede the development of interoperable tools and patient-facing applications. For instance, concepts critical to transplant workflows—such as waitlist status, organ offer history, sensitization metrics (e.g., a Calculated Panel Reactive Antibody (CPRA), and dialysis facility transitions—lack a consistent,

computable representation across systems. Without standardized terminologies, developers face significant hurdles building tools that allow patients to track their transplant status or that facilitate smoother care coordination across dialysis and transplant providers. CMS (the Centers for Medicare & Medicaid Services) should collaborate with ONC, Health Resources and Services Administration (HRSA), Organ Procurement and Transplantation Network (OPTN), and EMR vendors and other stakeholders to create and implement standardized vocabularies and data models that reflect the unique aspects of end-stage kidney disease (ESKD) care. Dialysis providers should be incentivized to allow interfaces with the EMRs and 3rd party communication platforms to allow for exchange of information, including hospitalizations, deaths and other clinically relevant data.

Supporting APIs for Seamless Registry Reporting and Data Exchange

Currently, reporting to registries like the EQRS (ESRD Quality Reporting System) and the OPTN registry and donorNet require complex manual data entry or proprietary interfaces. This impairs timeliness and data quality. APIs that align with FHIR-based standards should be developed, maintained and mandated to facilitate automated, realtime submission to these registries from EHRs and dialysis-specific electronic systems. Moreover, these APIs should be bidirectional, allowing providers and patients to view what has been submitted, flag errors, and reduce discrepancies.

Enabling this capability is essential not just for efficiency but also for the accuracy of national data used in policy and research and for the provision of patient-facing information. For example, improving access to available clinical trials, centers of excellence and transplantation requires a significant improvement in the breadth and quality of data captured by the OPTN and is likely to improve patient outcomes. There is currently a double data entry for transplant patient preferences in the EMR and the OPTN waitlist, resulting in significant discrepancies between the two systems. There is no easy way to overcome or identify errors that arise from this double data entry.

Large EMR vendors should be required to open their systems to third-party APIs. For example, currently, there is no way to directly interface with the Phoenix module in Epic to share transplant-related information, such as waitlist status or pending evaluation workup steps, with external referring providers and dialysis facilities, which impedes coordination of care.

Patient Access to Transplant Waitlist Status: A Key Use Case

Despite significant patient interest, there is no current mechanism that allows patients to directly access their transplant waitlist status or history in a reliable and understandable way. This information is siloed within transplant centers and is not made accessible through existing patient portals or APIs. CMS and ONC should prioritize development of technical standards and implementation guidance that require transplant centers to make waitlist information available to patients and other providers (such as dialysis facilities) via standardized APIs. This would empower patients and those who

coordinate their care to better understand their transplant journey, reduce misinformation, and support shared decision-making, especially in the context of multiple listing and transplant center shopping. Similarly shared decision making around organ offers requires patients to gain awareness and access to this information.

Integrating Linkages to the National Death Index (NDI) and other external data

Another critical gap in the current ecosystem is the lack of standardized linkages to external datasets such as the National Death Index (NDI), census tract-level SDOH data, or Medicaid claims. These linkages are vital for supporting population-level surveillance, understanding health inequities, and improving care planning. For example, combining SDOH and dialysis data could inform predictive models for missed treatments or hospitalizations. However, these data sources often exist in disconnected silos with restrictive governance policies. CMS and ONC should develop guidance and technical frameworks to facilitate responsible, privacy-preserving linkages across systems using unique identifiers or tokenization strategies.

Avoiding Data Loss from Restricting Medicare Claims Data for the United States Renal Data System (USRDS)

The recent requests for information that propose to limit access to physical Medicare data files to researchers represents a significant setback for the dialysis and transplant community. The USRDS relies on access to Medicare claims data and has long served as a cornerstone for evaluating care quality, informing policy, and supporting a robust evidence base. While integration and modernization of data systems is needed, threatening such a comprehensive dataset and/or access to it risks data fragmentation and long-term harm to research, clinical innovation, and oversight. CMS should ensure continuity of longitudinal, linked data on ESRD patients with enhancements in data functionality, such as the ability to provide linkages or use tools like ArcGIS (a software system for collecting and managing data, analyzing it, and easily sharing maps and apps within a connected and collaborative web geographic information system (GIS) that might now exist in CMS' Virtual Research Data Center (VDRC)).

Medicare Advantage claims data-related challenges

There has been a significant increase in patients with ESRD who are enrolled in Medicare Advantage (MA) over the past several years, with now over 50% of individuals with ESRD in MA plans. Patients enrolled in MA often face greater difficulty accessing their own health data compared to traditional Medicare beneficiaries. Plan-specific portals vary widely in functionality, interoperability, and timeliness. Many do not support standardized APIs or FHIR-based interfaces that would allow patients to export their claims or encounter data to third-party apps. CMS should enforce consistent, real-time API access to clinical and claims data across all MA plans, equivalent to what is expected in traditional Medicare.

MA enrollers frequently move between plans, where enrollment changes are common due to costs, coverage differences, or provider availability. However, there is no

infrastructure to ensure continuity of data across plans, leading to fragmented care. Patients may lose access to previous laboratory values, general clinical office visits, referrals, or transplant evaluation records. CMS should require MA plans to participate in standardized data exchange platforms (e.g., TEFCA) and implement continuity-of-care data bundles that transfer automatically when a patient switches plans.

MA plans often apply prior authorization, step therapy, or network restrictions that limit access to diagnostics, procedures (like transplant evaluation), and new technologies (e.g., home dialysis support tools). Patients and providers are frequently unaware of these restrictions until a denial occurs. CMS should require MA plans to expose real-time benefit tools and prior authorization status via standardized APIs that EHRs and accessible patient-facing applications (apps) allowing patients and clinicians to understand coverage pathways up front.

Notably, MA plans do not submit the same level of data granularity (e.g., labs, encounters, mortality) as fee-for-service (FFS) Medicare, making it harder to track outcomes or support national surveillance and research. This undermines systems like USRDS, EQRS, or the Scientific Registry of Transplant Recipients (SRTR) that rely on comprehensive data. CMS should mandate standardized data submission from MA plans—on par with what is required from providers in traditional Medicare—to preserve data equity and support research and oversight.

Medicare Cost Report

Despite their potential to inform policy, pricing, health equity analyses, and value-based care models, cost reports are still submitted in formats that are difficult to parse, lack standardized data definitions, and are siloed from clinical and operational datasets. No patient-level linkage is feasible at present, limiting our understanding of pretransplant care and access as well as limiting the ability of CMS, external researchers, and policy makers to use pretransplant claims data in any meaningful manner.

Conclusion

This letter represents ASN priorities in this area but is not an exhaustive list of items. ASN stands ready to work with CMS and ASTP/ONC Health IT to further refine digital health improvements for the 37,000,000 Americans with kidney diseases. To discuss this letter further, please contact David Whie, ASN Senior Regulatory and Quality Officer, at <u>dwhite@asn-online.org</u>.

Sincerely,

Pratis Roy Chandhungn

Prabir Roy-Chaudhury, MD, PhD, FASN President

^v <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</u>

ⁱ <u>https://www.kidneyfund.org</u>

ⁱⁱ Annual Data Report | USRDS, <u>https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet</u>, <u>https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease</u>

iii <u>AOPO Highlights Disturbing Crisis: Thousands of Kidney Patients who Died Waiting for Organs in 2023</u> <u>Could Have Been Saved - AOPO</u>

^{iv} <u>https://www.air.org/resource/brief/crash-dialysis-trends-show-potential-areas-medicare-quality-and-cost-improvement#:~:text=Key%20Findings,deaths%20after%20crash%20dialysis%20occurred.</u>

Instruments/ESRDQIP/Downloads/SHR-Methodology-Report.pdf

^{vi} <u>https://doi.org/10.1053/j.ajkd.2020.10.013</u>

^{vii} <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC8815747/</u>