



May 15, 2024

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

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,655 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to respond to the Request for Information (RFI) on the Research Data Request and Access Policy Changes issued by the Centers for Medicare and Medicaid Services on February 14, 2024 and updated March 1, 2024.

Recently, CMS announced its decision to discontinue the physical delivery of critical healthcare data in support of external research projects. Instead, beginning in 2025, researchers will be required to use the Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC) to conduct all research using CMS Research Identifiable File (RIF) data.

To respond thoughtfully to CMS' RFI, ASN solicited feedback from its diverse membership, including members who have direct experience conducting research with the U.S. Renal Data System (USRDS) Annual Data Report (ADR) and the USRDS Standard Analysis Files (SAFs) along with other health care data from other agencies within the federal government. ASN's response to the RFI, therefore, reflects perspectives of the society's members, leadership, and staff as well as the broader nephrology community.

ASN believes the proposal jeopardizes the future of research on kidney diseases and will likely directly harm Medicare and Medicaid beneficiaries' access to and quality of care. ASN respectfully requests that CMS pause the proposal to allow for time to address concerns of the kidney community, those of the broader health care community and, most importantly, those of individuals living with kidney diseases.

ASN is also equally concerned by:

- The lack of transparency regarding the future of CMS kidney-related data in light of this proposal.
- The unique nature of the federal government's role in kidney care given Medicare's end-stage renal disease (ESRD) program, and thus, the potential for

jeopardizing the real-time research necessary for policy makers to improve kidney care.

- The impact that a future dearth of research will have on disadvantaged populations given the inequities faced by kidney patients and their families.
- The impact of increased costs for researchers and their institutions, especially those at smaller, less financially endowed universities.
- The potential to impede the future capacity of researchers across specialties, but in particular in the realm of kidney diseases.

### *Kidney Disease in the United States*

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)<sup>i</sup>. Among those individuals, over 800,000 have kidney failure and require dialysis or a kidney transplant to survive. All 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<sup>ii</sup>. (word) although Medicare beneficiaries with ESRD represent merely 1% of total Medicare beneficiaries, their care accounts for 7% of traditional Medicare spending.

Additionally, kidney diseases exert a disproportionate burden on minority and underserved communities in the United State. Black Americans are 3.8 times more likely to develop kidney failure than White Americans, and Latinx Americans are 2.1 times more likely to develop kidney failure than White Americans. One out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Latinx Americans are less likely to receive a kidney transplant or initiate home dialysis when requiring treatment for kidney failure.

ASN is deeply concerned about how this policy change could further exacerbate the challenges faced by populations already disproportionately burdened by kidney diseases as well as the broader implications it may have on Medicare policy and spending. Claims-based research on kidney diseases serves as a critical tool for documenting and addressing health and health care inequities, optimizing Medicare spending, and improving the quality and efficiency of care for the millions of Americans affected by kidney diseases. Without equitable and affordable access to CMS data, researchers and policymakers will not be able to research, create, and enact policies that promote health equity, enhance high-quality care, and mitigate the economic impact of kidney diseases on the health care system.

### *Transparency in CMS Kidney Data*

Due to Medicare's enormous investment in kidney health, Congress mandated the USRDS, the largest and most comprehensive national ESRD and chronic kidney disease surveillance system.<sup>iii</sup> 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.<sup>iv</sup>

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 (NHANES), 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.<sup>v</sup> Many of these datasets are not available in the CCW VRDC (i.e., datasets from EQRS, the facility survey, the ESRD Death Notification form, UNOS data, and data from Special Studies). ASN is very concerned by the lack of transparency about whether these data sets can and will be migrated into the CCW VRDC.

The EQRS forms the backbone of the USRDS dataset and many of the analyses that comprise the USRDS' Annual Data Report, a report that is Congressionally mandated. In addition to ensuring that the government can identify every individual in the US with ESRD, the EQRS is a vital web-based data-collection system that enables dialysis facilities to meet portions of the Conditions for Coverage for ESRD Dialysis Facilities. Moreover, the EQRS helps the kidney community transition from a legacy paper-based data-collection method to an electronic "always on" format. The system is designed to help improve patient care efforts by reducing the time it takes CMS to produce clinical performance results. EQRS functions as an important data source for ESRD Quality Incentive Program (QIP) performance measures.<sup>vi</sup>

The USRDS' Annual Data Report cannot continue without giving the USRDS contractor access to the EQRS database. Entire sections of the report rely on EQRS data; without EQRS data, Chapters 1-4, 6, and 8 would be impossible to produce (50% of the ESRD chapters).

Moreover, the EQRS data are not available through the Research Data Assistance Center (ResDAC), and numerous researchers, who are members of ASN, have been told there is no date in sight for its availability. One researcher shared with ASN an email exchange in which they wrote to ResDAC in February 2024 inquiring:

*"I am a researcher at (name removed) and am writing about the availability of CMS End Stage Renal Disease Quality Reporting System (EQRS) data for research. EQRS is the replacement for REMIS/CROWNWeb, which was*

*discontinued in 2020. I didn't see this file listed on the ResDAC website but was wondering if there is a way to request access.”*

The response from ResDAC read:

*“Thank you for reaching out. This file currently is not available. We do not have a timeline for its release.”*

Equally concerning is the absence of UNOS (transplantation) data in the CCW VRDC. ASN commends CMS’ recognition that kidney transplantation is the optimal treatment for patients with ESRD. Indeed, the ESRD Treatment Choices and the Kidney Care Choices payment models heavily featured kidney transplantation as an important outcome. CMS also recently announced the Increasing Organ Transplant Access model to increase access to kidney transplantation. Unfortunately, CMS’ data proposal moves in direct opposition to its stated priority of increasing access to kidney transplantation and of improving transplantation outcomes. Under this proposal, CMS will provide no means for the USRDS or researchers to access UNOS data. In fact, the Annual Data Report heavily uses UNOS data to provide key epidemiological and economic data regarding transplantation; these analyses are most prevalent in Chapters 1, 7, and 8.

ASN is very concerned about this lack of transparency and believes that CMS kidney data comprise an invaluable resource that has advanced kidney research (and therefore practices to improve the wellbeing of people with kidney diseases). These data have been used extensively to shape regulatory and legislative policy. They have also allowed institutions and researchers with a wide range of resources to conduct impactful research. For example, our current knowledge of disparities among individuals impacted by kidney diseases has made possible CMS’ ability to risk adjust in the ESRD program and measure the prevalence and impact of social determinants of health (SDOH). Ready access to these robust kidney data at virtually no cost to the research community has supported best practices and sound policies across the board – one need only to review the study citations in the footnotes of the annual final rules of the ESRD Prospective Payment System (PPS) and Quality Incentive Program (QIP) to see its impact.<sup>vii</sup>

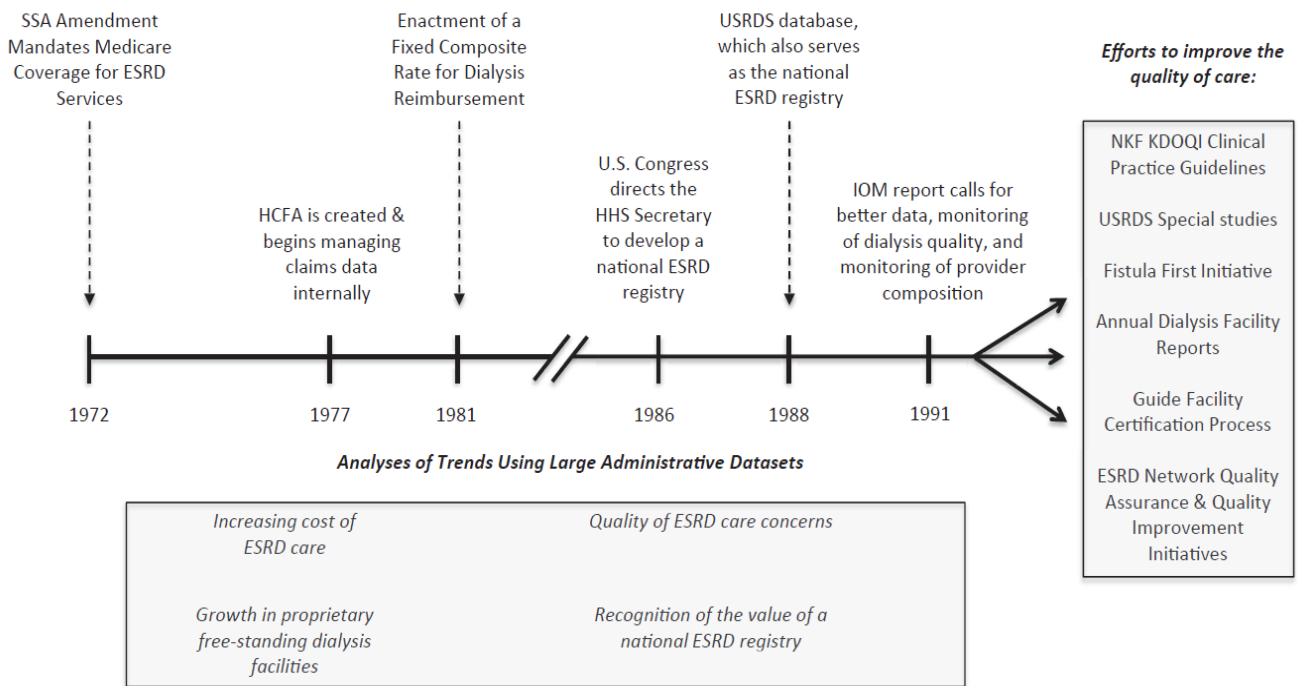
### *Importance of CMS Kidney Data*

The federal government has an outsized role in kidney care that does not have a parallel. Erickson, Qureshi, and Winkelmayer (2018) detailed how data – particularly large data sets – have been developed as a result of that role and how data availability has impacted policy and quality in kidney care – especially for people with kidney failure who require dialysis or a transplant to live. They wrote:

*Rapid growth in electronic communications and digitalization, combined with advances in data management, analysis, and storage, have led to an era of “Big Data.” The Social Security Amendments of 1972 turned end-stage renal disease (ESRD) care into a single-payer system for most patients requiring dialysis in the*

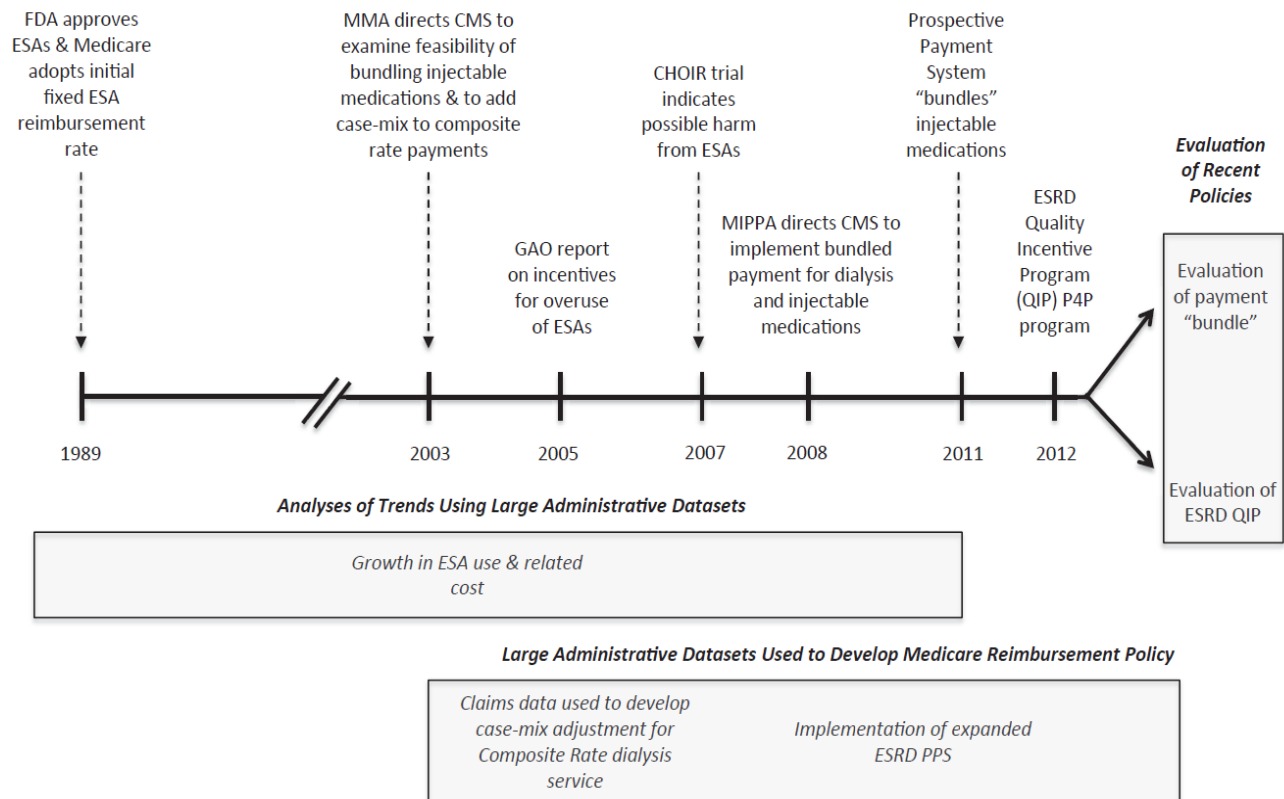
*United States. As a result, there are few areas of medicine that have been as influenced by Big Data as dialysis care, for which Medicare’s large administrative data sets have had a central role in the evaluation and development of public policy for several decades.<sup>viii</sup>*

Erickson and colleagues illustrated the early growth of data in dialysis care and some of the important policies it influenced in the figure below.



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The congressional mandate of a national ESRD registry housed within USRDS ushers in the rise in importance of kidney health data and has been expanded to include data on non-ESRD kidney diseases and kidney transplantation. Again, some of the milestones in the influence of large data sets in ESRD policy leading up to expansion of the dialysis payment bundle are illustrated below.



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With a federal investment of \$50 billion annually in ESRD care, the need to preserve and protect the integrity of these data is enormous as would be the ramifications of limiting researcher access to these data. These data also translate into vital quality information to help inform individuals on key decisions they face when kidney disease progresses, including decisions about kidney failure treatment options and dialysis and kidney transplant facilities.

### *Exorbitant Costs for Researchers and Their Institutions*

The proposed change to CMS data would require that researchers use the VRDC environment, which carries significant costs to facilitate access (initial fees of \$20,000 per user and \$15,000 per project fee, annual renewals of \$13,000 per user and \$10,000 per project, plus additional costs for software, drive space, and computation). In sharp contrast to the current pay-to-play model, researchers who obtain a data use agreement (DUA) may currently obtain data free of charge. The VRDC costs will add up quickly and will impose an insurmountable barrier for much of the next generation of researchers aiming to improve care for people with kidney disease. Similarly, the fees will also restrict opportunities for senior investigators to mentor junior researchers to properly use robust and generalizable clinical data. Given the complexities involved in the Medicare files, cutting off access to these mentorship opportunities for the next generation of researchers reduces the likelihood that future research findings will be useful to the broader health care community and will be able to assist the government in achieving its goals of optimizing care for beneficiaries.

Jencks, Williams, and Coleman (2009) used CMS data to analyze rehospitalizations among patients in Medicare fee-for-service. This seminal paper showed that nearly one-fifth of hospitalized and discharged patients were re-admitted within 30 days.<sup>xi</sup> This study led to major changes in health care and greater scrutiny of re-admission rates and was made possible by accessing readily available Medicare data that were collected and funded by taxpayers (as was much of the care provided in both the original hospitalization and the readmission). To add tens of thousands of dollars to the costs of conducting similar studies will impose an enormous impediment to future kidney research.

ASN members know firsthand that research in health policy and healthcare delivery – especially kidney care delivery – is often unfunded or funded through smaller grants with limited resources that could not support VRDC data access. These projects contribute meaningful evidence to further policy proposals, improve patient outcomes, and save care costs for millions of patients across the United States. Unfortunately, in the absence of the USRDS, these research projects would only be feasible at a handful of well-resourced institutions and research centers that have a large research infrastructure that can support an ongoing research program with CMS claims. Therefore, this policy has a strong potential to create disparities in career opportunities between under-resourced and better-resourced scholars.

#### *At What Costs for the Future?*

ASN believes there is a very real possibility that this proposal will cripple the future capacity of researchers and, more importantly, publicly available research vital to informing healthcare providers, scientists, and policymakers alike. Trying to quantify the value of existing research with CMS data in practices and policy is nearly impossible because of its vast impact. Calculating the future costs of this proposal is also extremely difficult. Cooper (2024) compiled “an incomplete list of high-impact scholarship that was conducted using Medicare claims data. This includes scholarship that:

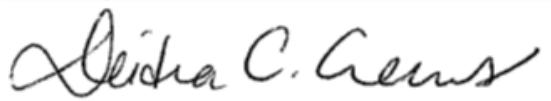
- Formed the intellectual basis for the Affordable Care Act
- Helped motivate the Medicare Hospital Readmission Reduction Program
- Informed and helped assess Medicare payment policy, including ACOs and bundled payments
- Analyzed the efficiency of the Medicare Advantage program
- Identified the causes of mortality differences across regions
- Identified the causes of the opioid epidemic
- Described the causes and consequences of variation in Medicare spending across the US and identified strategies to address it
- Documented racial disparities in the Medicare program
- Identified the effect of private equity firms on the survival of Medicare beneficiaries
- Illustrated how hospital competition and mergers impact mortality
- Proposed strategies to identify and root out Medicare fraud

- Documented how to measure providers' quality and insurance plan quality
- Described the presence of low value care delivered to Medicare beneficiaries

This list includes a sample of the types of research that would be curtailed with the recent CMS proposal to shift all Medicare claims data access to the CMS Virtual Research Data Center. This is research that has improved public policy, led to reductions in mortality, likely led to billions of dollars of savings for the federal government, and reduced Medicare fraud.”<sup>xii</sup> Mr. Cooper provided the Google doc link to this work as well as his permission for its use by ASN.

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. To discuss this letter, please contact David White, ASN Regulatory and Quality Officer, [dwhite@asn-online.org](mailto:dwhite@asn-online.org).

Sincerely,



Deidra C. Crews, MD, ScM, FASN  
President

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<sup>i</sup> [Chronic Kidney Disease in the United States, 2023 \(cdc.gov\)](https://www.cdc.gov/kidney-disease/ckd-education/ckd-in-us-2023/)

<sup>ii</sup> [Kidney Disease Statistics for the United States - NIDDK \(nih.gov\)](https://www.niddk.nih.gov/health-information/kidney-disease/kidney-disease-statistics)

<sup>iii</sup> <https://www.sciencedirect.com/science/article/pii/S2157171615321006>

<sup>iv</sup> <https://health.gov/healthypeople/objectives-and-data/data-sources-and-methods/data-sources/united-states-renal-data-system-usrds>

<sup>v</sup> *Ibid*

<sup>vi</sup> <https://www.qualityinsights.org/qirn3/data/eqrs>

<sup>vii</sup> <https://www.federalregister.gov/documents/2023/11/06/2023-23915/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis>

<sup>viii</sup> <https://pubmed.ncbi.nlm.nih.gov/29921451/>

<sup>ix</sup> *Ibid p. 2*

<sup>x</sup> *Ibid p. 5*

<sup>xi</sup> <https://www.nejm.org/doi/full/10.1056/nejmsa0803563>

<sup>xii</sup> <https://docs.google.com/document/d/1H-27k-tn3jQJ65UUvMRr1vgW3KVIgoYdOqihzTYpG0k/edit>