



February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244

RE: CMS-2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration Request for Information

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 respond to the request for information issued by the Centers for Medicaid and Medicare Services (CMS) for “End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration Request for Information (RFI)”.

ASN has divided its comments into four areas:

1. ‘Primary Cause of Renal Failure’
2. Laboratory Tests
3. Form functionality
4. Transplant

While these comments may exceed the scope of what CMS is seeking with this RFI, ASN believes a broader discussion of how this form is used, what data it collects, and what can reasonably be accomplished with its administration would be invaluable to improving kidney care at such a crucial health care moment for so many individuals.

‘Primary Cause of Renal Failure’

The ‘Primary Cause of Renal Failure’ list needs revisiting. While ASN appreciates the attempt to match to ICD-10-CM codes, this has resulted in a morass of disease states. Glomerulonephritis is not strictly a single disease, and its presentation depends on the specific disease entity. Many causes of glomerulonephritis are missing from the list, including IgA nephropathy, which is the most common glomerulonephritis worldwide. The list also exhibits an overreliance on pathology findings and no incorporation of disease states or causes. With many more diagnoses being made serologically, the reliance on pathologic descriptions is increasingly irrelevant. ASN suggests the list be

populated with disease entities, such as IgA nephropathy, APOL1-associated disease, C3GN, Membranous Glomerulonephritis, ANCA-associated glomerulonephritis, and others.

ASN also believes the additions of 'nephrotic syndrome with...' or 'nephritic syndrome with...' are somewhat vague. For example, what is 'Nephrotic syndrome with minor glomerular abnormality' supposed to capture? The term 'Wegener's Granulomatosis' is considered obsolete by many in nephrology. Other aspects of this list that ASN finds challenging include the lack of a means to identify cardiorenal syndrome aside from 'Heart Failure, unspecified' and the lack of a means to identify obstruction, such as seen with prostate disease; this latter example only appears in N13.8 'Other obstructive and reflux uropathy 2' designator.

ASN strongly urges CMS to revisit this entire classification system, abandoning the ICD-10 nomenclature and replacing it with entities seen and nomenclature used in clinical practice. If CMS wishes to keep an ICD-10 structure, these entities can be mapped on the back end to specific codes. This will result in far better data quality. We would be pleased to have nephrology members work with you on a refined list that aligns with the clinical approach to causes of kidney failure.

Laboratory Tests

ASN also urges CMS to consider deleting the lipid profile/LDL cholesterol. This field adds little and can be challenging to track down. We also question whether anyone has utilized the assay data/lower limit data for serum albumin and suggest eliminating these fields as well given minimal value added.

In addition, ASN urges CMS to consider adding optional fields for cystatin C and for measured kidney function (creatinine clearance, mean of creatinine and urea nitrogen clearance, isotope assessed, etc.) Nephrology has recognized the limitations of serum creatinine as an estimator of glomerular filtration rate and providing other options to provide information on kidney function will be informative. Additionally, cystatin C use may be increasing following the 2021 National Kidney Foundation (NKF) -- ASN final report recommending the adoption of the new eGFR 2021 CKD EPI creatinine equation that estimates kidney function without a race variable. The task force also recommended increased use of cystatin C combined with serum (blood) creatinine, as a confirmatory assessment of GFR or kidney function.

ASN urges CMS to clarify that the labs, particularly those reflecting kidney function, should reflect the labs **prior** to initiation of dialysis. If one has received dialysis multiple times already (even perhaps for months in the case of AKI-D or a prolonged hospitalization), the laboratory results within 45 days may be irrelevant and should not be the ones included here, even if they are most proximate to admission to an outpatient dialysis facility.

Form functionality

The current version of the form lacks direction on how to enter a 2728 for individuals without social security numbers and without a Medicare Beneficiary Identifier. The demographic section also fails to address homelessness, as there is no alternative for the 'patient mailing address'. CMS should discuss with the kidney community how to best capture data relating to issues such as housing insecurity, transportation barriers, and indicators of social economic status such as dual eligibility for Medicare and Medicaid whether in the 2728 or through another pathway.

ASN also has concerns over the wording of question 17 (question 20 on the 10/2022 proposed form). ASN suggests that CMS consider changing this question to "What access was used on first chronic dialysis". This reflects the need to access patient status prior to their treatment in an outpatient dialysis facility. Additional clarification will also be needed to reflect the existence of the AKI-D patients in outpatient dialysis facilities and how and when to define their initial access. We also note that, strictly speaking, neither arteriovenous grafts nor peritoneal dialysis catheters 'mature'. Grafts require approximately 2 weeks to incorporate with the surrounding tissue to minimize the risk of a hematoma collapsing the access. Peritoneal dialysis catheters can, theoretically, be used immediately, although a waiting period of 2 to 3 weeks is preferred for the tunnel to seal around the catheter, thereby reducing the risk of a peritoneal leak.

The current functional use of hemodialysis hours (minutes) per session is not a helpful field as the answer will change frequently over the first month, especially for outpatient starts. In the instructions, ASN also believes the concept of a physician writing a prescription in the inpatient setting for a "regular course of dialysis" is unlikely. For inpatients, most physicians will rewrite orders the day before or the day of each HD session. Additionally, this instruction does not apply effectively to peritoneal dialysis.

The form currently requires an original signature by all parties. Given current operational systems, we request that CMS consider a valid electronic signature as meeting criteria for 2728 form needs.

Also, as detailed above, the form has many areas that are not applicable or misleading for home dialysis patients. We request that individuals with expertise in home dialysis review this form to ensure ease of use for patients receiving both in-center and home dialysis.

Finally, ASN suggests the addition of a line for AKI-D initiation date in an outpatient setting for those first designated as AKI-D who then became ESRD. We feel that this is important to establish the baseline time for the transplant waitlist for individuals who do not recover from AKI, rather than these individuals potentially losing months of wait time.

Transplant

ASN thanks CMS for its emphasis on kidney transplantation, the optimal therapy for most people with kidney failure, in this set of proposed changes to the 2728 form. Maximizing patients' access to kidney transplant—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. The society stands ready to work with CMS through all possible avenues to achieve this goal and believes that data collection is a crucial aspect of this shared priority for the society and the agency.

Ensuring that all patients receive individualized education and detailed information about the benefits of deceased donor and living donor kidney transplantation, including regarding outcomes of transplantation relative to outcomes on dialysis, is a crucial component of access to kidney transplant. ASN concurs with CMS' observation that the current phrasing of the question on the 2728 form inquiring whether a patient has been provided with information regarding kidney transplant, is not sufficient to reflect true patient understanding or capture enough data to provide sufficient insights about the information provided.

At present, enough data are available to know that different populations of patients with kidney failure have significantly different access to consideration for kidney transplant, including inequitable variation across racial/ethnic, sociodemographic, and geographic lines. However, because no component of the kidney health ecosystem routinely collects meaningful data regarding people with kidney diseases who are considering transplantation until they are placed on the waitlist, there is a paucity of understanding regarding access to transplant – and likely missed opportunities to improve equity in access to kidney transplantation.

A major challenge to measuring and ensuring equity in access to transplant is the lack of data regarding this “pre-waitlist” period, particularly the referral process and steps prior to initiating medical evaluation. ASN has previously called on HHS to routinely capture pretransplant referral and evaluation data, including data on social determinants of health and key demographic data at the dates of referral for transplant and dates of transplant evaluation. In addition to the 2728, these data are also ideally collected from transplant centers directly, so that data on patients prior to kidney failure could also be captured (e.g., patients with CKD who are preemptively referred). It is key for CMS and HHS to work together to ensure that data collection is not duplicative, and that the data collected are done so in a holistic manner to document all referrals, not just those that occur after a patient starts dialysis. These data would be very helpful for patients' decision-making and could be used in shared decision-making tools to help guide patients through the transplant process.

The patient education and decision-making process related to transplant is complex, spans multiple care sites in the patient journey, and often spans many months or even years. There are numerous opportunities for improvement both in the data collected about this process, as well as in the education provided. For example, the society has also previously called for the creation and greater use of shared decision-making support tools that help patients, their nephrology care team, and their transplant care

team weigh transplantation options versus continued dialysis (including helping patients think about their preferences regarding the tradeoff between increased selectivity for organs and wait times for those organs). The advancement of such tools into routine practice at multiple care sites in the patient transplant journey, would help assuage concerns that data collection forms—including the 2728—are simply “check boxes,” inadequate to ensure true patient understanding and engagement.

In sum, ASN is very interested in improved collection of meaningful data (including sociodemographic data) earlier in patients’ transplant journey and supports CMS’ interest in moving in this direction, too. The 2728 form is an important tool in this effort, and ASN offers some specific feedback on the proposed transplant-related additions, below. However, most importantly, ASN also urges CMS (together with HHS and the patient and health professional community) to take and engage in a broader evaluation of all the possible tools it has at its disposal to collect this important data, some of which may be better suited to capture certain elements of the right data at the right time than the 2728. Throughout all data collection efforts related to transplant care, ASN urges CMS to ensure appropriate demographic information is collected to enable the agency and the research community to identify, understand, and maximize equitable access to kidney transplantation for all patients.

Proposed new question 20 (g)

ASN supports the addition of this question.

Proposed new question 28

ASN supports the addition of this question. The society is strongly supportive of increased patient engagement and shared decision-making and ensuring patients have ample understanding to be full partners in their care plans.

The society recommends that question 28 be revised to read “Does the patient understand kidney transplant options **NOW?**”

This change helps to distinguish question 29 from question 20 and creates an expectation for helping the patient gain an understanding of transplant options.

ASN recognizes and appreciates that the instructions related to the new draft 2728 form directs dialysis facilities to revisit transplant options with a patient who is not considered informed about transplant at the time the 2728 form is originally completed and integrate them into the care plan. The society concurs that transplant education and decision-making is often a process that requires significant time and multiple iterative conversations. This is a positive change that ASN supports.

ASN also recommends that clinical providers be provided with and encouraged to use standardized and validated educational or shared decision-making tools, such as those available from the UNOS Kidney Learning Center. Widespread adoption of these types

of standardized and validated tools ensures evidence-based best practices are used across facilities.

Proposed new question 29

ASN supports the addition of this question. The society recommends that the options under question 29 be slightly revised as follows in the table below. We recommend these revisions to ensure that options on question 29 on the form are not inappropriately selected for patients who have modifiable risk factors or relative contraindications for transplant.

Proposed language for #29 options	Suggested language for #29 options
• Patient has not been assessed	• Patient has not YET been assessed
• Patient is not medically eligible	• Patient has an absolute contraindication

The society believes dialysis facilities (as well as nephrologists) and transplant centers (and their multidisciplinary teams of providers) have a significant role to play in supporting people with kidney failure in navigating the journey to a transplant—and there are many improvements to be made in service of this goal throughout the kidney health ecosystem. ASN believes that changes to other levers under CMS’ control, such as the dialysis facility Conditions for Coverage, may be additional opportunities to address and ensure dialysis facilities are providing comprehensive, individualized information about transplantation. ASN also encourages CMS to consider other ways in which patients’ own input in the process, or their participation in shared decision-making, could be captured or documented.

Proposed new question 30 ASN supports the addition of this question; as described earlier, the capture of pre-waitlisting data is a huge current gap in our understanding of access and equity, and adding this question is an essential step for CMS to take. Inquiring whether a patient has already been referred to a transplant center is a crucial addition to the form for data collection purposes to increase our understanding of patterns of access and referral by patient population demographics.

ASN recommends that the transplant center that a patient was referred to also be captured on this form, in addition to the date the referral was made. If multiple referrals have been made, the option to enter multiple dates and centers should also be available.

In addition, a clear definition of what a “referral” constitutes must be established. Having a standardized definition of that term in the context of the 2728 is essential to ensure that different facilities are reporting on the same practice. Does it mean that a referral was faxed over; that confirmation from the center that the referral was received; or that (ideally) the referral was received and the patient or referring provider has heard back from the center. Ideally, the definition would be the second or third option.

ASN also notes that collection of this data on the 2728 form should complement and not replace, collection of pre-waitlisting referral data from transplant centers. Receiving information about this crucial step in the process of care from multiple stakeholders is important, enabling the research community to cross-reference the data and make inferences about opportunities for improvements in processes of care and patient access. (ASN is also actively encouraging HRSA, through the OPTN contractor, to collect pre-waitlisting referral data from transplant centers, which would include similar and additional elements.)

Question 38 ASN recommends that this question be rephrased slightly to read “Type of **Transplant**” instead of “Type of Donor,” and the options for responses broadened to include “Multi-organ” and “Swap.” This change would allow us to gather more granular information about the type of transplant a patient had, versus simply the donor type.

Additional recommendations for transplant-related questions

ASN also encourages CMS to make two additional modifications to the 2728 related to transplant.

1. Require completion of the 2728 for patients who return to needing dialysis post-transplant. At present, there is no requirement to complete the 2728 again if it was completed in the last three years. However, this means we miss collecting important data about patients whose grafts have failed early and who are lost to follow-up at their transplant center. Additional questions related to patients who require dialysis post-transplant should include:
 - Did the patient need dialysis post-transplant?
 - If yes, how many days passed from the time of transplant to the time of the first dialysis session?
 - If possible, collect information regarding the number of days of dialysis dependence.

These additions are important because patients who have graft failure are at significant risk of death as compared to patients who are just on the waiting list or starting dialysis with no recent transplant. The ability to track this information will enable us to identify ways to intervene and better support these vulnerable patients.

2. Consider additional modifications to the 2728 for patients who have the form completed at the time they receive a pre-emptive kidney transplant. ASN stands ready to have a detailed follow-up conversation about this recommendation.

Beyond the scope of the 2728, but worth reiterating in a conversation about potential ways CMS and HHS could help maximize patients’ access to kidney transplantation, is ASN’s desire to see the development of an interoperable centralized health information exchange that is accessible along entire transplant continuum (from nephrologists, CKD clinics, and dialysis providers through OPOs and transplant centers), using APIs to

facilitate the transfer of information across EMRs and healthcare systems. Such a development would allow for documentation at many points in time (versus the more one-time nature of the 2728) and for that documentation to be shared with all health professionals with a role to play in a patients' transplant journey.

This goal—to create a system resembling the exchanges that EMRs and pharmacies are on that seamlessly direct messages to the relevant stakeholders when prescriptions are written—would likely require coordination between HRSA, CMS, and possibly other elements of HHS, such as ONC. ASN stands ready to discuss this concept and help in any way should the agency wish to pursue it.

In summary, ASN believes that dialysis facilities have an important role to play in educating patients about transplant and supporting patients in their transplant journey – and in helping to ensure equitable access to transplantation. Ensuring that any data collection supports efforts to maximize equitable access to transplant is paramount. The society encourages CMS to consider not only the 2728 form, but also other mechanisms at its disposal that may be more well-suited to capturing dialysis facility efforts to support patients in their transplant journey, including the conditions for coverage. ASN also acknowledges that many other simultaneous changes to the current kidney health ecosystem must occur urgently to achieve the goal of maximizing access to transplant.

ASN stands ready to work with CMS on the many recommendations included in this letter. If you would like to discuss this letter further, please contact ASN Regulatory and Quality Officer David White at dwhite@asn-online.org .

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Josephson".

Michelle A. Josephson, MD, FASN
President