June 29, 2023

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

The Honorable Shalanda Delores Young
Director
Office of Management and Budget
725 Seventeenth Street NW
Washington, DC 20503

RE: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration (CMS-2728)

Dear Administrator Brooks-LaSure and Director Young:

The Renal Healthcare Association (RHA) appreciates the opportunity to submit comments on proposed changes to the End Stage Renal Disease (ESRD) Medical Evidence Report. We strongly support efforts by the Centers for Medicare & Medicaid Services (CMS) and the Office of Management and Budget (OMB) to improve the clarity, accuracy, and inclusivity of the CMS-2728 form. The recommendations outlined below reflect RHA's continued desire to partner with CMS and OMB to strengthen the integrity of CMS-2728 data, enabling the renal community to better understand ESRD patient complexities and provide quality care to meet their needs.

The RHA is a member-based trade organization representing over 150 dialysis providers throughout the United States that provide life-sustaining dialysis services to nearly 135,000 Medicare beneficiaries. Our membership primarily includes small and independent for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in both free-standing and hospital-based facilities.

The RHA offers the following comments in response to the Agency Information Collection Activities: Submission for OMB Review; Comment Request, published in the Federal Register on May 30, 2023.

1. Extend the CMS-2728 Completion Deadline from 45 Days to 60 Days

RHA members face significant challenges completing the CMS-2728 within the required 45-day submission timeline, often constrained by factors beyond their control. Before initiating dialysis, an ESRD patient may need to meet with a surgeon, have a catheter placed, and wait for the access to mature – a series of steps that can take well over 45 days to complete. Moreover, many nephrologists will sign the 2728 forms when at the dialysis facility doing their monthly physician rounds, which delays completion of the form further. Considering these limitations, dialysis providers should have additional time to complete the CMS-2728 form.

The 45-day completion deadline also results in the filing of more Supplemental CMS-2728 forms. These addendums can take months to process and add significant administrative and financial burden to providers. By way of example, one RHA member welcomed a patient for their first dialysis appointment who had never been informed of treatment modality options. Due to the patient's condition, the patient was started on hemodialysis at the outset. After receiving education on the modality options, the patient transitioned to home dialysis after receiving the required training and assuring he had the necessary supports in place. His transition took place 50 days after his first treatment. As a result, the Initial CMS-2728 form was no longer accurate, and a Supplemental CMS-2728 was required. In addition to the time spent completing and refiling the addendum, the dialysis facility staff member spent

significant time over the following 7 months monitoring the Medicare website and calling CMS to ensure the entitlement update was processed. By extending the CMS-2728 completion deadline by at least 15 days, CMS can improve CMS-2728 accuracy and reduce provider burden associated with filing supplemental forms.

2. Allow for CMS-2728 Forms to be Completed Electronically

Completion of the CMS-2728 is currently a two-step process: first, data are keyed into the ESRD Quality Reporting System (EQRS); then, a paper copy is signed by the physician in blue ink and mailed to the Social Security office. Beyond reducing administrative burden associated with submitting the form in hard copy, transitioning the CMS-2728 to a fully electronic platform – including electronic signatures – would mediate the inefficiencies in collecting physician signatures and processing supplemental forms noted above. The healthcare community increasingly relies on secure online portals for a variety of sensitive patient information, from electronic medical records to telehealth services. With access to the necessary online protections for sensitive healthcare data, CMS should enable electronic completion and submission of the Initial, Supplemental, and Re-Entitlement CMS-2728 forms.

3. Offer Providers the Option to Refile the CMS-2728 to Reflect Changes in Patients' Clinical Characteristics

The Initial CMS-2728, submitted after a patient is diagnosed with ESRD, provides the medical information needed to determine that patient's entitlement to Medicare. The data collected through this form, however, are also used to monitor and assess the quality and type of care provided by dialysis facilities to Medicare beneficiaries with ESRD.[1] While a claimant's entitlement to ESRD Medicare may remain unchanged throughout the duration of treatment, ESRD clinical complexities – and thus the level of patient care required – evolve and often intensify over time. This is especially true for ESRD patients, many of whom are on dialysis for over 20 years.[2] As such, CMS-2728 data from the time dialysis was initiated can present an incomplete picture of that patient's clinical characteristics years into treatment. Yet, this information is used as inputs on measures reported in the Dialysis Facility Report, the ESRD Quality Incentive Program, and the Dialysis Facility Compare, reports that are used by surveyors, ESRD Networks, and patients to monitor and in some cases adjust payment based on the performance of ESRD facilities.

CMS should offer providers the opportunity to update CMS-2728 forms for existing patients whose comorbidities or health risks have changed. With this data driving the quality and type of care provided to Medicare beneficiaries with ESRD, along with research and policy efforts focused on this patient population, CMS must ensure that CMS-2728 information is as accurate is possible. Moreover, CMS payments to providers are influenced in part by CMS-2728 data, affecting additional payments received through the comorbidity adjustment, as well as potential penalties under the ESRD Quality Incentive Program. Affording providers the ability to refile CMS-2728 forms with updated clinical information will preserve the integrity of ESRD patient data and protect against inaccurate payments to providers.

4. Collect Ongoing Patient Data on Social Determinants of Health Separately

RHA members strongly support CMS' efforts to improve the collection and use of comprehensive, interoperable, standardized individual-level social determinants of health (SDOH) data as part of the agency's framework for health equity.[3] This information allows RHA members to understand the complex needs of our patients and provide them the comprehensive care they deserve. Despite our commitment to collecting and understanding this information, we appreciate the sensitive nature of these questions and recognize that patients may be reluctant to answer honestly until trust with their provider has been established. Incorporating these SDOH questions into the CMS-2728 form will give providers a maximum of 45 days to collect this information, when building the necessary rapport with socially

[1] Supporting Statement: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration (CMS-2728; OMB Control number: 0938-0046)
[2] National Kidney Foundation, https://www.kidney.org/newsletter/how-long-can-someone-be-dialysis
[3] CMS Framework for Health Equity 2022-2032, https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf

vulnerable patients can take much longer. Moreover, as we noted previously, ESRD patient complexities – including SDOH – evolve over time. While a patient may be housing secure and have caregiver support at the time of dialysis initiation, social circumstances often change over the course of treatment. Constraining providers in their ability to collect and update this information may lead to inaccurate patient responses to SDOH questions, compromising the integrity of CMS-2728 data and undermining CMS efforts to advance health equity.

To capture these important data while mitigating concerns outlined above, RHA recommends that CMS collect information on SDOH needs separately from the CMS-2728 and in a manner that can be more regularly updated as patients' needs change.

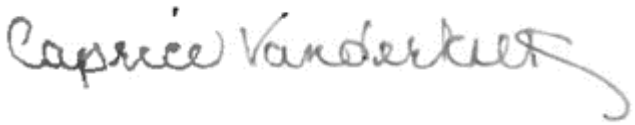
5. Engage with the Renal Community to Present Finalized CMS-2728 Changes

Once revisions to the CMS-2728 form have been finalized, we recommend that CMS host an interactive webinar with the renal community. Understanding the changes made to the form and offering an opportunity to ask clarifying questions would be of great benefit to RHA members and other ESRD providers responsible for administering the CMS-2728 with their Medicare patients.

Closing

In conclusion, the RHA again wishes to thank you for the opportunity to comment on this proposed regulation. We look forward to working with you as you continue to improve the ESRD Medical Evidence Report and other important data collection tools. If you have any questions concerning our comments, please do not hesitate to call RHA Executive Director Marc Chow at (215) 564-3484.

Sincerely,



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RHA President