



February 13, 2023

William N. Parham III  
Director  
Paperwork Reduction Act Staff  
Office of Strategic Operations and Regulatory Affairs  
Centers for Medicare & Medicaid Services  
Room C4-26-05,  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850.

**Re: Comments to Agency Information Collection Activities: Proposed Collection; Proposed Changes to End Stage Renal Disease Medical Evidence Report / Form CMS-2728.  
[Document Identifier: CMS-2728]**

***Submitted via regulations.gov***

Dear Director Parham:

Fresenius Medical Care North America (FMCNA) appreciates the opportunity to comment on the proposed revisions to the End Stage Renal Disease (ESRD) Medical Evidence Report (Form 2728). FMCNA is the largest integrated provider of kidney care services and products in North America. We support the revisions to the Form 2728 contemplated by the Centers for Medicare & Medicaid Services (CMS) and believe they will improve the ability monitor and assess the quality and type of care provided to Medicare beneficiaries on dialysis. As a national provider, reducing health disparities in access and quality for ESRD services is one of our key goals. We believe the proposed changes to this form will allow for an improved understanding of the demographics of the population we serve and support optimal care delivery when our patients begin dialysis.

We offer the following detailed comments which we believe align with the goals of CMS and this information collection and will further improve the form.

- **Section A #8** – Since certain states require pronouns, we recommend CMS include adding the following pronouns after asking about sex: He/Him, They/Them, Combination of Above.
- **Section A #9** – We recommend CMS use Cisgender Man, Cisgender Woman/ Transgender Man, Transgender Woman instead of Male/Female. Since gender is a social construct, the terms “man/woman” are more appropriate than “male/female.”
- **Section 10** – We recommend CMS consider adding the “MENA” category for race (Middle Eastern North Africa). This would conform with contemplated changes to the census and other government data collection.<sup>1</sup>

---

<sup>1</sup> <https://public-inspection.federalregister.gov/2023-01635.pdf>

- **Add Section on Sexual Orientation** – We recommend CMS include an additional section to collect data on sexual orientation. The categories could be: Straight/Heterosexual, Gay, Lesbian, Bisexual or Other
- **Sections A #20g and B #28** – We request CMS clarify the difference between A#20(g) and B#28 as they both appear to be asking the same question. CMS might consider deleting one of these questions to reduce the overall burden of completing the document.
- **Section 21** –CMS proposes to add the ability for providers to use laboratory values from the admission to the dialysis facility if previous laboratory values are not available within 10 days. CMS notes this is intended to provide an avenue to provide required information to the providers if there is an issue obtaining access to the previous medical record. We support this change. However, we request that CMS clarify how it will monitor whether the lab values were available to the facility or not. If the facility uses dialysis facility admission lab values, the snapshot might show a more stable patient compared to those when the patient was hospitalized.
- **Section A#21(g)** – We request that CMS clarify whether the proposed change is to collected LDL or LDH levels (there is a discrepancy between the form and the crosswalk document).
- **Section B#29** – We recommend the following choices for this section: Cognitive Impairment, Patient did not receive information, Patient is not medically eligible, or Other
- **Add Section on Advanced Care Planning** – We strongly support adding a question addressing whether the patient has engaged in advanced care planning. The question could ask whether the patient has completed a living will or Medical/Physician order for life sustaining treatment (MOLST/POLST).

Thank you again for CMS' ongoing efforts to improve the 2728 form. We appreciate the opportunity to share our thoughts and comments. Please do not hesitate to contact us if you have any questions or if you wish to discuss any aspects of our letter.

Sincerely,



C.M. Cameron Lynch  
Senior Vice President, Government Affairs