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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Document Identifier: CMS–2728; OMB control number: 0938–0046
Room C4–26–05,
7500 Security Boulevard, Baltimore,
Maryland 21244–1850.

RE: Agency Information Collection Activities: Proposed Collection; Comment Request
Document Identifier: CMS–2728; OMB control number: 0938–0046; CMS–2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

We are writing to provide our perspective on the comment request regarding proposed revisions to the CMS 2728 ESRD Medical Evidence Form. Broadly, RPA commends CMS for seeking to enhance data collection on the entry or re-entry of kidney patients into the ESRD program. We perceive this effort to be supportive of initiatives intended to increase rates of home dialysis and transplantation among persons with ESRD among other objectives, appropriately so. However, in addition to what we believe are positive aspects of the proposed revisions, certain others threaten patient-centeredness and also raise concerns from the perspective of the point-of-care nephrologist, as described below.

Our comments will address the following issues:

- Expanded collection of data and timing
- Administrative burdens
- Data accuracy
- Use of subjective questions
- Pediatric comorbidities

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Expanded collection of data and timing—The 2728 form is intended to register and qualify the patient for Medicare entitlement benefits and to that end needs to be completed immediately upon initiation. As noted, RPA supports CMS' efforts to improve data gathering for ESRD patients and the 2728 form is an appropriate vehicle for collecting certain data that is available at initiation of dialysis. That said, questions which are not applicable to all scenarios of dialysis initiation (such as patients who have abruptly started dialysis) may be ill-timed and thus not patient-focused, thus not appropriate for inclusion in the 2728.

For example, on question #28 of Section B, the instructions for completing the 2728 state that:

> *To be informed a patient must understand the material. The patient must be able to repeat: benefits and risk of transplant as a treatment option, the referral and evaluation process, and post-transplant recovery and coordination. Additionally, the patient should be able to verbalize why they did not choose transplant as a treatment option.*

Starting dialysis is a time of tremendous transition for patients, who often are overwhelmed with their illness, adjusting to dialysis, and meeting a new nephrologist providing dialysis care. We would note that it is not uncommon that the nephrologist completing the 2728 form may be seeing the patient for the first time, in which case, this is a substantial amount of information to cover, and does not reflect the reality of how transplant and dialysis modality discussions actually occur, often over time and with the participation of the entire interdisciplinary team. RPA urges CMS to reconsider the inclusion of questions on the 2728 form that are ill-timed in the context of dialysis initiation and do not contribute to optimal patient care.

Administrative burdens—While RPA acknowledges the potential benefit of adding and clarifying questions on the 2728 form, it does inherently cause an increased burden for the nephrologists completing the form, in an era of already tremendous stress for the nephrology workforce owing to the impact of the COVID-19 public health emergency and the consistently substantial growth of the U.S. kidney patient population.

RPA recognizes that some of the proposed changes streamline the process for completing the form (such as question #21 in Section A, which adds the ability for providers to use laboratory values from the admission to the dialysis facility if previous laboratory values are not available in 10 days); RPA supports and endorses this change.

We are also encouraged by the Agency's solicitation of comment on the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To this end RPA **strongly encourages** CMS to develop an option for electronic form completion and submission process so that the unnecessary documentation on and management of a physical paper form can be minimized.

Data accuracy—As with any data collection process that proposes to increase the volume of data being gathered, the risk of progressively comprising the accuracy of the data is present. To minimize the

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possibility of the quality of the output being adversely affected by the quality of the input (i.e., avoiding the "garbage in, garbage out" circumstance), RPA would encourage CMS to identify those questions that may be superfluous so that the nephrologist completing the form can focus on core elements. Suggestions for questions that could be eliminated are included in the next section of this comment.

This is another area where the timing of when the 2728 form is problematic, as premature completion of the form could result in data inaccuracies for some of the questions. RPA recognizes that CMS is in good faith seeking to ensure compliance with conditions for coverage requirements and promote quality. However, as noted the 2728 is a registration form, and is only filled out for the initial event. Given that a large percentage of patients have emergency starts (or "crash") into dialysis and many persons are dialyzing with providers other than those who may have been treating their chronic kidney disease (CKD), the physician of record may not be in position to answer some of these questions. This will almost by definition lead to inaccuracies and may result in form completion being postponed. Further, having these nephrologist-patient discussions on topics such as home dialysis and transplantation precipitously in order to "check this box" could lead care teams to consider that the issues have been addressed and decrease the likelihood of reintroducing these topics once the patient has better adjusted.

Concerns stemming from sequencing also are manifested in question 25, where the Agency requests information on the number of sessions and/or minutes of dialysis per week. RPA understands why CMS would seek this information, but we also believe that this is not the best time to collect that data in a world where incremental dialysis is more common. In many dialysis patient care scenarios, the initial number of sessions or minutes weekly will not end up being the usual prescription for prevalent patients, and thus the possibility of this data being not representative or misinterpreted increases significantly.

Use of subjective questions—RPA is concerned that the proposed changes include questions that compel the nephrologist to discern whether the patient *understands* the educational efforts being provided to them on modality choice. This circumstance is most directly present in questions #28 of Section B (Does the patient understand transplant options?) and #29 (seeking information on why the patient does not understand her or his transplant options) but is also inferred in questions #20f and #20g of Section A on home dialysis. To be clear, RPA strongly supports comprehensive and even expanded use of kidney disease education (KDE) wherever possible, and we recognize that patient education on transplantation and home dialysis modalities is a primary focus of those efforts.

However, given that this is a legal Medicare attestation document that uses the words 'perjury', 'fine', and 'imprisonment' directly above the physician's signature, requiring the nephrologist to determine and confirm in writing whether a patient *understands* the education provided seems excessive and possibly open to interpretation. RPA would therefore urge CMS to eliminate or minimize the use of subjective questions in the 2728 form.

Pediatric comorbidities—RPA commends CMS for working collaboratively with the American Society of Pediatric Nephrology (ASPN) to enhance its data gathering regarding pediatric dialysis patients. We

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concur with ASPN that the unique conditions and patient care needs of pediatric ESRD patients require specialized consideration, and CMS' proposal to collect information on pediatric-specific comorbidities to reflect the care and resources being delivered to this population more accurately is appropriate and welcome.

As always, RPA welcomes the opportunity to work with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work on the CMS 2728 Medicare ESRD Evidence Form. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

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