



June 27, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-4199-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules

Dear Administrator Brooks-LaSure:

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. Part of RPA's mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA is writing to offer our input on the immunosuppressive drug coverage section of the proposed rule implementing certain provisions of the Consolidated Appropriations Act of 2021. In general, RPA believes that CMS took an open-minded and forward-thinking approach to issues such as attestation and enrollment in creating the Part B-ID benefit that will facilitate the ability of qualified beneficiaries to enroll and be covered. Further, we are encouraged by the Agency's expedient use of the Executive Order (EO) on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government and the potential positive ramifications of the EO on future rulemaking. RPA's comments will discuss:

- Use of Verbal Attestation
- Proposed Enrollment Process
- Considerations Affecting Pediatric Kidney Patients

Use of Verbal Attestation

In the rule, CMS proposes that beneficiaries will be able to use a verbal (telephonic) attestation as part of enrolling in the Part B-ID benefit, in addition to having available the option of

submitting attestation in ‘pen-and-ink’ format. The Agency solicits public comment on all of these proposed methods of attestation, and other potential methods such as electronic submission, submission by fax, or a signed document.

Given the relatively finite census of patients with even potential eligibility for the Part B-ID benefit, RPA believes that the CMS is taking the correct approach by casting a wide net in facilitating attestation by all available processes. To the extent that an open methodology in this regard becomes a cause for concern, CMS outlines its plans to monitor developments in the Part B-ID benefit program, take appropriate action to address any potential areas of concern, and to evaluate opportunities to enhance oversight to ensure compliance with the eligibility requirements on an ongoing basis. RPA is satisfied that CMS’ recognition of the need for monitoring and oversight will enable it to address any concerns that may arise.

RPA believes that the confluence of the relatively small patient population for whom the Part B-ID benefit would be available and CMS’ pledge to monitor developments and exercise oversight regarding enrollment justifies the Agency’s decision to allow verbal attestation by telephone in addition to pen-and-ink and other methods. We commend the Agency for its transparency and open approach as well as for its adherence to the new EO on transforming the federal customer experience.

Proposed Enrollment Process

CMS proposes in the rule to allow eligibility for the Part B-ID program to be based on the aforementioned attestation and previous enrollment in the End Stage Renal Disease (ESRD) program. The rule states that: “We will have historical information about individuals who will be eligible to enroll in the Part B-ID benefit based on their Medicare entitlement at the time of their transplant. In light of this fact, we believe that submission of an attestation and confirmation of an individual’s eligibility as described previously will be sufficient for SSA to enroll individuals in the Part B-ID benefit.” As with the proposal for determining appropriate attestation, RPA believes that CMS’ plans for defining a suitable process and criteria for beneficiary enrollment in the Part B-ID program is simple, straightforward, and customer centric.

RPA does urge CMS to clarify the status of the Part B-ID program with regard to beneficiaries who received pre-emptive transplants. In our reading of the rule this issue appears to be unaddressed, and RPA member nephrologists have inquired about the applicability of the rule to pre-emptive transplant patients.

Broadly, we believe that the Agency’s proposal for enrolling potential participants minimizes access barriers to the benefit. Notwithstanding our request for clarity on the issue of pre-emptive transplants patients, RPA fully supports CMS’ plans with regard to enrollment in Part B-ID and urges the Agency to proceed with implementation as proposed.

Considerations Affecting Pediatric Kidney Patients

RPA supports the recommendations made by the American Society of Pediatric Nephrology (ASPN) that CMS consider the unique health needs and circumstances faced by pediatric dialysis patients and their families on issues either addressed in or adjacent to the Part-B ID benefit and rulemaking. These include:

- Development of outreach and education materials targeted to pediatric patients and their families on health insurance counseling, health care options, and other issues emanating from the Part-B ID benefit;
- Pursuit of a coverage pathway for compounded drugs frequently used in the treatment of pediatric kidney patients, which are typically covered by Medicare Part D; to the extent that such coverage is beyond CMS' authority in the context of the Part B-ID benefit, we second ASPN's call for the Agency to proactively seek to address this shortfall;
- Consideration within the Part B-ID benefit of coverage for mineral or electrolyte supplements, like magnesium, phosphorus, and bicarbonate related to post-transplant care that are particularly necessary in the care of pediatric patients.

RPA recognizes that because of both the mandates of the underlying statute and the fact that adult ESRD patients comprise the overwhelming majority of dialysis patients in the U.S., the rule understandably proposes policy in the context of adult care. However, addressing the issues related to the use of immunosuppressive drugs in children outlined above would have scant budgetary implications for the Medicare program while being of tremendous benefit to pediatric kidney patients and their families.

As always, RPA welcomes the opportunity to work collaboratively 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 immunosuppressive drug coverage for Medicare beneficiaries. 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,

A handwritten signature in black ink, appearing to read 'Tim A. Pflederer', written in a cursive style.

Timothy A. Pflederer, MD FASN FASDIN
RPA President