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The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure  
Administrator  
Center for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

The American Kidney Fund appreciates the opportunity to provide comments on the proposed rule referenced above.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

We focus our comments on the proposals that would implement the extended coverage of immunosuppressive drugs for certain kidney transplant patients, a benefit that was established in section 402 of the Consolidated Appropriations Act, 2021 and that becomes effective January 1, 2023. AKF has long supported legislation that would extend Medicare immunosuppressive drug coverage for kidney transplant recipients beyond 36 months, and we appreciate CMS' proposals that would implement the new Part B immunosuppressive drug benefit (Part B-ID)

to meet the legislative intent and to ensure eligible kidney transplant recipients can continue to access needed medications that prevent organ rejection.

### **Determination of Eligibility**

AKF supports CMS' proposal that beneficiaries will be able to primarily use a verbal, telephonic attestation that they are not enrolled and do not expect to enroll in excepted coverage that would make them ineligible to enroll in the Part B-ID benefit. We agree with CMS that having interested beneficiaries provide a verbal attestation with a representative from the Social Security Administration (SSA) is the simplest and most efficient method and would avoid potential delays with signing and mailing statements that could result in delays in accessing needed immunosuppressive drugs. We also support CMS' proposal that still permits beneficiaries to submit a written attestation with a pen-and-ink signature if they choose to do so.

To ensure beneficiaries have sufficient opportunity to provide an attestation and enroll in the Part B-ID benefit, we recommend CMS consider additional methods of attestation, particularly electronic submission. People who may be eligible to enroll in Medicare Parts A and B have the opportunity to apply online through the SSA's website. Individuals who may be eligible for the new Part B-ID benefit should have that electronic method available as well to provide their attestation and enroll in the Part B-ID benefit.

### **Enrollment in the Part B-ID Benefit**

AKF supports CMS' proposal that to enroll in the Part B-ID benefit, an individual must submit the required attestation, and CMS will confirm their eligibility for the Part B-ID benefit based on historical information CMS already has on the individual's Medicare entitlement at the time of their transplant. We agree with CMS that submission of an attestation and confirmation of an individual's eligibility for the Part B-ID benefit is sufficient for SSA to enroll individuals in the Part B-ID benefit. We appreciate this proposed streamlined approach to enrollment. We also support CMS' proposal that if SSA denies an individual's enrollment in the Part B-ID benefit, the individual will be afforded an initial determination entitlement appeal, which will ensure adequate protection for the beneficiary's statutory and due process rights.

AKF strongly supports the proposal that would allow an individual who had previously enrolled in the Part B-ID benefit but whose participation in the benefit was terminated may re-enroll in the Part B-ID benefit at any time if they meet eligibility requirements and submit the required attestation. We also support CMS' proposal that there would be no late enrollment penalties assessed, regardless of when an individual enrolls or disenrolls from the Part B-ID benefit. Given that an individual's circumstances may change during the year that results in a change to their health coverage, allowing this flexibility for eligible transplant recipients to enroll or reenroll in the Part B-ID benefit will ensure they will continue to have access to their needed immunosuppressive medications.

### **Termination of the Part B-ID Benefit**

AKF supports the proposal that would allow an individual to request a prospective termination date when they notify SSA that they are enrolling in other health coverage that will make them no longer eligible for the Part B-ID benefit (for example, an individual enrolling in employer coverage during an October open enrollment period for coverage that begins January 1). We agree with CMS that allowing an individual to choose their Part B-ID termination date in this situation to retain their immunosuppressive drug coverage up to the effective date of their new health coverage will alleviate potential gaps or overlaps in coverage. We believe this is an appropriate option that protects an individual's access to needed medications for the health of their transplanted kidney.

### **Promoting Awareness of Coverage Choices for Beneficiaries**

Throughout the proposed rule, CMS highlights the importance of informing ESRD Medicare beneficiaries of their coverage options upon the end of their Medicare coverage 36 months after receiving their kidney transplant. CMS notes actions it plans to take to inform and assist beneficiaries in assessing their health care options and enrolling in the Part B-ID benefit as needed, such as including information on the Part B-ID benefit and enrollment instructions in the pre-termination notice. CMS seeks comment on other steps it can take to assist beneficiaries and promote awareness of coverage choices upon loss of the ESRD Medicare benefit.

While we support CMS' plan to include information on the Part B-ID benefit in the pre-termination notice, AKF recommends CMS also provide that information and information on other comprehensive coverage options at the initiation of a beneficiary's 36-month post-transplant coverage. Raising awareness earlier in the process, including a clear explanation of the Part-B-ID benefit, would be helpful to beneficiaries. Presenting this information earlier would give beneficiaries more time to consider their future coverage options and prepare for their health care needs after their 36-month post-transplant coverage ends.

AKF also recommends CMS work with stakeholders, including states, State Health Insurance Assistance Programs (SHIPs), providers, and beneficiary and patient groups to develop and implement an effective outreach and education campaign that ensures beneficiaries are aware of and understand the new Part B-ID benefit and how it fits in the existing coverage landscape. An effective outreach and education campaign will be critical to ensure individuals do not have gaps in coverage and understand their options for enrollment in the most comprehensive coverage that is available to them.

Thank you for the opportunity to provide comments on this proposed rule.

Sincerely,



LaVarne A. Burton  
President & CEO