Nonprofit Kidney Care Alliance

June 27, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
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 (CMS-4199-P)

Dear Administrator Brooks-LaSure,

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments on the proposed rule implementing the Consolidated Appropriations Act (CAA) of 2021, and specifically the policies implementing coverage of immunosuppressives for kidney transplant recipients. NKCA represents eight nonprofit dialysis providers: Centers for Dialysis Care; Central Florida Kidney Centers, Inc.; Dialysis Center of Lincoln, Inc.; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; Puget Sound Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 22,500 patients at more than 326 facilities in 32 states. In an effort to keep patients off dialysis, we also serve more than 10,000 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). As providers of care for patients with kidney disease we see transplant as the optimal therapy and strive to enable our patients to prepare for and benefit from renal transplant.

Thank you for the opportunity to comment on Section 402 of the Consolidated Appropriations Act of 2021, which extends coverage of immunosuppressive drug therapy for kidney transplant patients, and related provisions. Section 402 makes a significant and long overdue improvement for transplant patients as well as offering the prospect of reducing Medicare costs due to transplant organ failure. NKCA has long advocated for this coverage as well as other policies to eliminate barriers to successful transplant. However, in the final version, Congress adopted a narrowly crafted provision, that will leave some patients still facing high, and possibly prohibitive, out-of-pocket costs. How CMS and the states, implement this benefit improvement will determine whether the promise of Section 402 is realized for transplant patients. Indeed, as we point out later, the platform that Section 402 provides to help patients understand *all* of their coverage options may be as, if not more, important as the extension of coverage for this narrow, stand-alone benefit.

The statute gives the Secretary authority to conduct public education activities to raise awareness of the availability of more comprehensive individual health insurance coverage, as an alternative

to the more limited coverage offered in the new Part B-ID program. As the Committee on Energy and Commerce acknowledged in its Report accompanying H.R. 5534:

"This *coverage of last resort* will help reduce the likelihood of graft loss and the demand for additional transplant, ultimately improving patients' health and reducing costs to the Medicare program." (italics added)

Comprehensive Coverage of Drugs Used in Immunosuppressive Therapy

CAA 2021 extends coverage of immunosuppressive drugs as described in Section 1861(s)(2)(J), which refers to "prescription drugs used in immunosuppressive therapy." While much of the commentary surrounding the enactment of this benefit, as well as in this proposed rule, refers to immunosuppressive drugs, there are some "prescription drugs used in immunosuppressive therapy" that are not categorized as immunosuppressive drugs, per se. Most transplant patients continue on antihypertensive medications for extended periods. Some continue on antiviral agents like valacyclovir because the immunosuppression puts them at risk of a variety of infections. Other long-term medications depend on co-morbid conditions like diabetes or complications of the transplant. We ask CMS to clarify this distinction in the final rule as well as in subsequent guidance to providers, beneficiaries, and its contractors.

Enrollment

In addition to limiting the extension of coverage only to drugs, the statute limits who may enroll in the new Part B-ID benefit to those who have no other coverage as described in Sec 402(b)(2) of the bill, apparently under the assumption that all the enumerated sources of coverage cover all the drugs used in immunosuppressive therapy. The only distinction that the statute draws in this regard is whether, under Title XIX, immunosuppressive drugs are covered under a state plan. CMS takes this distinction as a negative inference with respect to all of the other enumerated types of coverage. In other words, regardless of whether someone's health plan covers post-transplant immunosuppressive therapy, or whether it is as robust as Medicare Part B-ID, they are precluded from enrolling in Part B-ID. While we understand CMS' point about negative inference, the practical result of CMS' interpretation is that transplant recipients with coverage other than Title XIX will be disadvantaged. We doubt that is what Congress set out to do and ask CMS to reconsider its interpretation.

As proposed, a transplant recipient may apply through the Social Security Administration, or if currently covered within the 36-month post-transplant period, be deemed to be enrolled in Part B-ID. In either case, the individual must make an attestation to the Social Security Administration that they are not covered by other insurance. To make this as easy as possible for transplant recipients, CMS proposes that a verbal attestation, during a phone call with a SSA representative, would suffice. The option of using a printed version of the attestation and retuning it by mail would also be allowed. We support CMS' proposed two option approach to attestation—verbal or in-writing. While a verbal attestation would be the most convenient for many beneficiaries, some may find it less challenging to use a PDF fillable form on the SSA or CMS websites and then mail to SSA. The latter approach would also address the problem of long wait times on SSA phone lines.

CMS proposes that it would collaborate with SSA to provide transplant recipients with information on enrollment in Part B-ID as part of the standard SSA "pre-termination notices." While this will certainly help, as we discuss below, it is critical, both for enrollment, and even more so, ability to pay the significant out-of-pocket costs under this benefit (and what is not covered) that CMS take a more robust, forward-leaning, approach to help assure continuity of coverage when eligibility for full Medicare benefits terminate. As CMS states in the proposed rule, "…continuity of coverage depends on many factors, including the timing of when an individual attests to not having disqualifying insurance coverage under 407.59 as well as coordination among multiple entities including states, CMS and SSA." Transplant recipients need more assistance than the current SSA pre-termination notices to navigate these multiple entities.

Out of Pocket Costs

As we note above, the extension of coverage for immunosuppressive drugs, is an important and overdue step. It is estimated that the average per person cost for immunosuppressive drugs is around $3400 per year. While Part B-ID will cover part of that cost, beneficiaries would be liable for the usual 20% coinsurance, or roughly $680/year, on average. Moreover, since the benefit is limited to only coverage of prescription drugs, the beneficiary will be responsible for paying the necessary physician and lab services out-of-pocket, since no other coverage is allowed. While the circumstances will vary from patient to patient, a typical patient will need to see their nephrologist two to four times per year and will bear 100% of those costs along with the necessary lab tests. As CMS itself notes in its Claims Manual, transplant patients on immunosuppressives are routinely subject to changes in dosage as well as switching to other drugs, hence Medicare Administrative Contractors (MACs) are instructed to approve payment only on a 30-day, non-refillable basis. In addition to physician visits, they will have a battery of lab tests including routine chemistries, complete blood count (CBC), urine albumin-to-creatinine ratios, viral studies, donor specific antibody levels, and cholesterol levels at least annually. Any signs of concern will lead to a kidney biopsy often done under ultrasound guidance. Screening with these lab tests is necessary to properly dose transplant recipients. After three years, and again, depending on the patient, these labs could be done as often as every two to three months. Rarely, in the setting of an acute event, some patients would need these to be done monthly. Depending on the underlying disease, DEXA bone scanning may be done every two years and ultrasounds of the transplant kidney every one to two years. Part B-ID recipients will be liable for the entire cost of all of these services –not just coinsurance.

At the same time, Part B-ID beneficiaries will be subject to monthly Part B-ID premiums (paid directly or deducted from their monthly Social Security check if they are age 62-64 or disabled but still in the 24-month period prior to Medicare coverage). The proposed rule states that, as with the standard Part B premium, the CMS Office of the Actuary will establish a monthly premium amount. However, unlike the standard Part B premium calculation which assumes that beneficiaries will contribute 25% of the program's cost, Congress established that the Part B-ID beneficiaries will bear *35%* of the cost. The rule commentary is silent on the amount of the premium. However, the Congressional Budget Office has estimated that the monthly Part B-ID premium in 2023 will be $243 per month ($2916, per year), rising to $345 per month in 2030 ($4140 per year.) It is not going too far to say that for many who *could* benefit from Part B-ID these costs may well be prohibitive. Indeed, CMS acknowledges this very point in its regulatory

impact analysis in which it states, "Even with access to immunosuppressive drug benefits, low-income individuals may be unable to afford these immunosuppressive drugs due to their high cost.[1]"

Benefit Education

Accordingly, it is all the more critical that CMS use other tools including, but not limited to, those provided by Section 402 so that transplant recipients understand all their options. CMS proposes to work with states to educate transplant patients prior to the termination of their Medicare transplant benefits of their options:

- apply for Medicaid; or for those currently covered by Medicaid navigate the redetermination process or,
- apply for a qualified health plan and APTC coverage through their state's Marketplace.

In either case, they would then not need to enroll in Part B-ID. In the alternative, and as provided for under Section 402, transplant recipients might qualify for one of the Medicare Savings Plans (MSP) that can cover premiums, and for some, coinsurance as well. This can be critical for those who would not qualify for full Medicaid benefits. In this case it will be up to the states to make that determination, and imperative that they do so timely. CMS suggests that this may be most important in those states that have not adopted Medicaid expansion. However, there remains the challenge of variation in resource restrictions that vary across state Medicaid programs, even if their income thresholds are more generous. It also seems to overlook the problem highlighted in a recent HHS/ASPE report of "churning" that is endemic to the dual-eligible program. And, at least initially, these determinations would come at a time when states will be undertaking a major Medicaid redetermination process which will be triggered when the end of the Public Health Emergency (PHE) is declared. Accordingly, it will be critical that CMS work with SSA, as well as with all stakeholders in the transplant sector, to help transplant patients apply for Part B-ID prior to termination. By doing so, their rights will be better protected during the states' Medicaid redetermination process and MSP determination.

Notwithstanding these challenges, if CMS can take a more robust approach to working with SSA and the states, then the more important benefit authorized by Section 402 is the platform that it provides to educate transplant recipients, *early,* of their options and help them navigate to full coverage either in Medicaid or in a Marketplace QHP with APTC. In this regard, we recommend that CMS educate—*well before Medicare benefits are terminated*—both transplant recipients and their physicians (whom CMS should be able to identify from claims data) of the importance of the Medicaid redetermination process, including the requirements on states which CMS refers to in the rule at 435.916 (d), as well as 435.1200 to coordinate with state Exchanges and other insurance affordability programs. CMS could also do more than "encourage" states to inform beneficiaries about Part B-ID, by including it as part of their responsibilities under 435.916.

CMS should also consider the role that CMS-approved transplant centers, and other stakeholders can play in encouraging their patients to understand their options and connecting them with local, state and national resources that can help them navigate the system.

[1] (FR April 27, 2022, p.25127)

Thank you for the opportunity to comment on the implementation of CAA as it relates to immunosuppressant drug coverage and for all that CMS is doing to make the experience of beneficiaries with kidney disease a positive one. If you have any questions, please feel free to contact me at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director