Nonprofit Kidney Care Alliance

June 17, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Fiscal Year 2023 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule (CMS-1771-P)

Dear Administrator Brooks-LaSure,

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments on the FY 2023 Hospital Inpatient Prospective Payment System Proposed Rule. 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). Several of our member companies collaborate with area hospitals to provide dialysis services.

We appreciate the opportunity to comment on the 2023 Proposed IPPS Rule, and specifically CMS' proposed policies regarding the New Technology Add-On Payment Alternative "Breakthrough" Pathway, including the Alternative Pathway for Qualified Infectious Disease Products (QIDPs). Among a dozen other QIDP's, CMS asks for comment on its proposed conditional approval of CorMedix Inc's **DefenCath**, an antimicrobial/anti-coagulant catheter lock solution of taurolindine and heparin, beginning in FY 2023.

As providers of dialysis services, any product that offers the prospect of reducing the incidence of catheter-related infections merits attention. However, we find that we are unable to comment on this product—positively or negatively--for lack of FDA approval, which would bring greater transparency to its clinical basis from its single clinical trial, as well as the lack of manufacturer cost data. There is no doubt that catheter-related blood stream infections are a significant problem for patients on dialysis. Yet, without published data, it is difficult to make any statement about the potential impact of this product. The lack of cost data is noteworthy since, as the applicant company notes, the demand for catheter lock solution runs in the tens of millions of vials annually for hemodialysis alone.

Yet, without taking a position on any particular product, CMS' proposed conditional approval *does* lead to a larger set of concerns on the process CMS is following with respect to the use of the FDA's Breakthrough Pathways as a precursor to CMS Transformative New Devices Pathway and the Alternative Pathway for Certain Antimicrobial Products. In both cases, CMS, since FY2021, provides additional payment based only on two of the three criteria that would normally apply for add-on payment--newness and cost--but not whether the new product represents a substantial clinical improvement. We believe that this process conflates two separate and distinct governmental functions that merits revisiting by CMS in this, or more likely, future rulemaking.

First, the FDA's "breakthrough" process was intended to shorten *the time* it takes to bring a promising drug or device to market—*not* short-circuit its determination of safety and effectiveness. In this regard, CMS has already taken steps to shorten the time between FDA approval and CMS coverage and payment. For example, CMS has streamlined its HCPCS process so that new drugs and devices can be covered more quickly. And, as noted in this rule, CMS has dedicated staff to assist developers navigate CMS coverage and coding processes.

Second, as CMS points out in this rule the roles and responsibilities of FDA and CMS *are different*. While they are complementary, they are rooted in separate statutes with different responsibilities. The FDA is responsible for marketing authorization through its determination of a product's safety and effectiveness. CMS, on the other hand is responsible for determining whether that same product warrants coverage (i.e. is "reasonable and necessary") in the Medicare program and for its beneficiary population and for establishing how much taxpayers and beneficiaries should pay a product or service.

Accordingly, we recommend that CMS reconsider the policy it adopted in the FY 2021 Final Rule, and in future rulemaking, incorporate a substantial clinical improvement criterion to its decision-making on transformative new devices and QIDP/Antimicrobial products. There is certainly precedent for doing so as CMS took similar action in the 2020 End Stage Renal Disease (ESRD) Final Rule when it created a new pathway for new renal equipment and supplies and incorporated a substantial clinical improvement criterion. More recently, CMS went so far as to reverse a similar breakthrough policy directed at new innovative devices in its repeal via a final rule (CMS-3372-F3) of the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule.

In our comments on the 2020 ESRD proposed rule, we expressed our support for CMS's proposal, subsequently adopted, to incorporate both "newness" and "substantial clinical improvement" as necessary to qualify for the TPNIES. In particular, we concurred with CMS's proposal to apply a test of substantial clinical improvement similar to that used in the Inpatient Prospective Payment System (IPPS) to spur innovation for products that offer more than minor, if any, real clinical improvement. In such a system, developers and manufacturers know up-front by what criteria a new product will be judged.

However, as we noted then, new equipment and supplies need not be "blockbusters" to qualify. Rather, they may: (i) offer a treatment option for a patient population unresponsive to, or

ineligible for, currently available treatments; (ii) offer the ability to diagnose a medical condition in a patient population where that condition is currently undetectable, or diagnose a medical condition earlier in a patient population than allowed by currently available methods; or (iii) significantly improve clinical outcomes for a patient population as compared to currently available treatments. We believe that by setting the bar higher than only "newness," and cost, CMS can help ensure that increased Medicare expenditures and beneficiary copayments are better justified.

At the same time, as we noted in our ESRD PPS 2022 comments, because the Medicare program is by far the largest payor for dialysis services, it is the primary if not sole gatekeeper on whether new products serving the dialysis field will come to market. As such, the prospect of Medicare coverage plays a critical role in any assessment of return on investment by developers and manufacturers. Robust clinical trials, while the gold standard from a statistical perspective, can be particularly daunting due to the nature of the ESRD population.

Thank you for the opportunity to comment on the FY 2023 IPPS 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