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Nonprofit Kidney Care Alliance

December 31, 2019

Joanne Chiedi
Office of Inspector General
Department of Health and Human Services
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0936-AA10-P. Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Ms. Chiedi:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments regarding the proposed rule revising safe harbor protections under the Anti-Kickback Statute and other related matters. We appreciate the Department of Health and Human Services Office of Inspector General (OIG)'s interest in removing barriers to care coordination as the health care sector moves toward more value-based payment arrangements, as well as ensuring that such arrangements do not create inappropriate incentives.

NKCA represents six nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Center of Lincoln; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 21,000 patients at more than 300 facilities in 30 states. We also serve more than 5,700 patients with chronic kidney disease (CKD) with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). We are committed to promoting kidney transplantation, eliminating barriers to access, and reducing organ discards. To that end, many of our member companies participate in value-based care arrangements such as the Comprehensive ESRD Care (CEC) model and will likely continue to expand their participation in such initiatives under new models as part of the Administration's Advancing American Kidney Health Initiative. Through the CEC model, many of our member companies are pursuing partnerships with various providers and suppliers, not only in nephrology, but across the care continuum, from primary care to hospice.

We applaud changes to encourage coordination of care while protecting our patients from harm and protecting Medicare and Medicaid from waste, fraud, and abuse. We share the OIG's concern, as expressed in the proposed rule, regarding market consolidation in the dialysis sector as value-based care arrangements grow in the industry. We urge the OIG to partner with CMS and the Center for Medicare and Medicare Innovation (CMMI) to strike the right balance. The Administration's kidney care initiative represents a major opportunity to transform care for Medicare beneficiaries with kidney disease. Achieving success will require both flexibility to innovate *and* close review and monitoring.

To that end, we would be happy to be a continued resource as this balance is navigated to ensure patient access and choice in their care.

Promoting Care Coordination and Value-Based Care

We support the overall approach the OIG is proposing to promote value-based care through the creation of Value-Based Enterprises (VBE) that include clearly documented purposes, accountable governance structures, and written agreements that provide transparency and promote accountability. We also concur with the OIG's intention to "scale" requirements in proportion to VBE participants' size and scope. The current CEC model requirements have largely worked well. We are encouraged that CMMI plans to build on those parameters for the forthcoming Kidney Care Choices (KCC) initiative, and we recommend that the OIG look to those requirements in setting VBE requirements in the kidney care sector.

A comprehensive approach to improving kidney care requires earlier attention to CKD, increased opportunity for kidney transplant, improvements in the care of ESRD patients, and thoughtful end-of life planning and care for patients and with end-stage kidney disease. Successfully achieving these goals will require collaboration between nephrologists and providers outside of direct kidney care. We seek to encourage collaboration among providers and ensure innovation across the continuum of care, encouraging greater participation in VBE models while keeping participants accountable. One way of promoting these goals will be to improve collaboration across CMMI models. To that end, we recommend that providers be allowed to participate in multiple value-based care models simultaneously. For example, it could be very beneficial in a CEC model to include primary care providers and specialists who provide care to the many ESRD Seamless Care Organization (ESCO) beneficiaries with multiple chronic health conditions. It may be necessary for a patient to participate in only one model, but providers would not be limited in their participation to provide coordinated care. To facilitate such developments, it is critical that waiver policies be harmonized across payment models. This would allow a physician participating (whether as a "participant" or "owner") to refer and/or treat patients seamlessly across models. In a similar vein, civil and monetary penalties (CMP) policy may need to be harmonized across models so that financial or other incentives to beneficiaries function along the care continuum between two separate models.

We share the OIG's concern about distinguishing between care coordination and mere referral. The OIG suggests that one measure to preclude abuse would be to exclude safe harbor protections where the referral is to an entity of the same parent organization. While such a policy could serve as a default, to thwart funneling, we recommend that the OIG provide an alternative safe harbor protection for entities that refer to a related entity that can demonstrate improved patient outcomes, such as slowing of disease progression or fewer referrals to more acute levels of care than otherwise expected. In this regard, VBE participants attesting to the proposed "Requirements of a Value-Base Arrangement," notably the requirement not to direct or restrict referrals, can serve as an additional safeguard.

Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency

In our experience, beneficiary incentives can be effective in encouraging appropriate patient behavior, such as adherence to a care plan. For example, there is great benefit to both a patient with kidney

disease and the Medicare program, of encouraging transplant evaluations or for a patient to receive a permanent access. Having the ability to incentivize the required additional visits with a gift of "nominal value" can easily make the difference in how care is delivered for a patient with kidney disease. We believe the current annual aggregate limit of $75 is sufficient but that the $15 per item limit is overly constraining. Currently, beneficiaries of Accountable Care Organizations (ACOs) can receive incentives over $15 from both the Coordinated Care Reward and the new ACO Beneficiary Incentive Program. Incentivizing behaviors for CEC model participants often involves more time and effort than a wellness visit or other primary care services in these ACO programs. Therefore, we request that the OIG eliminate the $15 per item limit, to allow providers to use incentives to encourage medically necessary services that encourage quality outcomes.

The OIG proposes a series of limitations on the types of remuneration that might be employed. *At this time*, we concur that limiting their use to only VBE participants is warranted. And while we understand the limitation on no cash or cash equivalent forms of remuneration (such as debit cards), we recommend flexibility on the proposed allowed use of "vouchers." In particular, we call attention to the OIG's consideration of including tools and supports that address social determinants that can have a bearing on health outcomes, including food and nutrition, housing and related features, and transportation. Providing a beneficiary with a recognized chronic condition—such as those enumerated by CMS in the Medicare Advantage (MA) Chronic Special Needs Plan (C-SNP) program and MA supplemental ("not primarily health related") benefits—with additional tools and supports may promote improved outcomes or avoid worse outcomes. Administering a "voucher" through a debit-card-like mechanism for food or transportation should not be ruled out if appropriate safeguards can be employed.

Current Fraud and Abuse Waivers

We are appreciative of the current waivers allowed under the CEC model. We have also appreciated the assistance from CMMI staff in providing guidance to us in order to remain compliant within the waivers. We believe these waivers give us the ability to better coordinate care, incentivize participation in the model, and innovate care.

As we noted in our comments on the OIG's August 27, 2018, request for information, one challenge we have encountered in the process has been the limited amount of time from when the waiver is announced to the deadline for adding participant owners into an ESCO. For example, using a telemedicine waiver can provide many opportunities to provide a wider range of care in the ESCOs. Some provider specialties that may benefit from telemedicine may not be typical ESCO providers. However, with limited time to identify relevant providers, engage in the necessary discussion and coordination, and sign contracts for them to be owners to participate in the ESCO, we are restricted in our ability to fully utilize telemedicine. With more time between notice of a waiver opportunity and the deadline to add providers to an ESCO, more innovative approaches can be created, and new providers included.

Accordingly, we support the OIG's proposal to standardize and broaden protection under CMS-sponsored models. We concur with the OIG's assessment that the ongoing oversight and monitoring that CMS performs, particularly through the CMMI, warrant the increased flexibility and streamlining the OIG proposes. We hope that such an approach will allow more time and/or a later deadline for

adding model participants in the future. We also believe a more transparent and clearer announcement of waiver opportunities would help potential model participants decide whether to make the substantial financial and human resource commitments to participate in a CMS model. As NKCA represents several smaller providers, we believe that waivers made available in the future should consider the needs and resources of smaller providers and, at the same time, provide safeguards to maintain a competitive environment for both large and small dialysis providers.

In the proposed rule, you request comment on whether the safe harbor protections should terminate when a model ends, or participation is terminated. Generally, we believe that most safe harbor protections should end at the conclusion of the model, although we believe there are some instances where the OIG should consider continuation. For example, if the safe harbor effects continuity of care for patients who may still be under care of a provider after the model ends or if the safe harbor has promoted positive outcomes for the patient, continuation should be considered to ensure beneficiaries are realizing the maximum benefits of the models when their care does not fit squarely in the timeline of the model.

Telehealth (Section 50302(c) of the Bipartisan Budget Act of 2018)

Section 50302(c) of the Bipartisan Budget Act of 2018 created a new exception to the definition of "remuneration" in the beneficiary inducements CMP. This exception applies to "telehealth technologies" provided on or after January 1, 2019, by a provider of services or a renal dialysis facility,to an individual with ESRD who is receiving home dialysis for which payment is being made under Medicare Part B. Under the statute, "telehealth technologies" is a term to be defined by the Secretary. The exception requires that (i) the telehealth technologies not be offered as part of any advertisement or solicitation, (ii) the telehealth technologies must be provided for the purpose of furnishing telehealth services related to the patient's ESRD, and (iii) the provision of the telehealth technologies must "meet[ ] any other requirements set forth in regulations promulgated by the Secretary."

NKCA has always supported home dialysis. It is usually better for patients to receive treatment at home, thereby avoiding the need for three visits each week to a clinic while also improving overall quality of life. The use of clinically appropriate services via telehealth can enhance care by improving communication between patients and caregivers. These services include, but are not limited to, nutrition education; social services; pharmacy consultations; and virtual visits from physicians, nurses, and others.

We support CMS's and OIG's implementation of the legislation that Congress enacted last year. By allowing both home and dialysis facility to be originating sites for home dialysis patients' clinical assessment, telehealth will be beneficial for patients. In some cases, telehealth may replace in-person home visits, and in others, it can be an adjunct.

It is important that as this policy is being implemented it not be abused. For example, free at-home technologies—both devices and connectivity—must not be used to entice patients to use a particular provider. Understanding that devices used for telehealth can also be used for other purposes, provision of such capabilities could constitute a benefit to patients that goes far beyond

provision of telehealth services. While the statute directly prohibits advertising or solicitation based on the use of telehealth technologies, the OIG must ensure that beneficiaries have a clear understanding of what is involved in telehealth, and how telehealth services are actually provided.

We believe "telehealth technologies" should be defined in a manner that ensures that the intended healthcare use can be accomplished. For equipment, this would include computers, tablets, and smartphones. Software must be easily downloadable, easy to use for patients, and meet HIPAA standards, allowing for secure video communication for the visit. Connectivity includes both cellular data communication and Wi-Fi. Overall, we believe the OIG should consider the myriad uses for telehealth technologies, including the value of remote patient monitoring as long as it improves the coordination of care and services provided to the patient.

As a general matter, we support the OIG's proposal to define technology in functional terms—as proposed—rather than an exclusive list of specific technology, whether hardware, systems, or software, since this is a rapidly evolving sector. To the extent that the OIG is concerned about potential fraud and abuse, it could include a list of excluded items that it sees as problematic, as well as clarifications where it perceives potential "dual-use" problems. For example, we note and concur with the OIG's clarification to protect smart phones that allow for secure, two-way communication and teleconferencing. To further curb the potential for abuse, a monetary cap, as suggested by the OIG, could be imposed to cover the necessary technology but deter "gold-plating" that might be employed to steer patients.

With respect to the statutorily enumerated exceptions, we recommend that the OIG recognize that telehealth services for a patient with ESRD will often be more than the cost of provision of dialysis. ESRD patients typically suffer from multiple comorbidities, many if not all of which have a bearing on, or are complicated by, their dialysis care. The statute in fact refers to "services *related* to the individual's end-stage renal *disease*" not to end-stage renal dialysis.

We fully support the OIG's proposed requirement around patient freedom of choice. Simply put, the use of telehealth services, whether in whole or in part, should be explained to the patient (and family), and they should be informed that they have the choice whether to use it and that their choice will not in any way influence the care to which they are entitled.

Conclusion

Thank you for the opportunity to comment on updates to the Anti-Kickback Statute for value-based care arrangements. Please feel free to contact us to discuss any of these issues further. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director