



December 31, 2019

Acting Inspector General Joanne Chiedi
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P, Room 5521, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Dear Acting Inspector General Chiedi:

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 provide comment on selected sections of the OIG proposed rule on the Anti-Kickback Statute (AKS) and Civil Monetary Penalty Rules.

Civil Monetary Penalty Law Changes and In-Home Dialysis Telehealth

In the proposed rule, the OIG seeks to implement legislatively mandated policies intended to facilitate the advancement of home dialysis by allowing these services to be provided via the use of telehealth technologies that are furnished by a nephrology practice or dialysis facility. Accordingly, RPA supports the OIG's interpretation of the legislative phrase "for the purpose of furnishing telehealth services related to the individual's end stage renal disease" to mean:

That the technology contributes substantially to the provision of telehealth services related to the individual's ESRD, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes.

Appropriately, the OIG is seeking to identify reasonable and meaningful guardrails to ensure that the provision of the technology does not serve as an inducement for engaging with a

particular provider of service, and as such we share the concerns of OIG regarding providers offering telehealth technologies to patients with whom they do not have a prior clinical relationship in an attempt to inappropriately steer patients to their facility or practice. Below is RPA's input on some of the issues on which the OIG solicited comment in the proposed rule pertaining to telehealth technologies and home dialysis.

Ownership of Telehealth Technology - In the proposed rule, the OIG solicits comment on the issue of ownership of the telehealth technology, and whether the provider or facility should be required to retain ownership of the technology. RPA believes that ideally in most cases the concept of ownership will be rendered moot since the useful life of the device will expire first. However, flexibility in this policy should be maintained such that the provider or facility can retain ownership interest for when a beneficiary tries home dialysis but because of clinical or social reasons (such as the loss of a caregiver) decides not to remain on home dialysis. This would allow the nephrology practice or facility to provide the technology to another home dialysis telehealth patient.

Interpretational Scope of Telehealth and ESRD - Additionally, the OIG also seeks comments on "whether the exception should protect telehealth technologies that provide the beneficiary with no more than a de minimis benefit for any purpose other than furnishing telehealth services related to the individual's ESRD. We also are considering for the final rule and seek comments on another standard that would protect telehealth technologies only when furnished predominantly for the purpose of furnishing telehealth services related to the individual's ESRD." Further, comment is sought on a potential interpretation of "telehealth services related to the individual's end stage renal disease" to mean only those telehealth services paid for by Medicare Part B." RPA would urge the OIG to take a holistic approach and thus view the benefit to an individual's ESRD somewhat broadly. It is important to bear in mind that the Administration is seeking to promote penetration of the use of home dialysis in the U.S. as part of its Advancing American Kidney Health Initiative. Unnecessarily limiting the use of the technology to Part B services could complicate efforts for home dialysis patients to receive care coordination, dietary counseling, and patient education (depending on how services such as these are provided and by whom since they may not always be covered by Medicare Part B).

Consistent Provision of Necessary Technology - Comment is also solicited on a safe harbor condition that would require providers and renal dialysis facilities to provide the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients satisfying specified, uniform criteria. The technology should be provided to patients on an as needed basis, and that some home dialysis patients will not need the technology to receive services, and would prefer to use their own technology when doing so, and thus we would urge OIG to not establish such a requirement.

Notice to Patients - The OIG notes that it is considering adding in the final rule a condition that requires providers or facilities to provide a written explanation of the reason for the technology and any potential “hidden” costs associated with the telehealth services to any patient who elects to receive telehealth technology. RPA concurs with the comments of the AMA that we support communicating to patients the benefits and risks of telehealth technology, but that no need exists for a formal, technical requirement to comply with the civil monetary penalty statute. This communication should be a part of the physician-patient relationship.

Patient Freedom of Choice – The proposed rule also indicates that the OIG is considering a condition in the exception that would require offerors of telehealth technologies to advise patients when they receive such technology that they retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting. RPA unequivocally supports a patient’s freedom of choice among nephrologists and dialysis facilities (and all health care providers) as well as dialysis modality choice under arrangements that would use the proposed exception. That said, at a time when CMS is pursuing reduction of administrative burdens under the Patients Over Paperwork initiative, such a requirement would run counter to those efforts. Additionally, this condition would duplicate existing requirements in the ESRD Conditions for Coverage, and thus does not seem necessary.

Local Transportation

Expansion of Mileage Limit for Patients Residing in Rural Areas – The OIG notes in the proposed rule that the current transportation safe harbor provides that transportation is protected if provided “within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area.” Accordingly, the Agency proposes to increase the limit on transportation for residents of rural communities to 75 miles but solicits comments on whether an increase to 75 miles is sufficient. RPA would recommend that the limit be increased to 100 miles. For example, a dialysis patient living in a rural area and receiving vascular access services will often be more than 75 miles away from a vascular access center, where they receive critically important surgical procedures to preserve the access through which they are dialyzed. A vascular access center typically must serve in excess of 500 ESRD patients (in addition to larger numbers of late stage CKD patients) to be financially viable. In less populous areas these centers tend to be centrally located where patients from a large surrounding geography travel to receive care. Minimizing the possibility of an unnecessary hospitalization and its attendant expense to the Medicare program by maintaining a functioning access is of paramount importance to dialysis patients. We therefore urge the OIG to increase the mileage limit to 100 miles.

Personal Services and Management Contracts and Outcomes-Based Payment Arrangements

Elimination of Requirement to Specify Schedule of Part-Time Arrangements - OIG includes in the rule a proposal to eliminate the requirements relating to agreements for services provided on a periodic, sporadic, or part-time basis. This paragraph of the safe harbor requires contracts that provide for services on such a basis to specify “exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.” Removing this requirement would afford parties additional flexibility in designing bona fide business arrangements, including care coordination and quality-based arrangements, where parties provide legitimate services as needed. RPA urges the OIG to proceed with this proposal. Dialysis facility medical directors provide their services on a part-time basis and thus this provision would apply to their activities. Additionally, the unpredictable nature of dialysis care and the frequent need to respond to urgent and often life-threatening medical emergencies at the very least confounds the ability of nephrologists serving as dialysis facility medical directors to adhere to a predictable schedule for their medical director activities. Their work gets done, but not necessarily according to a predetermined schedule. Accordingly, removing the ‘exact scheduling’ requirement is a common-sense improvement beneficial to all parties. RPA commends the OIG for this proposed modification, and we urge the Agency to finalize it as proposed.

As always, RPA welcomes the opportunity to provide comment on the proposed rule and to work collaboratively with OIG to ensure accountability in the delivery of to the nation’s kidney patients. We stand ready as a resource to OIG in its future work. 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, reading "Jeffrey A. Perlmutter" followed by a stylized flourish.

Jeffrey A. Perlmutter, MD
President