PEPC
PARTNERSHIP TO EMPOWER PHYSICIAN-LED CARE

Submitted electronically via www.regulations.gov

December 31, 2019

Acting Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, D.C. 20201

Re: RIN 0936–AA10; 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 Acting Inspector General,

Thank you for the opportunity to provide input on proposals to revise safe harbors under the anti-kickback statute, and civil monetary penalty rules regarding beneficiary inducements. We share your goal of breaking down barriers to value-based care, particularly barriers that make it difficult for independent practices and physicians to move away from fee-for-service and that stifle provider competition.

The Partnership to Empower Physician-Led Care (PEPC) is a membership organization dedicated to supporting value-based care to reduce costs, improve quality, empower patients and physicians, and increase access to care for millions of Americans through a competitive health care provider market. We believe that it is impossible to achieve truly value-based care without a robust independent practice community. Our members include Aledade, American Academy of Family Physicians (AAFP), California Medical Association, Florida Medical Association, Medical Group Management Association (MGMA), and Texas Medical Association's Practice Edge. We also have individual and small medical group supporters across the country, many of whom are independent physicians or practices and wish to remain so.

Below are our specific comments on the proposed rule. Where possible, we have aligned our comments on this rule with the Center for Medicare & Medicaid Services' (CMS') rule on modernizing and clarifying the physician self-referral law.

New Safe Harbor: Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency

OIG proposes a new safe harbor that would protect in-kind remuneration exchanged between qualifying VBE participants with value-based arrangements that satisfy certain requirements. One of the proposed requirements of the safe harbor is that the recipient must pay at least 15 percent of the offeror's total cost for the in-kind remuneration. OIG is considering for the final rule whether it should require a more specific methodology for determining value, and is alternatively considering contribution amounts ranging from 5 to 35 percent and whether it should require different contribution amounts for different types of remuneration or different recipients.

With respect to the proposed 15-percent contribution requirement, we urge OIG not to apply the requirement to independent practices and physicians. Our preferred approach would be to eliminate the

requirement altogether, reflecting that it could be cost-prohibitive for an independent practice or physician and thus serve as a disincentive for experimenting with value-based arrangements.

If OIG is unwilling to drop the requirement altogether, we believe that OIG should instead adopt a contribution requirement that is proportional to the finances of the entity. A 15-percent contribution toward non-monetary remuneration may not be a significant investment for a well-resourced, large provider, but would be a significant investment for an independent practice or physician. If the goal is to reduce the risk of fraud and abuse by requiring the provider to have "skin in the game," we believe that OIG should require a comparable investment across provider types.

Finally, with respect to how OIG should define "small and rural practices," we urge OIG to be consistent with other standards already adopted in other programs. To that end, we suggest that OIG use the definition of "small practice" used in the CMS Quality Payment Program – a TIN or virtual group associated with 15 or fewer clinicians.

New Safe Harbor: CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

OIG proposes a new safe harbor to (i) permit remuneration between and among parties to arrangements under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act and the Medicare Shared Savings Program under section 1899 of the Act; and (ii) permit remuneration in the form of incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model.

We noted in our response to CMS's Request for Information on modernizing and clarifying physician self-referral regulations that we generally found the model-specific fraud and abuse waivers issued by CMS sufficient for supporting alternative payment models, from launching the model to payment distribution to beneficiary incentives. Nonetheless, we support the additional clarity and uniformity that comes from the proposed safe harbor, which essentially acts as an umbrella policy sitting over all of the models currently being tested by CMS.

New Safe Harbor: Cybersecurity Technology and Related Services

OIG proposes to protect nonmonetary remuneration in the form of certain types of cybersecurity technology and services. "Cybersecurity" is proposed to mean the process of protecting information by preventing, detecting, and responding to cyberattacks. The new exception would protect nonmonetary remuneration in the form of certain types of cybersecurity technology and related services, and would cover any software or other types of IT (excluding hardware).

OIG is considering, but not proposing, to require a recipient contribution if the donation includes hardware. This contribution requirement could be 15 percent or another contribution amount. OIG is considering excepting small and rural practices, and is interested in comments on this approach including how "small and rural practices" should be defined.

We support the addition of this exception, but urge clarification that the exception should not be used to support intentional or unintentional anti-competitive behavior. We also support OIG's decision not to require the recipient to contribute toward the cost of the item or service. This could be a disincentive for independent practices and physicians given the potential magnitude of the cost and the administrative burden associated with tracking and calculating the cost of the item/service. If OIG does require a contribution, we urge you to consider a comparable investment across provider types rather than a flat percentage that does not account for the unique circumstances of particular providers

Modified Safe Harbor: Electronic Health Records

OIG proposes to update the existing exception for electronic health record (EHR) items and services to align with other regulations. OIG proposes to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the Public Health Service Act (PHSA), in connection with the donated items or services. While OIG is not proposing specific amendments to the existing 15 percent contribution requirement, it is soliciting comments on alternative requirements.

PEPC strongly supports the addition of specific language preventing donors from engaging in information blocking. We have heard anecdotally that donated software is not capable of fully exchanging necessary information with EHRs used by other inpatient and ambulatory providers. We support the proposed additional clarifications to address intentional or unintentional information blocking given the potential to improve patient care.

OIG notes that it is considering whether and, if so, how to eliminate or reduce the 15 percent contribution requirement for a specific subset of recipients such as small or rural practices. If such flexibility is recommended, OIG is soliciting comments on how "small or rural practices" should be defined.

Finally, with respect to how OIG should define "small and rural practices," as noted above, we urge OIG to be consistent with other standards already adopted in other programs. We suggest using the definition of "small practice" used in the CMS Quality Payment Program – a TIN or virtual group associated with 15 or fewer clinicians.

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Thank you for the opportunity to provide comment on the proposed rule. Please do not hesitate to reach out if PEPC or its members can be a resource to you.

Sincerely,

Kristen McGovern
Executive Director