PEPC
PARTNERSHIP TO EMPOWER PHYSICIAN-LED CARE

Submitted via www.regulations.gov

December 31, 2019

Mrs. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1720-P; Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

Thank you for the opportunity to comment on the proposed rule modernizing and clarifying the physician self-referral regulations. 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 HHS Office of Inspector General's (OIG) proposed rule on modifications to the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Penalties (CMPs).

FACILITATING THE TRANSITION TO VALUE-BASED CARE AND FOSTERING CARE COORDINATION

Value-Based Arrangements

CMS proposes a new exception for value-based arrangements that meet specific criteria, including that the arrangement is set forth in writing; that the performance or quality standards against which the recipient will be measured, if any, are objective and measurable; and that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. CMS notes that, while not proposed at this time, it is considering whether to require the recipient of any non-monetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the non-monetary remuneration. CMS seeks comment regarding the appropriate level for any required contribution and whether certain recipients such as small or rural physicians, providers and suppliers should be exempt from compliance with the requirement.

PEPC supports the addition of new exceptions for value-based arrangements. We appreciate that CMS has created a range of flexibilities reflecting that providers may be interested in greater accountability for

patient outcomes and costs but not yet ready to take on financial risk. These entry-level arrangements are valuable in that they aim to achieve the same goals as more advanced risk-taking models while giving providers the necessary time to make needed infrastructure and staffing investments, workflow improvements, and cultural changes.

However, as proposed, exception at 411.357(aa)(3) for "value-based arrangements" does not create enough value nor provide enough protection to beneficiaries to warrant the exception.

The most significant issue is that CMS proposes no limits on the upside of remuneration. Specifically, we are concerned that declining to propose limits based either on fair market value or commercial reasonableness opens the door to organizations using otherwise laudable value-based activities to change remuneration for competitive reasons unrelated to the value-based activities. Under the proposal, it would be simple to create a value-based arrangement with a minimal set of value-based activities incorporating standards that are very easy to meet for the purposes of creating remuneration arrangements designed to spur referrals and/or for anti-competitive recruiting practices.

In the field, we have experienced cases where clinically integrated networks (established to gain antitrust exemptions) are used not just for clinical integration, but also as a tool to intimidate competitors into accepting unrelated and onerous terms. For example, under the proposal, a value-based enterprise (VBE) could offer a value-based arrangement that gives a physician practice higher remuneration than the combination of the value created through the value-based activity and the value of the remuneration captured by the revenue generated by the physician practice. This loss leading offering is only possible by entities with other funding streams to draw on to subsidize the value-based activity. The VBE could then offer a physician practice participation in the value-based activity only if they agree to other unrelated terms. There does not appear to be any active protection against a VBE using a value-based arrangement as an incentive for providers to agree to other terms completely unrelated to the value-based activity.

In order to be protected under this exception, we propose that CMS require that the value-based arrangements proposed at the exception at 411.357 (aa)(3) meet a fair market value standard. In meeting the standard, the VBE could transfer all of the value created by the participants through the value-based activity to the physician practice, but could not transfer more than the value created as no market can consist only of loss leaders nor should any one market participant be able to remain in a market over the long term as a loss leader.

Additionally, with respect to the proposed 15 percent contribution requirement, we urge CMS 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 CMS is unwilling to drop the requirement altogether, we believe that CMS should instead adopt a contribution requirement that is proportional to the finances of the provider. 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 CMS should require a comparable investment across provider types.

Finally, with respect to how CMS should define "small and rural practices," we urge CMS to be consistent with other standards it has adopted in other programs. To that end, we suggest that CMS use the

definition of "small practice" used in the Quality Payment Program – a TIN or virtual group associated with 15 or fewer clinicians.

Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician

CMS also proposes a new exception for remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement. CMS defines "meaningful downside financial risk" to mean that the physician: 1) is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or 2) is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payer for each patient in the target patient population for a specified period.

While we support the addition of the new exception, we are concerned that the VBE itself is not at risk. A VBE not at risk could qualify for this arrangement and then set standards for achievement in its value-based arrangements that remove the risk to the physician. We believe that it would be most appropriate for this exception to focus on the amount of risk assumed by the entity, similar to the assessment of "more than nominal risk" for an advanced alternative payment model (APM) under the Quality Payment Program. With the VBE at risk it has a greater incentive to ensure that the VBE participants share in that risk to the degree deemed appropriate by the VBE.

FUNDAMENTAL TERMINOLOGY AND REQUIREMENTS

CMS proposes to define "commercially reasonable" to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, CMS requests comment on defining "commercially reasonable" to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

In general, we believe it is most appropriate for providers to be compared to other similarly situated providers. As a result, we prefer the alternative approach of defining "commercially reasonable" to mean that it makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

RECALIBRATING THE SCOPE AND APPLICATION OF THE REGULATIONS

Exception for Physician Recruitment

Under the physician self-referral regulations, there is an existing exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. CMS proposes to modify this exception by requiring the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

PEPC appreciates that CMS is modifying this exception to impose additional requirements for protection under the exception; however, we believe that this exception could be used anti-competitively and serves to disadvantage recruitment efforts by independent practices. We believe that CMS should either expand

this exception to cover recruitment efforts by physician practices, or remove it altogether to ensure that independent practices are competing with hospitals on a level playing field.

Exception Electronic Health Records Items and Services

CMS proposes to update the existing exception for electronic health record (EHR) items and services to align with recent regulations updating certain terms like "interoperable" and "information blocking." One specific proposal is to prohibit the donor of EHR items and services (or any person acting on the donor's behalf) from engaging in information blocking, as defined in section 3022 of the Public Health Service Act (PHSA), in connection with the donated items or services.

PEPC strongly supports the addition of specific language preventing donors from engaging in information blocking. In our response to CMS' Request for Information on modernizing the physician self-referral regulations, we noted that we continue to hear anecdotally that donated software is not capable of fully exchanging necessary information with EHRs used by other inpatient and ambulatory providers. We urged CMS to consider additional clarifications to address intentional or unintentional information blocking, and applaud you for doing so now.

PROVIDING FLEXIBILITY FOR NONABUSIVE BUSINESS PRACTICES

Cybersecurity Technology and Related Services (Proposed 411.357(bb))

CMS proposes a new exception to protect arrangements involving the donation of certain cybersecurity technology and related 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 type of IT (excluding hardware).

CMS proposes a requirement that neither a potential recipient, nor a potential recipient's practice (including employees or staff members) may make the receipt of cybersecurity technology and related services, or the amount or nature of the technology or services, a condition of doing business with the donor. However, at this time, CMS is not requiring the recipient to contribute toward the cost of the item or service.

We support the addition of this exception, but similar to our past comments on the exception for EHR items and services, we urge clarification that the exception should not be used to support intentional or unintentional anti-competitive behavior. We also support CMS' 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 that the potential magnitude of the cost and the administrative burden associated with tracking and calculating the cost of the item/service. If CMS 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.

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Please do not hesitate to reach out to me if the Partnership to Empower Physician-Led Care can be a resource to you. I can be reached at kristen@physiciansforvalue.org or 202-640-5942.

Sincerely,

Kristen McGovern
Executive Director