AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 27, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response to the proposed rule titled, "Modernizing and Clarifying the Physician Self-Referral Regulations" as published by the Centers for Medicare & Medicaid Services (CMS) in the October 17, 2019 *Federal Register*.

The AAFP is committed to transforming the Medicare program into one that prioritizes the delivery of high-quality, patient-centered, and efficient care. As we have previously stated, and literature supports, achieving meaningful transformation of our health care system starts with creating such a system based in foundational primary care – and one which supports an increased investment in primary care to sustain its' transformation.

As the agency refines these policies, we wish to share the AAFP's position that it is improper for physicians to receive payment from an entity, including non-monetary items of value, to induce or reward the generation of business by that entity. This policy is not intended to preclude any safe harbors defined within the context of the Federal Anti-Kickback legislation, Stark legislation, accountable care organization contracts, bundled episodes of care payment, or other similar business arrangements, such as legal gain sharing agreements or risk contracts.

As the agency modernizes these regulations, the AAFP calls for a greater focus on outcomes related to quality and cost and less on procedural safeguards. Such an approach would be more consistent with the guiding principle of choice and competition in the market based on quality, costs, and outcomes compared to the current approach of subjecting beneficiaries and physicians to increasingly stringent administrivia, coverage criteria, and documentation requirements.

There is a clear need to recognize the importance of experimentation with provider payment methodologies that incentivize medical practices to expand the provision of preventive services, improve clinical outcomes, and enhance patient safety and satisfaction. The AAFP continues to support physicians moving away from receiving payments in an antiquated fee-for-service (FFS) context. Instead we strongly support efforts to shift primary care payments into alternative payment models (APMs) and value-based care arrangements that are more consistent with the continuous, comprehensive, and longitudinal nature of primary care. As such, the AAFP fully appreciates that CMS is addressing the burden of the physician self-referral law by proposing

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exceptions for certain value-based compensation arrangements between physicians, providers, and suppliers. From a broad perspective, we strongly encourage CMS to:

- Ensure that policies do not hinder family physicians' ability to transform their practices and collaborate with other physicians and health care professionals to provide team-based, patient-centered care that incorporates new technologies and focuses on reducing the total cost of care.
- Issue broad and clear safeguards for value-based payment arrangements.
- Remove barriers that inhibit or prohibit patients from receiving needed care (e.g. durable medical equipment, x-rays, laboratory services) in a value-based care framework at the primary care point of setting.
- Ensure that all Center for Medicare & Medicaid Innovation (CMMI) models tested that utilize waivers are not in violation of the self-referral regulations, so these models can be expanded and used by other payers.
- Increasingly reduce the medical, legal, and financial documentation primary care practices must complete as the practices evolve away from a FFS environment and into one that takes on financial risk.
- Make available clear safe harbors for advanced primary-care models, covering operational and financial arrangements as well as physician practice and flexibility.
- Create a simple decision tree for medical practices to help determine if further costly legal opinions may be needed.

The AAFP is pleased to offer the following feedback on this proposed rule.

II.A Facilitating the Transition to Value-Based Care and Fostering Care Coordination

Summary

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 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.

AAFP Response

The AAFP supports the addition of new exceptions for value-based arrangements, and we likewise support a greater range of flexibilities reflecting that physicians may be interested in greater accountability for patient outcomes and costs but are not yet ready to take on financial risk.

Regarding the 15-percent contribution requirement, the AAFP urges caution. CMS should not apply the requirement to small, independent, and rural primary care practices and physicians. CMS should eliminate this requirement since it serves as a disincentive for experimenting with value-based arrangements.

On the definition of "small and rural practices," we urge CMS to be consistent with other standards it has already adopted in other programs. To that end, we suggest that CMS use the definition of "small practice" used in the Quality Payment Program – a Tax Identification Number or virtual group associated with 15 or fewer clinicians.

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

Summary

CMS 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 value-based enterprise 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.

AAFP Response

Generally, the exceptions involving financial risk do not capture any aspect of risk that does not involve activities or services that are reimbursable by a payer. Thus, no matter how much a physician practice incurs in unreimbursed costs to qualify for an "upside-only" bonus, the physician would not be viewed as being in a "meaningful downside financial risk" arrangement. Thus, the AAFP believes the focus on risk should not just be on downside financial risk. Instead, CMS needs to address other risks such as upside, clinical, operational, contractual, or investment.

While the AAFP supports the new exception, we again urge CMS to be consistent in all definitions and risk-taking standards across programs. Specifically, we urge CMS to focus on the amount of risk assumed by the entity rather than the clinician, like the assessment of "more than nominal risk" for Advanced APMs. We therefore call on CMS to align the definition of "meaningful downside financial risk" with the minimum total amount an APM Entity must put at risk to quality as an Advanced APM – at least 8% of the average estimated total Medicare Parts A and B revenues of all providers and suppliers participating in the APM Entity, or 3% of the expected expenditures for which the APM Entity is responsible for under the Advanced APM.

Finally, the AAFP asks CMS to provide an explicit safe harbor for withholds of physician payment when a clinically integrated network or group practice assumes the risk on behalf of their individual physicians.

B. Fundamental Terminology and Requirements

Summary

CMS proposes to define "commercially reasonable" to mean that the 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.

AAFP Response
In general, CMS should compare physicians to other similarly situated physicians. Therefore, the AAFP prefers the 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. This broad definition does not differentiate between types of entities.

C.2.a. Distribution of Revenue Related to Participation in a Value-Based Enterprise
Summary
CMS proposes to add a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under the proposal, when such profits are distributed to the participating physician, they would be deemed not to directly take into account the volume or value of the physician's referrals.

AAFP Response
The AAFP supports the proposal to add a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a VBE. The current restriction discourages physician participation in value-based arrangements because physicians cannot be suitably rewarded for their accomplishments in advancing value-based purposes. Moreover, physician decisions drive health care spending and patient outcomes. Thus, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other clinicians. Accordingly, by removing the restriction, physicians in a group practice setting can be rewarded for providing value-based care.

D. Recalibrating the Scope and Application of the Regulations
Summary
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 and document 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 the remuneration from the hospital.

CMS proposes to update the existing exception for electronic health records (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 in connection with the donated items or services.

AAFP Response
Regarding physician recruitment, the AAFP believes this exception could be used anti-competitively and serves to disadvantage recruitment efforts by independent practices. We believe CMS should either expand this exception to cover recruitment efforts by physician practices or remove it altogether to ensure independent practices are competing with hospitals on a level playing field.

Regarding EHR items and services, the AAFP strongly supports the addition of specific language preventing donors from engaging in information blocking. We urge CMS to consider additional AAFP suggestions to address information blocking that we suggested in a June 3, 2019 letter.

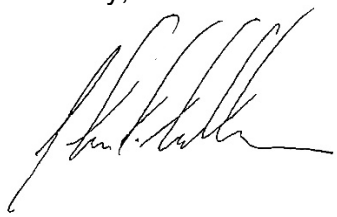
E. Providing Flexibility for Nonabusive Business Practices
Summary
CMS proposes a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services. "Cybersecurity" is proposed to mean the process of protecting information by preventing, detecting, 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 information technology but excludes 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, currently, CMS is not requiring the recipient to contribute toward the cost of the item or service.

AAFP Response
While the AAFP supports the addition of this exception, we also urge clarification that the exception should not be used to support intentional or unintentional anti-competitive behavior. We 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 practices.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or rbennett@aafp.org with any questions.

Sincerely,



John S. Cullen, MD, FAAFP
Board Chair