AGS Geriatrics Healthcare Professionals

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1720-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

The American Geriatrics Society ("AGS") greatly appreciates the opportunity to comment on the proposed rule published by the Department of Health and Human Services Centers for Medicare and Medicare Services ("CMS") related to changes to the physician self-referral law ("Stark Law") ("Proposed Rule").[1] The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners (NPPs) who are devoted to improving the health, independence and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy. One goal of our mission is to improve care coordination for patients with multiple chronic conditions. This will not only improve the quality of care these individuals receive, but will also increase beneficiary satisfaction and reduce the growth in Medicare spending.

The AGS is pleased that CMS has proposed revisions and updates to the exceptions to the Stark Law, and believes that, generally, protecting the types of arrangements contemplated in the Proposed Rule will be beneficial to physicians and patients. The AGS particularly appreciates CMS' efforts to "alleviate the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties."[2] Nevertheless, CMS proposed a number of changes that raise concerns for the AGS. Both our general support for the proposals and our specific concerns regarding the proposals are described in more detail below.

[1] 84 Fed. Reg. 55766 (Oct. 17, 2019).
[2] 84 Fed. Reg. at 55772.

I. Recommendations

AGS recommends that CMS:

- Define "full financial risk" to include arrangements where the risk pertains to a limited bundle of services and excludes certain extraordinarily expensive and infrequently furnished items and services from risk;
- Permit the participants in a value-based arrangement with meaningful downside financial risk to allocate the financial risk among participants at their discretion;
- Redefine the level of risk required to meet the definition of "meaningful downside financial risk" to align with Advanced Alternative Payment Models and other Innovation Center models;
- Modify the proposed exception that protects certain value-based arrangements without requiring the value-based enterprise to take on financial risk to require fewer conditions and clarify certain of the conditions; and
- Remove the 15 percent contribution requirement for all practices proposed as a condition of the proposed new cybersecurity exception.

II. Exception to "All Items and Services" in the Definition of "Full Financial Risk"

In the Proposed Rule, CMS proposes that "full financial risk" for purposes of the exception to the Stark Law for value-based arrangements ("VBAs") under which the value-based enterprise ("VBE") is at full financial risk will mean that "the VBE is financial responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target population for a specified period of time."[3] In other words, CMS specifically proposes that an enterprise may be protected only if it receives a prospective, capitated payment for all items and services covered by Medicare Parts A and B. CMS clarifies that "full financial risk" cannot take the form of payment approaches other than capitation payments or global budget payments.[4] CMS does not define "all items and services" and does not provide for any exceptions to the definition of "full financial risk," but does seek comment regarding whether a value-based enterprise should be considered to be at full financial risk if it is responsible for the cost of only a defined set of patient care services.[5]

The AGS strongly recommends that CMS define full financial risk to include arrangements where the "full financial risk" pertains to items and services related to a disease or condition for a defined patient population (*e.g.*, an arrangement under which the physician receives an episode-based payment for all care related to one disease) and that exclude certain extraordinarily expensive and infrequently furnished items and services from full financial risk. Medicare has developed a number of different payment models that utilize bundled payments and episodes of care over the past few years that should qualify under this exception. For example, there have been a number of episode-based payment initiatives developed by the Center for Medicare & Medicaid Innovation ("CMMI"), such as the Comprehensive Care for Joint Replacement Model and the Medicare Acute Care Episode

[3] 84 Fed. Reg. at 55846.
[4] 84 Fed. Reg. at 55779.
[5] 84 Fed. Reg. at 55779.

Demonstration, both of which involve testing episode-based payments to physicians. We recommend that CMS implement a policy that protects value-based arrangements between VBE participants who are subject to financial risk similar to providers participating in such CMMI demonstrations. We also recommend that CMS implement a policy that protects value-based arrangements between VBE participants that involved capitated payments for a limited set of services. In some cases, such as with respect to arrangements that involve primary care services, the limited set of services could represent nearly the entire payment received by the provider.

Additionally, the AGS believes that forcing the VBE to bear the financial burden of extraordinarily expensive and infrequently furnished items and services, or of costs unrelated to the disease or condition covered by the arrangement, is unreasonable and would deter providers from entering into such agreements. Permitting a VBA to exclude extraordinarily expensive and infrequently furnished items and services aligns with other policies related to such items and services. For example, some Medicare Advantage plans place provider entities at full risk, but exclude extraordinarily expensive and infrequently furnished items, such as organ transplants, which are not services evenly furnished by different provider specialties. Even with stop-loss programs, Medicare has recognized that such extraordinary costs should be excluded. To ensure the proposed exception aligns with these current coverage policies, the AGS believes that a VBA should be permitted to exclude extraordinarily expensive and infrequently furnished items and services, or costs unrelated to the relevant disease or condition in bundled payment arrangements. Without such changes, this exception may be irrelevant and unavailable to even large provider entities, which would need to rely upon a different exception.

III. Exception for Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician

The AGS generally supports CMS' proposal related to an exception for VBAs that involve meaningful downside financial risk. However, we recommend changes to the proposal, including with respect to 1) whether a physician must take on the downside financial risk and 2) the definition of "meaningful downside financial risk."

a. Meaningful Downside Financial Risk to the Physician

In the Proposed Rule, CMS proposes that the exception for VBAs with meaningful downside financial risk to the physician would apply to arrangements under which the physician is at meaningful downside risk, irrespective of whether the remuneration is paid to or from the physician.

In drafting this proposed requirement, CMS states that *the physician* must take on the meaningful downside financial risk. CMS' reference to "*the physician*," as a singular entity, concerns the AGS. We suggest CMS clarify that the provider members of the VBE must collectively assume meaningful downside risk, but physicians need not individually take on meaningful downside risk through his or her own performance with respect to their own patients. Similar to CMS rules with respect to risk sharing among Advanced Alternative Payment Model ("APM") entity participants, we recommend that CMS require that the VBE take on the downside risk, but provide flexibility to the VBE to distribute responsibility for the financial risk among participants at its discretion.

Additionally, CMS seeks comment on whether "the physician would have the same incentives to modify his or her practice and referral patterns in a manner designed to achieve the important goals described in [the Proposed Rule] if the party that has assumed the meaningful downside financial risk and is paying remuneration under the arrangement is the entity furnishing the designated health services."[6] AGS strongly believes that when any entity in an arrangement takes on financial risk, there are sufficient incentives for that responsible entity to ensure that the physician modifies relevant behavior to best achieve the goals of the arrangement. Accordingly, the AGS recommends that CMS finalize that any VBA participant, such as a professional corporation, may take on the required meaningful downside financial risk.

b. Proposed Definition of "Meaningful Downside Financial Risk"

In the Proposed Rule, CMS proposes that "meaningful downside financial risk" for purposes of the exception for VBAs with meaningful downside financial risk will be defined as an arrangement in a which a physician:

- is responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the VBA; or
- is financially responsible to the payor or the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.[7]

The AGS is disappointed with CMS' proposed approach definition of "meaningful downside financial risk." We believe that the risk levels proposed are too high to allow most physicians to utilize the exception. However, we believe that CMS' definition of risk for purposes of this exception is crucial to encourage providers to utilize this exception and enter into value-based arrangements. The level of risk CMS proposes to require is daunting and would deter physicians and physician groups from entering into such VBAs and, therefore, the proposal is inconsistent with CMS's intent to encourage participation in VBAs. The AGS encourages CMS to develop a definition of "meaningful downside financial risk" that imposes a more restrained risk requirement and that would, therefore, maintain incentives for providers to enter into VBAs.

Payment models that would facilitate protection under the proposed exception are relatively new to most physicians, and therefore most physicians would find it extremely challenging to take on meaningful downside financial risk, as currently defined. For example, a repayment obligation of no less than 25% of the value of the remuneration received under the VBA would be financially challenging for most physicians or physician groups. This possible take home payment amount is unlikely to attract providers, such as primary care physicians, that might otherwise be interested in capitation for a defined set of capitated primary care services. Therefore, AGS strongly believes that CMS should modify the proposed definition of "meaningful downside financial risk." We recommend that CMS align the definition of "meaningful downside financial risk" with the amount of risk that Advanced APM entities are required to take on under the CMS Quality Payment Program ("QPP") or that providers are required to take on under other CMMI payment models. The amounts of risk required by the QPP and CMMI

[6] 84 Fed. Reg. at 55781-82.
[7] 84 Fed. Reg. at 55782.

payment models has been tested, validated, and implemented, and are a reasonable basis for establishing financial risk requirement in the proposed safe harbor.

IV. Exception for Value-Based Arrangements with No Financial Risk Requirement

In the Proposed Rule, CMS proposes to protect certain financial arrangements involving the provision of at least one value-based activity for a target population, regardless of the level of risk undertaken by the VBE or any of its participants. The AGS strongly supports finalizing an exception that protects certain VBAs without requiring any entity to take on financial risk. However, we believe that the final exception should include fewer conditions than were proposed. We believe such a final exception will help CMS further its goal "to alleviate the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties."[8]

CMS proposes a large number of conditions that must be met for an entity to fit within the requirements of the exception, including:

- The arrangement must be set forth in writing;
- The performance or quality standards against which the recipient will be measured are objective and measurable;
- The methodology used to determine the remuneration must be set in advance;
- The remuneration is for or results from activities undertaken for patients in the target population;
- The remuneration is not an inducement to limit medically necessary items or services;
- The remuneration is not conditioned on referrals who are not part of the target population or on business not covered under the VBA; and
- Records must be maintained for at least 6 years and made available to the Secretary of HHS upon request.[9]

Although AGS generally supports the purpose of this exception, we believe that the proposed requirements present unnecessary hurdles for physicians to overcome to enter into a protected arrangement. The AGS has serious concerns that the scope and number of requirements proposed by CMS will deter physicians from attempting to enter into arrangements that meet the requirements of the proposed exception.

In addition, some of the proposed requirements are vague and physicians may have difficulty confirming that each requirement has been met. Utilizing the proposed exception may be particularly difficult for small physician practices, solo practitioners, and rural practitioners who may not have the resources required to set up and enter into a protected arrangement. Moreover, physicians that do attempt to satisfy all these requirements may have difficulty doing so, despite their best efforts, potentially exposing them to strict liability under Stark. For example, the AGS believes that, because CMS does not define "expected to," the proposed requirement that the writing setting forth the

[8] 84 Fed. Reg. at 55771.
[9] 84 Fed. Reg. at 55783-86.

arrangement describe how the value-based activities are "expected to further the value-based purpose(s) of the value-based enterprise" is vague and would be difficult to implement and monitor.

These examples demonstrate that the proposed exception is overly burdensome and vague, and will be difficult to implement. Therefore, AGS recommends that CMS redesign the proposed exception to include fewer and clearer safeguards to implement a protected arrangement.

V. Cybersecurity and EHR Technology

The AGS supports CMS' proposal to add a new cybersecurity exception that would protect donations of software or other non-hardware information technology that are "necessary and used predominantly" to "protect implement, maintain, or reestablish cybersecurity."[10] The AGS supports CMS' proposal not to require a recipient contribution requirement as part of the proposed exception. As healthcare providers work to improve information sharing across care transitions and foster coordination, it is critical that health IT systems are protected against cyberattacks. Vulnerabilities in physicians' IT systems expose other providers, such as hospitals, skilled nursing facilities, and other outpatient facilities, to attack. Therefore, it is appropriate and in the best interest of patients' health and information security to allow entities with the financial ability to donate cybersecurity technology to other providers with whom they coordinate care.

In addition, the AGS generally supports CMS' proposal to update EHR technology exception provisions pertaining to interoperability and data lock-in, clarify that donations of certain cybersecurity software and services are permitted, remove the existing sunset provisions, and modify the definitions of "electronic health record" and "interoperable" to be consistent with the 21st Century Cures Act. However, the AGS disagrees with CMS' proposal to include a requirement that the recipient to pay 15% of the donor's cost of the technology. Instead, the AGS supports the alternative proposal to waive the percentage contribution requirement for all practices.[11] The AGS believes any contribution requirement may be burdensome for a physician practice and would deter physician practices from adopting modern EHR systems and cybersecurity technology that will help protect patients and patient data. Certain organizations will only permit practices to utilize their EHR systems if the physician has certain cybersecurity protections, but the security system provides no other benefit to the practice other than enabling the use of an integrated EHR system. Therefore, it is appropriate that the party requiring the cybersecurity protection pay any costs associated with the system. Practices may not otherwise have access to patient information through an EHR system for timely care coordination. In the alternative, we recommend that CMS adopt its alternative proposal to eliminate the contribution requirement for small and rural practices. As CMS implicitly acknowledges, small and rural practices typically do not have the resources to contribute to EHR and cybersecurity technology. Requiring any contribution for such technology would deter widespread adoption of interoperable EHR and cybersecurity.

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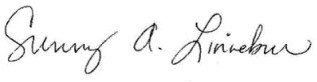
Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

[10] 84 Fed. Reg. at 55831.
[11] 84 Fed. Reg. at 55835.

Sincerely,



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