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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Verma:

On behalf of AMGA and its members, we appreciate the opportunity to comment on the “Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations” (CMS-1720-P).

Founded in 1950, AMGA represents more than 450 multispecialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one in three Americans. Our members work diligently to provide innovative, high-quality, cost-effective, patient-centered care. Many of our medical groups already participate in the Medicare Shared Savings Program (MSSP), the Next Generation Accountable Care Organization (ACO) model, the Comprehensive Primary Care Plus demonstrations, and other pay-for-performance (P4P) demonstrations. AMGA, therefore, has a strong interest in seeing improvements made to the Physician Self-Referral regulations so that more providers can successfully continue the transition to value-based care.

Federal legislation and regulations governing physician self-referral—collectively termed the “Stark Law”—were intended to prevent financial conflicts of interest around physician self-referrals in fee-for-service (FFS) settings. However, the practice of medicine and the delivery system has evolved significantly since the Stark Law was enacted. Now, the environment is shifting to one which seeks to reward clinicians for the value of care provided. The framework created by the Stark Law, however, creates complexities for physicians and medical groups that are concerned with how their arrangements could implicate the law.

AMGA’s member groups spend significant resources on consultants and lawyers to ensure their arrangements comply with the Stark Law. These funds could more appropriately be used for patient care. In other instances, our members shy away from innovative care designs due to the concern that they may implicate the Stark Law. As such, AMGA is pleased that the Centers for Medicare & Medicaid Services (CMS) has worked to create avenues for innovative arrangements that seek to reward clinicians for the value of care they provide to patients. AMGA also is supportive of CMS’ work with the Department of Health and Human Services Office of Inspector General (OIG) to ensure alignment between the Physician Self-Referral regulations and the Anti-

Kickback Statute regulations. However, there are areas where CMS and OIG's rules should be more aligned. AMGA's member groups need consistent frameworks to operate successfully. Alignment would clarify and simplify regulatory compliance.

AMGA is pleased to offer these recommendations for your consideration.

Key Recommendations

Value-Based Arrangements Exceptions: CMS proposes three new exceptions to the Physician Self-Referral Law that would apply to value-based arrangements. AMGA is supportive of these exceptions, which would allow providers to take more innovative approaches in their financial arrangements while encouraging and removing barriers to value-based care.

Group Practices: CMS provides clarification regarding the distribution of profits from designated health services, where profits from designated health services cannot be distributed on a service-by-service basis. AMGA recommends that CMS not finalize this change to the group practice definition.

Additionally, CMS is proposing to add a provision that would address current barriers that impede a physician's ability to participate in alternative payment models (APMs). AMGA supports this addition to the special rules for profit-sharing and productivity bonuses.

Limited Remuneration to a Physician: CMS is proposing a new exception for limited remuneration from an entity to a physician for items and services provided by the physician. AMGA supports this exception.

Electronic Health Records and Donation of Cybersecurity Technology: CMS is proposing to remove the 15% recipient contribution requirement for either small or rural physicians or for all physicians. AMGA contends that CMS should remove the 15% recipient contribution requirement for all physicians.

Additionally, CMS is proposing an exception to protect arrangements that involve the donation of certain cybersecurity technology and related services. AMGA supports this exception.

90-Day Grace Period Expansion: CMS is proposing a new special rule for noncompliance with the writing or signature requirement of an applicable compensation arrangement exception by proposing a 90-day grace period to obtain required documentation. AMGA supports this proposal.

Comments

Exceptions for Value-Based Arrangements

As Medicare transitions to a more value-based care system, the incentives to over-utilize health care and concerns associated with self-referral diminish. CMS recognizes that value-based models, such as the MSSP, pose less of a risk for the Medicare program because the financial incentives push providers to improve the continuity, coordination, and continuum of care for assigned ACO beneficiaries. However, the waivers currently available to providers exist on a program-by-program basis and do not apply to value-based models broadly. Recognizing that the

Stark Law's prohibitions impede the relationships necessary to coordinate and participate in value-based arrangements, CMS has proposed exceptions to the Stark Law that would apply to different value-based arrangements. The proposed exceptions seek to remove barriers to more coordinated care and aid the transition of the delivery system to one that prioritizes value.

In the proposed rule, CMS defines several terms that a compensation arrangement must meet to qualify for one of the new proposed Stark exceptions. CMS defines a value-based arrangement, a value-based enterprise (VBE), a VBE participant, a value-based activity, a value-based purpose, and a target population. The definitions are one area where AMGA would like to express the need for alignment across CMS' proposed regulations and OIG's proposals. For example, in the definition of "VBE participant," OIG's rule explicitly excludes pharmaceutical manufacturers, manufacturers or distributors of Durable Medical Equipment, Prosthetics/Orthotics & Supplies (DMEPOS), and pharmaceutical benefit managers; wholesalers; or distributors. CMS' rule does not make the same exclusions. CMS and OIG should align their definitions. In our comments to the OIG, we recommend such entities be included, as these suppliers can work closely with providers within a value-based arrangement to improve quality and control costs. By including such entities, providers will have access to additional data on how and when their patients receive care and will better be able to understand DMEPOS and pharmacy utilization and spending. With this data, our members can better care for their patients and reduce their cost of care.

The exceptions that CMS proposes include the full financial risk exception, the meaningful downside risk exception, and the value-based arrangement exception. AMGA's member organizations have been pioneers in the move to value-based care and have seen the Stark Law's complexity as an impediment to the move to value. As such, AMGA is supportive of exceptions that would make it easier for providers to engage in care coordination efforts and in other arrangements that would improve outcomes for patients. These exceptions are a good start and a departure from the current program-by-program waivers that providers must use, which create undue burden. However, AMGA cautions CMS against adding to the complexity that already exists in Stark compliance. To reduce the confusion and complexity, it would be beneficial to the provider community for CMS to provide examples of arrangements it believes could exist in its new proposed framework that currently would violate the Stark Law.

The rule does not address how the new proposed exceptions will interact with existing exceptions. The proposed rule does not describe how physicians should proceed if they currently have an arrangement that fits into an existing Stark exception but may also fit into one of CMS' new exceptions. For example, some Stark exceptions contain a fair market value requirement, which is not required for the new CMS exceptions. AMGA agrees that the exceptions should not include fair market value, commercial reasonableness, or a "volume or value of referrals" conditions. Such requirements are rooted in the FFS environment and only serve to create a barrier to the adoption of value-based models of care. AMGA similarly is recommending that the OIG's new safe harbors not be subject to the fair market value requirement.

Full Financial Risk Exception

CMS proposes an exception to the Stark Law that would apply to value-based arrangements where the VBE is at full financial risk on a prospective basis for the cost of all patient care items and services covered by the applicable payer for each patient in the target population for a specified period of time. Under this exception, the VBE must be at full financial risk within the six

months following the commencement of the value-based arrangement. CMS seeks comment on whether six months is an appropriate amount of time to construct arrangements and begin preparations for the implementation of VBE's full financial risk payer contract.

While we applaud CMS' efforts to remove the regulatory barriers to broader adoption of value-based care, it may not be feasible for many providers to utilize the full financial risk exception. The majority of providers in value models are not assuming full financial risk for a defined population. Additionally, the six-month implementation timeframe CMS proposes is not sufficient for parties to construct and prepare to implement these arrangements. The cultural and operational changes that need to take place in order for these arrangements to be successful take time, and AMGA member organizations' experience indicate more than six months is needed. For example, the literature shows that ACOs that spend more time in the MSSP are generally more successful than newer ACOs. This example shows the immense amount of structural change that must take place for organizations and illustrates that a longer implementation timeframe is needed for VBEs.

Meaningful Downside Financial Risk Exception

CMS also is proposing an exception for meaningful downside risk, recognizing that many providers are not able to assume full financial risk. CMS is defining "meaningful downside financial risk" to mean that the physician is responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the value-based arrangement. The 25% requirement in the meaningful downside financial risk exception is too high. CMS should incentivize physicians to participate in efforts to create value in the delivery system and should ensure that the downside risk taken on is manageable for them.

Value-Based Arrangements Exception

The third exception that CMS is proposing would apply to compensation arrangements that qualify as value-based arrangements regardless of the level of risk undertaken by the VBE or any of its participants. AMGA supports this exception and urges CMS to finalize it. The value-based arrangement exceptions would allow providers to begin the move to value and would encourage the shift of the delivery system to one that prioritizes outcomes.

CMS seeks comment on whether to limit the scope of the exception to nonmonetary remuneration only. The agency should not impose this limitation. Limiting the exception to nonmonetary remuneration would create inflexibility and limit the kinds of innovative arrangements that these exceptions seek to encourage.

AMGA is supportive of CMS' requirement that performance and quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. Quality measurement is an important aspect of value-based care. However, CMS should not include a requirement that "performance or quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in the delivery system." Who defines what is meaningful improvement is not explicitly detailed in the regulatory text and creates unnecessary ambiguity and complexity in compliance with this exception.

Additionally, CMS is considering whether it should require the recipient of any nonmonetary remuneration under the value-based arrangement to contribute at least 15% of the donor's cost. CMS should not adopt this provision, as it could stifle the adoption of value-based arrangements

and create burden for small and rural providers. Adding the 15% requirement would create unnecessary barriers to the adoption of value-based arrangements and may be cost prohibitive.

Group Practices

In response to stakeholder inquiries regarding the methods practices can use to distribute profits from designated health services, CMS clarified “the profits derived from all the designated health services” to mean that group practices must aggregate and distribute profits from designated health services. Therefore, under the proposal, a practice that wishes to meet the qualifications of a group practice could not distribute profits from designated health services on a service-by-service basis. This clarification will impact physician practices. For instance, this proposal has implications for a practice’s ability to use the In-Office Ancillary Services Exception, as one of the requirements of this exception is that a practice meets the definition of group practice. Our member organizations heavily rely on this Stark exception, and this additional requirement would only serve to disqualify hundreds of providers from utilizing this exception. The disruption this change could cause could be enormous. As such, CMS should not finalize this change to the group practice definition. We believe that currently distributing profits from designated health services on a service-by-service basis is not an issue, and those in the industry should not have this flexibility removed.

Additionally, CMS proposes a number of policies and clarifications that would apply to the special rules for profit-sharing and productivity bonuses. Specifically, CMS is proposing to add a provision that would address current barriers that impede a physician’s ability to participate in APMs and continue the transition to value-based care. CMS’ current special rules for profit-sharing and productivity bonuses paid to physicians in group practices prohibit calculation methodologies that directly take into account the volume or value of the recipient physician’s referrals to the group practice. CMS cites and shares the concerns of stakeholders that current regulation may discourage physicians from participating in APMs or other value-based arrangements because physicians cannot be suitably rewarded for their accomplishments in advancing the goals of value-based care. In the proposed rule, the agency provides an example of a 100-physician group practice where two of the physicians participate in an APM arrangement with a commercial payer or hospital. Under current policy, “the profits from designated health services ordered by the physicians and furnished by the group practice to beneficiaries assigned to the model participants may not be allocated directly to the two physicians.” As such, CMS is proposing to add a provision in regulation that would allow for the distribution of profits for designated health services that are directly attributable to the physician’s participation in a value-based enterprise. AMGA supports this addition to the special rules for profit shares and productivity bonuses. Allowing clinicians to be rewarded for their accomplishments in an APM encourages physician participation in these models. As such, this provision should be finalized.

Limited Remuneration to a Physician

CMS is proposing a new exception for limited remuneration from an entity to a physician for items and services provided by the physician. The proposed exception would apply only when remuneration does not exceed \$3,500 per calendar year. This exception would protect limited remuneration even in the absence of a prior documentation. The agency believes that the provision of limited remuneration would not pose a risk to the Medicare program. CMS believes \$3,500 to be a reasonable figure as it is sufficient to cover the typical range of items or services that a physician may furnish to an entity on an infrequent or short-term basis. AMGA supports

this exception and believes the \$3,500 CMS proposes is an acceptable amount.

Electronic Health Records and Donation of Cybersecurity Technology

15% Recipient Contribution

CMS is proposing to eliminate or reduce the 15% recipient contribution requirement for either small or rural physician organizations or all physician recipients. AMGA urges CMS to eliminate this requirement for all physician recipients. We contend that donations of EHR systems do not incentivize or induce referrals. Additionally, well-functioning EHR systems are vital for the move to value-based care. Removing barriers to acquiring these systems would allow for real-time information-sharing needed for success in value-based arrangements and also continue the move to more interoperable systems.

Donation of Cybersecurity Technology

CMS proposes an exception to protect arrangements that involve the donation of certain cybersecurity technology and related services. This exception should be adopted, as AMGA believes physicians should be prepared for the growing threat that is posed by cybersecurity attacks. As we strive for health information technology that is more interoperable, this concern grows exponentially. Cybersecurity attacks pose a risk to patients' health information and, as such, an exception that would protect arrangements that include the donation of these technologies is important.

90-Day Grace Period Expansion

CMS is proposing a new special rule for noncompliance with the writing or signature requirement of an applicable compensation arrangement exception. CMS states that "under this proposal, the writing requirement or signature requirement would be deemed satisfied if 1.) The compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirements and 2.) The parties obtain the required writing or signatures within 90 consecutive calendar days." AMGA supports this proposal, as it seeks to provide relief and reduce the burden on providers.

We thank CMS for consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Senior Director of Regulatory Affairs Darryl Drevna at 703.833.0033 ext. 339 or ddrevna@amga.org.

Sincerely,



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President and Chief Executive Officer