

December 31, 2019

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

File Code: CMS-1720-P

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations* (hereafter referred to as the Proposed Rule) published in the Federal Register on October 17, 2019.

HFMA is a professional organization of more than 49,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction

HFMA would like to commend CMS for its thorough analysis and discussion of the many issues related to the physician-self referral regulations addressed in the Proposed Rule. Our members would like to comment on the proposals related to the:

- Definitions Related to Facilitating the Transition to Value-based Care and Fostering Care Coordination
- Value-based Exceptions to the Physician Self-Referral Rule
- Recalibrating Scope and Application of Regulations

Below, please find specific comments on the items above.

Definitions Related to Facilitating the Transition to Value-based Care and Fostering Care Coordination.

HFMA members greatly appreciate CMS's efforts to clarify or define key terms related to value-based care as they are implicated by the exclusions described in the proposed rule. In general, our members believe these terms will, as the proposed rule intends, make it easier for hospitals, physicians, and other

entities to enter into relationships that will foster care coordination, improved patient outcomes, and reduce the total cost of care by addressing avoidable and unnecessary utilization. Below please find specific comments on several of the terms.

- 1) **Value-based Activity**. CMS proposes to define a value-based activity as, “Any of the following that is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: provision of an item or service; taking of an action; or refraining from taking an action.”

HFMA members appreciate that CMS defined value-based activity so it is broad enough to incorporate a wide range of activities currently in use and that may be used in the future to improve care coordination, help patients comply with care plans, improve outcomes, and reduce the total cost of care. **However, our members are concerned that the definition is so broad that it leaves regulators significant discretion to second guess the intent of an activity.** Therefore, our members ask that CMS, in the final rule, provide a list of the categories of activities that could be considered a value-based activity.

- 2) **Value-based Enterprise (VBE)**. CMS proposes to define a VBE as, “Two or more VBE participants — (1) Collaborating to achieve at least one value-based purpose; (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE; (3) That have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) That have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).”

In general, HFMA members support this definition. We ask that, in the final rule, CMS clarify in the regulation itself that the requirement is met where two or more parties to an arrangement specify in the agreement between them (i) the value-based purposes they are pursuing collectively, (ii) who is responsible for financial and operational oversight of the collaboration, (iii) the criteria for identifying the target population for their collaboration (or the process for establishing and documenting such criteria).

- 3) **Commercially Reasonable**. CMS proposes to add a definition of commercially reasonable to its regulations. CMS believes that the key question in determining whether an arrangement is commercially reasonable is whether the arrangement, from the perspective of the parties involved, makes sense as a means to accomplish the parties’ goal. The issue is neither one of valuation nor whether the arrangement is profitable. CMS proposes to clarify in its regulation text that compensation arrangements that do not result in profit for one or more parties may nonetheless be commercially reasonable.

HFMA members strongly support this definition of commercial reasonableness. As the proposed rule discusses, HFMA members agree with CMS that there are many bona fide arrangements, particularly related to community need, ensuring timely access to health services, requirements under EMTALA, provision of charity care, or improvement of quality and health outcomes, that will not be profitable for one party, and therefore encourage CMS to finalize its clarification as proposed.

4) ***Fair Market Value.*** Fair market value (FMV) is defined in section 1877(h)(3) of the Act and generally means the value in an arm's length transaction that is consistent with general market value. The statute also provides additional conditions for leases generally (e.g., the value of the rental property for general commercial purposes-not taking into account its intended use) and for office space leases (e.g., the value of the rental property is not adjusted to reflect additional value a lessee or lessor would attribute to proximity or convenience to the lessor who is a potential source of patient referrals). CMS initially codified the statutory definitions and later added a definition of general market value. In its rulemaking, CMS initially suggested a connection between the FMV requirement and requirements relating to volume or value of physician referrals and other business generated. In the Phase II rulemaking, it incorporated a reference to the volume or value standard in many exceptions to the self-referral law.

CMS proposes to eliminate the connection to the volume or value standard in the definition of FMV. It now believes that the volume or value standard should not be incorporated in the definition of FMV, observing that the requirements are separate and distinct from each other in the statute. If finalized, CMS would revise its definition of general market value to be consistent with the recognized valuation principle of market value. The proposed definition is as follows:

(1) General. The price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.

(2) Rental of equipment or office space. The price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.

HFMA members strongly support this change. Given that as much of what's done to improve outcomes and reduce the total cost of care is about inaction as it is action, it is notoriously difficult to develop an FMV for some activities related to value-based arrangements. HFMA members have expressed some concern about how FMV consultants and evaluators will interpret these new guidelines. Therefore, we ask that CMS be willing to provide additional guidance as unintended issues may emerge once the industry has experience with the new guidelines.

Value-based Exceptions to the Physician Self-Referral Law

The proposed rule defines three exceptions for value-based arrangements in which the VBE is at full financial risk, the physician has meaningful downside risk, and a general exception for value-based arrangements. Conceptually, HFMA members support CMS's attempt to define exemptions to the Stark law based on the level of risk they're assuming and titrate participants' compliance obligation based on the level of risk they assumed.

Each of the three exemptions is predicated on multiple factors, some specific to the level of risk contemplated in the arrangement. However, the following factors are included in all three exemptions and cause HFMA members concern:

- Remuneration is for (or results from) specified action/inaction by a recipient physician reasonably designed to achieve a value-based purpose for the target population.
- Remuneration is not an inducement to reduce or limit medically necessary items or services.

Neither “medically necessary” nor “reasonably designed to achieve” are defined in the proposed rule. This introduces a significant degree of subjectivity into whether or not a VBE or a provider are in compliance with the rule. Given the potential large overpayments resulting in False Claims Act actions and the related reputational liability of noncompliance, HFMA members are concerned that the practical effect of this subjectivity will deter providers from relying on the proposed exemptions and not engage in arrangements that could improve outcomes and reduce the total cost of care for both Medicare beneficiaries and other patients, which is contrary to the intent of the rule.

HFMA members strongly recommend CMS include language in the final rule providing that each of the requirements identified above is met if the party paying remuneration possesses credible data or literature supporting its conclusion, even if conflicting data or literature exists.

Specific comments about each of the proposed exemptions is provided below.

Full Financial Risk Exception. The rule proposes an exception to the physician self-referral law for remuneration paid under value-based arrangements that meet all the conditions described below.

- The VBE is at full financial risk (or is obligated contractually to be at full risk within 6 months of the start of the arrangement) over the entire duration of the arrangement.
- The VBE is financially responsible 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 patient population for a specified period of time.
- Remuneration is for, or results from, value-based activities undertaken by the recipient of the remuneration for members of the target patient population. A direct, one-to-one relationship between payment and an item, service, or value-based activity would not be required (e.g., gainsharing would be permissible). In-kind remuneration must not take the form of technology or infrastructure already possessed by the recipient.
- Remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient (unrelated to payer identity or target population membership).
- If remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

HFMA members are concerned that, as currently written, the full financial risk exemption will be available to few VBEs. As this provision in the proposed rule is currently interpreted, the definition of full risk implies that the VBE will be responsible for the costs of everything within the scope of coverage. However, this is contrary to how health plans, including Medicare, contract with providers in value-based arrangements. As an example, for employer-sponsored insurance under ERISA, it is not uncommon for items to be “carved out” of the employer’s contract with the third-party administrator (TPA) such as pharmaceuticals and mental health services. As a result, if the TPA were to contact with a VBE in a “full risk” model, that model would likely not include “all of the items and services covered.” As another example, none of Medicare’s shared savings models (e.g., Next Gen ACO or Medicare Shared Savings Program [MSSP]) includes Part D drugs.

To address this issue, HFMA members strongly encourage CMS to revise the final rule to make this exception available based on whether the designated health services (DHS) entity paying remuneration is at risk for any services referred by a physician for the target population.

HFMA members are also concerned that the 6-month window for parties to construct arrangements and begin preparations for implementing full risk assumption by the enterprise is too short. **Based on our members' experience, we strongly recommend providing VBEs a full 12 months to complete preparations.**

Meaningful Downside Financial Risk Exception. In the proposed rule, CMS recognizes that most physicians and providers are not yet willing or prepared to assume full financial risk. However, CMS also states a belief that assumption of meaningful downside risk for failing to achieve performance benchmarks under value-based arrangements offers inherent protections against program or patient abuse. Therefore, CMS proposes an exception to the physician self-referral law for remuneration occurring under the latter scenario when all of the conditions below are met.

- 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.
- A description of the nature and extent of the physician's downside financial risk is set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. The special rule on compensation at §411.354(d)(1) would also apply.
- Remuneration is for, or results, from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- Remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.
- Meaningful downside financial risk means that the physician is either A) responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the value-based arrangement, or B) 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 of time.

HFMA members have several concerns regarding the meaningful downside risk exception.

- 1) **Amount of Risk.** For retrospective risk models similar to the MSSP, physicians only qualify for the exemption if they are responsible to repay the entity no less than 25% of the value of the remuneration the physician receives under the value-based arrangement. HFMA members believe this level of risk is too high. It will ultimately discourage physician practices from availing themselves of this exemption. While Medicare shared savings/loss models have their own

waivers, few, if any, of them convey this level of risk. **Instead, we strongly recommend CMS replace this with a requirement that a physician receiving remuneration from a party be at risk for 10% or more of the cost of any services furnished to the target population by the compensating party.**

- 2) ***Preparation Period.*** As currently proposed, the exception does not include a window for parties to construct arrangements and begin preparations for risk assumption. While physicians under this exemption are not accepting full risk, they are taking material risk which will impact the practices' economic viability (and therefore their willingness to remain in the arrangement) if they are not successful. **Based on our members' experience, we strongly recommend providing participants a full 12 months to complete preparations in which they are covered by the exception, even though they are not currently bearing risk.**
- 3) ***Renumeration Methodology – Quality Measures.*** For this exemption, the proposed rule requires that the renumeration methodology be established in advance. HFMA members report that one of the challenges in developing value-based arrangements is that often they are predicated on being able to measure certain things (e.g., a specific quality measure) that to date have not been measured. In some instances, after the performance period has begun and participating physicians have made DHS-covered referrals, parties to the agreement realize they cannot measure all the items that are included in the renumeration methodology. Frequently, this is a result of either the plan's inability to provide the data or the VBE's IT system's inability to generate the data as it was defined in the arrangement. **HFMA asks CMS to address this issue in the final rule and provide a framework that can be used to preserve the exemption.**

Value-Based Arrangement Exception. CMS proposes an exception for compensation arrangements that qualify as value-based arrangements regardless of their risk parameters. Remuneration could be monetary and/or nonmonetary and would be protected from the self-referral law when all the conditions below are met.

- The arrangement is set forth in writing and signed by the parties.
- The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.
- Remuneration is for, or results from, value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- Remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
- If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

HFMA members have several concerns regarding the value-based arrangement exception.

- 1) **Preparation Period.** As currently proposed, the exception does not include a window for parties to construct arrangements and begin preparations for participating in the model. While participants under this exemption are not accepting risk, they are assuming significant start-up and operational costs which need to be covered if they are to remain in the arrangement. **Based on our members' experience, we strongly recommend providing participants a full 12 months to complete preparations in which they are covered by the exception, even though they are not currently bearing risk.**
- 2) **Renumeration Methodology/Performance Standards.** For this exemption, the proposed rule requires that the renumeration methodology and performance standards be established in advance. HFMA members report that one of the challenges in developing value-based arrangements is that often they are predicated on being able to measure certain things (e.g., a specific quality measure) that to date have not been measured. In some instances, after the performance period has begun and participating physicians have made DHS-covered referrals, parties to the agreement realize they cannot measure all the items that are included in the renumeration methodology or defined as a performance standard. Frequently, this is a result of either the plan's inability to provide the data or the VBE's IT system's inability to generate the data as it was defined in the arrangement. **HFMA asks CMS to address this issue in the final rule and provide a framework that can be used to preserve the exemption.**

Recalibrating Scope and Application of Regulations.

CMS proposes multiple changes to how it will apply the physician self-referral regulations, which HFMA's members generally support. Our members strongly support the proposed changes related to the period of disallowance and special rules on compensation arrangements.

Denial of Payment for Services Furnished under a Prohibited Referral—Period of Disallowance. The period of disallowance refers to the period of time during which a physician may not refer for DHS to an entity and the entity may not bill the program for the referred DHS when the financial relationship failed to satisfy conditions for an exception. Determining when the period begins (i.e., when the financial relationship failed to satisfy all the requirements of the applicable exception) is not as challenging as when the period ends.

Under current regulations, where the noncompliance is unrelated to the payment of compensation, the period of disallowance is deemed to end no later than the date that the financial relationship satisfies all those requirements. However, where the noncompliance relates to the payment of excessive or insufficient compensation, the period of disallowance is deemed to end no later than the date on which the excess compensation was repaid (or the additional compensation was paid) and the financial relationship satisfies the requirements of the exception.

CMS proposes to delete its rules on the period of disallowance entirely; it now believes they are overly prescriptive and impractical. However, this proposal would not impact parties who have relied on those regulations in the past.

HFMA members strongly support this proposed change.

Special Rules on Compensation Arrangements. Section 50404 of the Bipartisan Budget Act of 2018 (P.L. 115-123) amended the physician self-referral statute regarding writing and signature requirements in certain compensation arrangement exceptions. The law permits the Secretary to determine how those requirements may be satisfied, such as through a collection of documents including contemporaneous documents evidencing the course of conduct between the parties. It also created a special rule for temporary noncompliance with signature requirements of an otherwise compliant compensation arrangement, permitting the signatures to be provided 90 days after the date of the noncompliance. CMS codified these policies and struck its own rule that limited use of the temporary noncompliance for signatures to once every three years.

CMS proposes to strike its existing regulations at §411.353(g) on this issue and to create a special rule for noncompliance with the signature or writing requirements of an applicable compensation arrangement. It proposes a new section §411.354(e)(3) as follows:

In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if:

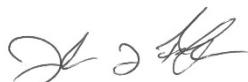
- 1) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and
- 2) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.

HFMA members strongly support this proposed change.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve regulations governing physician relationships and referrals. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS, and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA
President and Chief Executive Officer
Healthcare Financial Management Association

About HFMA

HFMA is the nation's leading membership organization for more than 49,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices, and standards.