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Via electronic submission (www.regulations.gov)

December 30, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations (CMS 1720-P)

Dear Administrator Verma:

The Association of American Medical Colleges ("AAMC" or "the Association") appreciates the opportunity to comment on the proposed rule entitled "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 84 *Fed. Reg.* 55766 (October 17, 2019) issued by the Centers for Medicare & Medicaid Services (CMS).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

The AAMC appreciates CMS's acknowledgment of the "effect the physician self-referral law may have on parties participating or considering participation in integrated delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost." The Association supports health care delivery and payment reform models that use incentives for higher-value care for patients, foster greater coordination among providers, and generally improve overall population health. AAMC members have been leaders in testing new payment models, including Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), Next Generation ACOs, Comprehensive Primary Care Plus (CPC+), Bundled Payments for Care Improvement (BPCI), BPCI Advanced, and other models.

We commend CMS for its comprehensive efforts in this proposed rulemaking to increase opportunities for hospitals and physicians to engage in innovative arrangements to enhance care coordination, improve quality, and reduce costs. In this rulemaking, CMS takes a major step forward by addressing many of the real-world challenges that hospitals and physicians encounter when trying to structure arrangements that comply with the Stark regulations. These changes would benefit patients, families, and communities by enabling the delivery of comprehensive coordinated care that will improve their health. The AAMC welcomes the opportunity to provide feedback as CMS modernizes the Stark regulations.

The AAMC's key recommendations on the physician self-referral proposed rule include the following:

Facilitating the Transition to Value-Based Care and Fostering Care Coordination: Definitions and Exceptions

- ***General Framework***: CMS should adopt the proposed general framework, including the three value-based arrangement exceptions, and related definitions, with some modifications.
- ***Value-Based Arrangement***: CMS should finalize the definition of value-based arrangement as proposed. CMS should not limit the definition of value-based arrangement to arrangements that involve care coordination or management as such a requirement could restrict innovation in the future.
- ***Value-Based Purpose***: Rather than focusing only on payers when referencing reducing costs, CMS should revise the language to also acknowledge that providers (such as hospitals) can and do reduce the rate of rising costs. With regard to the goal of "improving the quality of care for a target population," CMS should clarify that success is not required to qualify for the protection.
- ***Target Patient Population***: CMS should have a flexible definition of "legitimate and verifiable" criteria to enable innovation. Examples of criteria could include medical and health characteristics, geography, and payor status, in addition to other characteristics.
- ***Exclusion of Conditions from Exceptions***: CMS should adopt its proposal to exclude the fair market value, commercial reasonableness, or "volume or value of referrals" as conditions in the new exceptions.
- ***Exception for CMS-Sponsored Models***: CMS should create an exception for CMS-sponsored models, parallel to the OIG proposed safe harbor for CMS models.
- ***Full Financial Risk Exceptions***: The full financial risk exception should be revised to state that a value-based enterprise is considered at full risk when it takes responsibility for the costs of a defined set of services or when it takes responsibility for all services for a target population.
- ***Meaningful Downside Risk Exception***: CMS should state that the party that has assumed the meaningful downside financial risk under the arrangement can be the entity furnishing designated health services rather than the individual physicians. The proposed 25 percent meaningful financial risk threshold is too high and should be set below 10 percent in the final rule to encourage physician participation in these value-based arrangements. CMS should define risk to capture additional risks beyond only downside financial risk related to payments from the payer.
- ***Value-Based Arrangement Exception***: CMS should adopt an exception that protects arrangements that assume only upside risk. This will encourage more physicians to participate in care coordination activities while they continue to build towards being able to enter into two-sided risk-sharing arrangements in the future. CMS should finalize its policy that this exception protects monetary and non-monetary remuneration. We urge CMS not to establish a requirement that the recipient of any nonmonetary remuneration under a value-based arrangement contribute at least 15 percent of the donor's cost of the non-monetary remuneration.
- ***Price Transparency***: While the AAMC supports efforts to ensure consumers have information concerning their cost-sharing obligations, CMS should not include a price transparency requirement in the self-referral exceptions. We believe that there are more appropriate mechanisms through which patients could receive pricing information and of most importance to the patient their contribution or co-pay information.

Fundamental Terminology and Requirements

- ***Commercially Reasonable***: CMS should finalize its proposal to add regulatory language to clarify that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties, which dispels the widespread misconception that a commercially reasonable arrangement must be profitable.

- ***Volume or Value Standard and Other Business Generated Standard***: The Association generally supports the proposed definition of "takes into account the volume or value of referrals." We commend CMS for clarifying that a productivity bonus does not take into account volume or value of employed physician's referrals solely because corresponding hospital services (e.g., DHS) are billed each time the employed physician personally performs a service.
- ***Fair Market Value (FMV)***: CMS should adopt its proposal to remove from the FMV definition references to taking into account the volume or value of referrals.

Recalibrating Scope and Application of Regulations

- ***Decoupling the Physician Self-Referral Law from the Federal Anti-Kickback Statute***: CMS should finalize its proposal to remove requirements from exceptions in the physician-self-referral regulations that an arrangement not violate the antikickback statute or any federal or state law.
- ***Designated Health Services***: CMS should adopt its proposal to revise the definition of "designated health services" (DHS) to clarify that a service provided by a hospital on an inpatient basis does not constitute a DHS if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Hospital Inpatient Prospective Payment System (IPPS). CMS should expand it proposal to state that services provided by a hospital on an outpatient basis are not DHS if they do not impact the amount of payment under the outpatient prospective payment system.
- ***Electronic Health Records Items and Services***: While we appreciate CMS's proposal to remove the 15 percent recipient contribution requirement for small and rural practices, we urge CMS to remove the contribution requirement for all physician recipients. The AAMC supports CMS's proposal to allow donations of replacement EHR technology. The Association opposes the proposal to incorporate ONC's definition of electronic health information (EHI) for purposes of defining the type of information that is part of the EHR.

Providing Flexibility for Non-Abusive Business Practices

- ***Limited Remuneration to a Physician***: CMS should finalize the $3,500 per year limited remuneration exception as proposed.
- ***Writing and Signature Requirements***: CMS should adopt its proposal that both the writing requirement and the signature requirement would be deemed to be satisfied if the parties obtain the required writing and signatures within 90 days after the date on which the arrangement fell out of compliance, provided the arrangement otherwise satisfies all of the requirements of an applicable exception.
- ***Cybersecurity Technology and Related Services***: CMS should finalize this exception for cybersecurity with a modification that would allow protection for hardware that is necessary for cybersecurity.

GENERAL COMMENTS

To achieve the goals of delivery system reform, changes need to be made to federal laws and regulations affecting hospital-physician arrangements including the Physician Self-Referral Law (also known as "Stark"), the Anti-kickback Law, and the Civil Monetary Penalties (CMP) Law, that were enacted to address concerns in a fee-for-service (FFS) payment system. In the over 25 years since the enactment of the physician self-referral law (referred to as the Stark law), there have been major changes in health care delivery and payment, including many initiatives to align payment with quality and to improve coordination of care. Our members report that provisions in these laws present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs. Ultimately, these barriers negatively affect patients and families.

The Department of Health and Human Service Office of Inspector General (OIG) and CMS have played critical roles in the development and growth of delivery and payment reforms by establishing waivers for the federal program integrity laws for specific alternative payment models, such as the shared savings accountable care organization (ACO) program and the Comprehensive Care for Joint Replacement (CJR) model. However, these waivers only apply on a case-by-case basis to the specific models. Physician participation in new innovative payment and delivery models is critical for their success; however, physicians are reluctant to participate in these models because the self-referral and other federal laws prohibit the financial relationships necessary to achieve the clinical and financial integration necessary to be successful in reform.

Given the increasing prevalence of payment programs that focus on meeting well-defined quality standards combined with requiring participants to accept more risk, and the need to, at a minimum, allow for gainsharing with physicians and other providers, we are pleased that CMS is proposing numerous changes to the Stark self-referral regulations. With the ample protections against program and patient abuse that are now, and increasingly will be, part of the Medicare program, the focus should be on simplifying the criteria for the exceptions and making them broadly available as an important tool to encourage wider participation.

Our recommendations for specific changes to the Stark law regulations, including the exceptions for alternative payment models, refinements to the compensation exceptions, definitions of fundamental terms, cybersecurity, and other areas are enumerated below.

FACILITATING THE TRANSITION TO VALUE-BASED CARE AND FOSTERING CARE COORDINATION PROPOSED DEFINITIONS AND EXCEPTIONS

CMS proposes three new exceptions to the physician self-referral law for value-based compensation arrangements: the full financial risk exception, the meaningful downside risk exception and the value-based arrangements exception. These exceptions are differentiated by their arrangement characteristics and the risk levels assumed by participants.

To implement the proposed value-based arrangement exceptions, CMS proposes six interrelated definitions: value-based activity, value-based arrangement, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population. To qualify for the exceptions, there must be an arrangement between a value-based enterprise and one or more of its VBE participants or between VBE participants in the same value-based enterprise, for the provision of at least one value-based activity for a target population. Also, the arrangement must be reasonably designed to achieve at least one value-based purpose. CMS solicits feedback on the six proposed definitions. **The AAMC recommends that CMS adopt the proposed general framework, including the three value-based arrangement exceptions, and related definitions with some modifications enumerated below.**

Value-Based Arrangement

CMS proposes to define a value-based arrangement as a compensation arrangement for the provision of at least one value-based activity for a target patient population between or among 1) the value-based enterprise and one or more of its VBE participants; or 2) VBE participants in the same VBE. CMS expects that most value-based arrangements will involve activities that coordinate and manage the care of a target patient population but does not propose to limit the universe of compensation arrangements that would qualify as value-based arrangements to those arrangements specifically designed for care coordination and management. CMS requests comment on whether they should require care coordination and management in order to qualify as a value-based arrangement.

We agree with CMS that most value-based arrangements will involve activities that coordinate and manage the care of a target patient population. More efficient transitions for patients moving across settings and providers, reduction of duplicative tests and services, and open sharing of medical records are critical for patient care coordination. We appreciate CMS's flexible approach in defining a value-based arrangement. **CMS should not limit the definition of value-based arrangement to arrangements that involve care coordination or management as such a requirement could restrict innovation in the future.** Being less prescriptive with respect to the types of value-based arrangements the proposed exceptions would allow for innovation and experimentation in the health care marketplace. Therefore, **we support the definition of value-based arrangement as proposed and believe that it does not pose a risk of program or patient abuse.**

Value-Based Purpose

CMS states that only arrangements reasonably designed to achieve at least one value-based purpose may potentially qualify as a value-based arrangement to which the exception will apply. CMS proposes to define "value-based purpose" by identifying four core goals related to the target population, which are: 1) coordinating and managing the care of a target population; 2) improving the quality of care for a target population; 3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing quality of care for a target population; or 4) transitioning from health care delivery and payment mechanisms based on the quality of care and control of costs of care for a target patient population.

CMS seeks comment on permissible ways to determine whether quality of care has improved; a methodology for determining whether costs are reduced, or expenditure growth has been stopped; or what parties must do to show they are transitioning from health care delivery and payment mechanisms based on volume to mechanisms based on quality and cost control.

Overall, the Association supports the four goals with some modifications. We recommend revisions to the value-based purpose identified at proposed section 411.351 (definition of the third acceptable value-based purpose) related to reducing costs or growth in expenditures without reducing quality. **Rather than focusing only on payers when referencing reducing costs, we recommend that CMS revise the language to also acknowledge that providers (such as hospitals and physicians) can reduce costs.** It is common to have arrangements under which the physician reduces hospital costs by following protocols identified by the hospital, and these initiatives should also qualify as a value-based purpose.

We are supportive of CMS's recognition that the value-based enterprise should improve quality or maintain the quality for the target population in addition to appropriately reducing the costs or growth of expenditures. We urge CMS not to replace this purpose with the alternative discussed in the preamble that would require a value-based enterprise to improve quality or maintain already-improved quality of care for the target population in addition to reducing the costs.

With regard to the goal of "improving the quality of care for a target population," CMS should clarify that success is not required to qualify for the protection. In the text of the rule, CMS's solicitation of permissible ways to determine if quality of care has improved or costs are reduced implies that demonstrating successful improvement may be required. Because success in quality can be challenging to measure and relies on a multitude of factors, it is not always guaranteed. Such a requirement could deter quality improvement efforts. Therefore, CMS should clarify that to qualify for protection there should be a quality improvement process in effect that includes regular evaluation and monitoring.

Target Patient Population

CMS proposes that a target patient population would mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose. CMS seeks comment on legitimate and verifiable selection criteria. **We recommend that CMS have a flexible definition of "legitimate and verifiable" criteria to enable innovation. Examples of criteria could include medical and health characteristics, geography, and payor status, in addition to other characteristics.**

PROPOSED EXCEPTIONS: GENERAL COMMENTARY

CMS proposes three separate exceptions to the physician self-referral law applicable to value-based arrangements, dependent upon financial risk, ranging from full financial risk, meaningful downside financial risk, or arrangements that meet specified requirements regardless of financial risk level**. The AAMC supports CMS's proposal to apply these three new exceptions to arrangements involving Medicare beneficiaries, patients outside of Medicare, or mixed patient populations.** Innovation can take place in many different places and in many ways - therefore flexibility is essential.

The AAMC strongly supports CMS's proposal not to include the fair market value, commercial reasonableness, or "volume or value of referrals" as conditions in the new exceptions. Inclusion of these requirements would inhibit the innovation necessary to achieve coordinated care that results in better outcomes and reduces costs. Rather than preventing abuse, these existing requirements have been a barrier to value-based care transformation. We believe that the other requirements incorporated in the value-based exception proposed by CMS will protect against any program or patient abuse.

CMS anticipates that, if finalized, these value-based compensation exceptions will eliminate the need for future new waivers of section 1877 of the Act for CMS-sponsored value-based arrangements. Even so, CMS states they are interested in learning whether stakeholders view the proposals as leaving gaps in protection from the physician self-referral law's prohibitions for certain arrangements that are permissible under a CMS-sponsored model. **The AAMC recommends that CMS create an exception for CMS-sponsored models, parallel to the OIG proposed safe harbor for CMS models.** We do not believe that the proposed value-based arrangement exceptions will offer the same flexibility to participants that is necessary for the CMMI models.

SPECIFIC REQUIREMENTS FOR EACH VALUE-BASED COMPENSATION EXCEPTION

Full Financial Risk Exception

CMS proposes a full financial risk exception that would apply to value-based arrangements between VBE participants and a VBE that has assumed full financial risk for the cost of all patient care items and services covered by the payer for each patient in a target population during the entire duration of the value-based arrangement. The financial risk must be prospective. In addition, the VBE must be at full risk (or obligated contractually to be at full risk within 6 months of the start date of the arrangement) over the entire duration of the arrangement. Full financial risk mechanisms could include, but would not be limited to, capitation or global budget arrangements.

Related to the full financial risk exception, CMS seeks comment on whether 6 months suffices for parties to construct arrangements and begin preparations for implementing a full risk assumption of the enterprise; whether a minimum period of full financial risk should be necessary to qualify for the

exception; and whether a value-based enterprise is at full financial risk if is responsible for the costs of a defined set of patient care services for a target population.

The AAMC believes that there should be a minimum of 6 months for the parties to construct the arrangements. CMS should consider allowing for a one-year period of protection similar to the Medicare Shared Savings Program pre-participation waiver.

We have concerns with CMS's commentary in the rule stating that full financial risk would mean taking on responsibility for *all* items and services covered under Medicare Parts A and B. Such a policy would mean that a hospital providing pay-for-performance bonuses for reducing the costs of inpatient care only would not be protected. **The AAMC recommends that the exception be revised to state that a value-based enterprise is considered at full risk when it takes responsibility for the costs of a defined set of services or when it takes responsibility for all services for a target population.**

Meaningful Downside Risk Exception

CMS recognizes that many physicians and providers are not yet prepared or financially able to assume full financial risk. However, CMS believes that assumption of meaningful downside risk for failing to achieve performance benchmarks under value-based arrangements offers inherent protections against program or patient abuse. CMS proposes an exception when the physician is at meaningful downside risk for failure to achieve the value-based purpose during the entire duration of the arrangement and sets forth conditions that must be met. CMS proposes that "meaningful downside risk means that the physician is either A) responsible to pay the entity no less than 25 percent of the value of 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 payor for each patient in the target patient population for a specified period of time.

CMS seeks comment on whether a physician would be incented sufficiently to modify his/her practice and referral patterns if the party assuming meaningful downside financial risk and who is paying remuneration to the physician under the arrangement is the entity furnishing DHS; whether the definition of meaningful downside risk is sufficient to curb incentives associated with FFS payment; and whether the VBE should be protected for a 6-month period prior to start of risk arrangement to facilitate preparation for risk assumption.

The AAMC recommends that CMS state that the party that has assumed the meaningful downside financial risk under the arrangement can be the entity furnishing designated health services. We are concerned that physicians will be discouraged from participating in the arrangement if they have to assume a high level of downside risk. We believe that the entity will be motivated to monitor and respond to a physician's practice referral patterns if these patterns have any negative impact financially on the entity.

The AAMC believes that the 25 percent meaningful financial threshold is too high. Physicians must be prepared and financially able to participate in order for value-based arrangements to succeed. It is highly unlikely that physicians would put 25 percent of their compensation at risk. Many physicians in rural practices or urban practices caring for the disadvantage cannot reason ably assume this amount of downside risk because the margin on their practice is either negative or very small. This high threshold will discriminate in the types of practices that will be financially able to participate. Existing programs have financial risk of 8 percent (Advanced APMs), 5 percent (medical homes) and 9 percent (MIPS). Therefore, **we recommend that the level of meaningful financial risk be set below 10 percent in the final rule to encourage physician participation in these value-based arrangements.** We believe that

this level of financial risk is high enough to prevent the influence of FFS volume-based payment and will help the shift toward value-based goals.

The AAMC also recommends that CMS should define "risk" to capture more than *only* downside financial risk related to payments from the payer. CMS should clarify that risk could include loss of a bonus payment. For example, if the physician has potential to earn a $2,000 bonus payment and does not receive it because he/she did not achieve the value-based purpose, that should qualify as financial risk.

The AAMC recommends inclusion of a provision related to meaningful downside risk that parallels the provision in the full financial risk arrangements exception allowing protection for value-based arrangements entered into in preparation for the implementation of the VBE for at a minimum of 6 months prior to the effective date of the contract.

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 certain conditions set forth by CMS are met.

CMS seeks comment on whether the exception should be limited to nonmonetary remuneration and the impact of such limitation on value-based care; whether to require performance or quality standards be designed to drive meaningful improvements and the burden of such a requirement; whether to require the recipient of any nonmonetary remuneration to contribute at least 15 percent of the donor's cost of renumeration.

The AAMC commends CMS for establishing an exception that protects arrangements that assume only upside risk. This will encourage more physicians to participate in care coordination activities while they continue to build towards being able to enter into two-sides risk-sharing arrangements in the future. **The AAMC recommends CMS finalize its policy that this exception protects monetary and non-monetary remuneration.** It is common in these types of arrangements for there to be a monetary exchange in order to encourage certain physician behavior. For example, in the rule, CMS discusses a scenario in which a hospital pays community physicians $10 each time physicians order dual modality screening rather than single modality screening for a certain type of cancer based on new guidelines. The new guidelines recommend screening by two modalities in order to achieve more accurate results and improve the quality of care for patients by detecting more cancers and avoiding false positives. In this instance, the provision of $10 for each service helps to shape physician behavior to follow the recommended care protocol.

We urge CMS not to establish a requirement that the recipient of any nonmonetary remuneration under a value-based arrangement contribute at least 15 percent of the donor's cost of the non-monetary remuneration. This 15 percent requirement currently applies to the existing exception for EHR items and has acted as a barrier to adoption of EHR technology. We are concerned that this 15 percent requirement would also be burdensome in the context of other nonmonetary forms of remuneration, and would similarly serve as a barrier to participation, particularly with respect to small and rural physicians and other providers that cannot afford the contribution.

CMS asks whether a physician must cease referring DHS to the entity if they determine the value-based purpose will not be achieved. **The AAMC urges CMS not to terminate the ability to comply with the exception simply because a goal or metric is difficult to achieve.** There are numerous factors that can impact the ability to achieve a quality outcome or reduce cost. While the goal of value-based

arrangements should be to achieve more effective care at a lower cost, requiring constant achievement is not feasible in the practice of medicine. The adoption of such a policy would discourage innovation, as VBEs would only seek to enter arrangements with value-based activities that are demonstrably likely to meet their goals.

CMS also seeks input on whether to require that the VBE enterprise or participant providing the remuneration monitor to determine if the value-based activities are achieving the purpose. We believe that monitoring is an implicit requirement of any Stark exception and therefor no explicit regulatory requirement should be imposed. While it is important to monitor progress toward achieving the goals, it can take a significant amount of time and analysis to determine whether the purpose is achieved. Achievement of goals may take many years and time may be necessary to tell if goals have unintended consequences that should lead to a change in the goals. Feedback on performance on quality measures and cost measures is often provided retrospectively and can be delayed. If a monitoring requirement is established, CMS must be clear on exactly what the providers are required to monitor, should provide flexibility, and should limit the scope so that it is practical.

PRICE DISCLOSURE REQUIREMENTS

CMS seeks comment on how to pursue price disclosure in the context of the physician self-referral law. Specifically, CMS is interested in comments that address the availability of pricing information and out-of-pocket costs to patients (e.g., satisfaction of deductible); the appropriate timing for dissemination of information (e.g., whether information should be provided at time of referral, time the service is scheduled, or some other time) and the burden associated with compliance with a requirement in an exception to provide information about factors that may affect the cost of services.

Comments are sought on whether a price disclosure requirement would provide extra protection in a value-based exception against program or patient abuse through active participation of patients in selecting health care providers.

The AAMC supports efforts to ensure consumers have information concerning their cost sharing obligations; however, we oppose the inclusion of a price transparency requirement in the self-referral exceptions. These exceptions are intended to allow for arrangements that will protect against fraudulent or abusive practices between physicians, hospitals, and other providers of designated health service. CMS has both proposed and implemented various price disclosure regulations in other rulemaking. It is widely recognized, including by CMS, that what patients most want to know is their out-of-pocket costs. While CMS has yet to find a way to get that information to patients, a number of AAMC members have worked over several years to make available tools that patients can use to determine their out-ot-pocket costs. **Inclusion of pricing information as another element of compliance with t the self-referral exceptions is not the appropriate avenue for achieving this goal.**

FUNDAMENTAL TERMINOLOGY AND REQUIREMENTS

CMS notes that stakeholders have regularly approached the agency seeking clarification on when an arrangement is commercially reasonable; under what circumstances compensation is considered to account for the volume or value of referrals or other business generated between the parties; and how to determine the fair market value of compensation. CMS proposes to clarify these definitions.

Commercially Reasonable

CMS proposes to add a definition of commercially reasonable to its regulations. CMS believes the key question in determining whether an arrangement is commercially reasonable is whether from the

perspective of the parties involved the arrangement makes sense as a means to accomplish the parties' goal. CMS offers two alternative definitions of commercially reasonable:

- The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.
- 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. (Note this definition is the same language from Stark II Phase II rulemaking)

The AAMC recommends that both alternative definitions be available so a party can demonstrate compliance with the definition that more closely reflects the arrangement in question. While a definition of this key term is welcome, there are still at least two issues. First, both definitions include numerous undefined terms, such as legitimate business purpose, commercial sense, and reasonable entity. Second, the definition discussed in the Stark II Phase II rulemaking seems to offer less flexibility because it would require the parties to determine what constitutes a "reasonable entity of similar type and size" and "reasonable physician of similar scope and specialty" whereas the first definition mentions only "similar terms and conditions as like arrangements."

The AAMC strongly supports the addition of regulatory language to clarify that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties. This will dispel the widespread misconception that a commercially reasonable arrangement must be profitable. As CMS points out in the proposed rule, health care providers have a variety of business reasons for entering into arrangements with physicians. For instance, parties may enter into arrangements that result in losses to address community needs, provide timely access to health care services, to provide charity care, and to improve quality and outcomes. Particularly at teaching hospitals, entire services, such as behavioral health may operate at a loss but continue to be maintained to address needs in the community.

Volume or Value Standard and Other Business Generated Standard

CMS proposes that compensation take? into account volume or value of referrals only when the mathematical formula used to calculate that compensation includes referrals or other business generated as a variable and the amount of compensation correlates with the number or value of the physician's referrals to, or the physician's generation of, other business for the entity.

The AAMC generally supports the proposed definition of "takes into account the volume or value of referrals." Defining when compensation will account for the volume or value of referrals provided needed clarity. **We commend CMS for clarifying that a productivity bonus does not take into account volume or value of employed physician's referrals solely because corresponding hospital services** (e.g., DHS) **are billed each time the employed physician personally performs a service.** This clarification is a recognition of the way in which hospitals and physicians commonly interact with each other.

Patient Choice and Directed Referrals

CMS is concerned that its proposal for the volume or value standard may reduce or eliminate the instances in which the special rule for patient choice and directed referral applies. Under the current special rules on compensation, health care entities can require physicians to refer to a particular provider, practitioner, or supplier as a condition of the physicians' compensation without the compensation being considered to be taking into account the volume or value of referrals only if the referral requirement does not apply if a patient expresses preference for a different provider or supplier, the patient's insurer determines the provider or supplier, or the referral is not in the patient's best medical interests in the

physician's judgment. The referral requirement also must be set out in writing and signed by the parties, the compensation must be set in advance and at fair market value, and the compensation arrangement must comply with an applicable Stark exception.

Currently, the special rule on referral requirements allows for a deeming provision, CMS is proposing to make it an affirmative requirement for a number of exceptions, including the exceptions for academic medical centers, employment relationships, personal service arrangements, physician incentive plans, group practice arrangements with a hospital, FMV compensation, and indirect compensation arrangements. **While the AAMC supports allowing for patient preference in referrals, we urge CMS not to make these requirements affirmative as it will place additional burden on physicians and other providers.**

Fair Market Value (FMV)

An overarching principle running through most of the Stark Law exceptions is that the compensation must be consistent with FMV. CMS proposes to replace the current regulatory definition with a general definition of FMV with more specific definitions applicable to rental of office space and rental of equipment.

The Association strongly supports CMS's proposal to remove from the FMV definition references to taking into account the volume or value of referrals. We agree that this is an independent requirement that should not be part of the definition of FMV.

We support CMS's clarification that "fair market value" is the value of an asset or service to hypothetical parties in a hypothetical transaction and that general market value is the value of an asset or service to actual parties in a transaction that occur within a specific time frame. We appreciate the interpretation that the particular circumstances of each party (such as the particular physician's level of specialty and skill and the number of physicians in the area) should be relevant to determining general market value. In addition, **we appreciate CMS's acknowledgement that extenuating circumstances may dictate that parties to an arm's length transaction veer from general market values (such as those identified in salary surveys) and other hypothetical valuation data that is not specific to the actual parties to the transaction.** This clarification is particularly important for physicians in academic medicine that may be highly sought after due to their clinical and/or research expertise in a particular area and thus could reasonably receive compensation outside the range in a survey.

We recommend that CMS provide more guidance on how to document and establish FMV in light of the new methods of physician payment for value-based care, such as incentive payments.

Group Practices: New Special Rules for Distribution of Revenue Related to Participation in a Value-Based Enterprise

The Stark Law rules provide group practices with greater leeway than other designated health services (DHS) entities in determining how to divide revenues among their physicians, specifically with regards to profit shares and productivity bonuses. These regulations include special rules for profit shares and productivity bonuses paid to physicians in a group practice that prohibit calculation methodologies that directly take into account the volume or value of the physicians' referrals to the group practice.

The AAMC supports CMS's proposal for a deeming provision related to the distribution of profits from DHS that are directly attributed to a physician's participation in a value-based enterprise.

This provision would allow physicians in a group practice setting to be rewarded for providing value-based care.

Group Practices: Distribution of Overall Profits

CMS also proposes some clarifying revisions related to the "overall profits" provision. Currently, "overall profits" means the profits derived from all the DHS payable by Medicare or Medicaid of any component of the group which consists of at least five physicians and, which may include all physicians in the group. CMS proposes to amend its interpretation of overall profit distributions for group practices such that "a physician practice that wishes to qualify as a group practice could not distribute profits from DHS on a service-by-service basis." **The AAMC opposes CMS's proposal change of the overall profit distribution policy, as it creates additional regulatory burden for group practices.** The AAMC believes that group practices should be able to share profits from one type of DHS with a subset of physician in a group practice and the profits from another type of DHS with a different subset of physicians in the group practice. If CMS decides to finalize this provision, it must allow sufficient time for group practices to make the necessary changes to comply, as this is a significant change for group practices and will require legal consultations to review current arrangements and amend if necessary.

RECALIBRATING SCOPE AND APPLICATION OF REGULATIONS

Decoupling the Physician Self-Referral Law from the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

While the Stark statute does not specifically require that its exceptions for its arrangements do not violate the anti-kickback statute (AKS) or any state law or regulation governing billing, many of the exceptions CMS has established through rulemaking contain that requirement. **The Association recommends CMS finalize its proposal in the rule to remove requirements that an arrangement not violate the anti-kickback statute or any federal or state law from exceptions contained in the physician-self-referral regulations.** The physician self-referral law is a strict liability statute and compliance with each element is mandatory if the entity submits a claim for DHS referred by a physician with which it has a financial relationship, while the anti-kickback statute is intent-based and compliance with a safe harbor is not required. Including the requirement for compliance with the anti-kickback statute in the Stark regulations is inappropriate because it incorporates an intent-based requirement into a strict liability statute and therefore it can be virtually impossible to ensure compliance. It creates another barrier to providers that are trying to comply with the exception. As CMS stated in the commentary, when a compensation arrangement violates the antikickback statute, it will likely also fail to meet one or more of the key requirements of an exception to the physician self-referral law. Therefore, it is not necessary to include this requirement in the exceptions.

Designated Health Service

The AAMC supports CMS's proposal to revise the definition of "designated health services" (DHS) to clarify that a service provided by a hospital on an inpatient basis does not constitute a DHS if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Hospital Inpatient Prospective Payment System (IPPS). As CMS states, physicians have no financial incentive to over-prescribe services that do not affect the rate of payment. **We recommend CMS expand its proposal to state that services provided by a hospital on an outpatient basis are similarly not DHS if they do not impact the amount of payment under the outpatient prospective payment system**.

Electronic Health Records Items and Services

The AAMC appreciates CMS's efforts in this rule to update the current EHR exception. Specifically, the AAMC supports the proposal to expand the EHR exception to make it clear that an entity donating EHR software and providing training and other related services may also donate related cybersecurity software and services to protect the EHR. We also support the elimination of the sunset provision, which is important to ensure widespread adoption of EHR technology. CMS should also clarify whether the EHR exception includes the ability to donate telemedicine equipment.

While we appreciate CMS's proposal to remove the 15 percent recipient contribution requirement for small and rural practices, we urge CMS to remove the contribution requirement for all physician recipients. This will remove barriers to participation in value-based arrangements due to the critical need for EHR technology to support data sharing and care coordination. The 15 percent contribution requirement can serve as a significant barrier for physician adoption of EHR technology, even for larger, non-rural practices. This may become a greater concern for more physicians due to the Office of the National Coordinator for Health Information Technology (ONC) pending final rule, which as proposed, would require more complex and costly functionalities for vendors, and if finalized, is likely to increase the costs for purchasers.

The AAMC supports CMS's proposal to allow donations of replacement EHR technology. Physicians may want to switch to a different EHR vendor system for numerous reasons or may wish to significantly upgrade their current systems. However, under the current requirements it would be difficult to change or significantly upgrade systems because physicians would have to pay the full amount for a new system. This change would make it more feasible for a practice to upgrade to a more advanced system with better functionality.

The Association opposes the proposal to incorporate ONC's definition of electronic health information (EHI) for purposes of defining the type of information that is part of the EHR. In comments to the ONC on the proposed interoperability rule, the AAMC opposed the definition of EHI for being overly broad. Since the ONC rule has not been finalized we do not know if our concerns with the definition of EHI were addressed.

Providing Flexibility for Non-Abusive Business Practices: Limited Remuneration to a Physician

CMS recognizes that there are nonabusive arrangements under which limited amounts of remuneration are paid to a physician for the provision of items or services to the entity but are not covered by any existing exceptions. CMS cites the example of the appointment of a temporary medical director while the hospital is finalizing its engagement of a new medical director. In this case, the arrangement fails to satisfy existing exceptions because compensation was not set in advance or in writing.

To address these situations, CMS proposes a new exception for remuneration that does not exceed an aggregate of $3,500 per year from an entity to a physician for the physician to provide items or services if certain conditions are met. **The AAMC recommends CMS finalize the $3,500 per year limited remuneration exception.** It is very common for hospitals to hire a medical director for a new service line or to temporarily cover medical director responsibilities. In large academic medical centers, setting the payment amount in advance and putting together a written document can require review and sign off from a number of people and therefore take time. In the interim, it is important to have a medical director at the facility. This provision would be very helpful to avoid liability for this non-abusive conduct.

Writing and Signature Requirements

Many Stark Law exceptions require that the compensation arrangement be set forth in a writing signed by the parties. These procedural requirements are vexing for many health care entities because physicians often begin performing services before the parties have a signed, written agreement in place, whether due to necessity or lack of oversight. Recognizing that there is a low risk of program or patient abuse as long as the arrangement otherwise meets all of the requirements of an applicable exception, CMS has been chipping away at these requirements for the past several years. CMS is proposing to make the writing and signature requirements even less restrictive. **We strongly support CMS's proposal in the rule that both the writing requirement and the signature requirement would be deemed to be satisfied if the parties obtain the required writing and signatures within 90 days after the date on which the arrangement fell out of compliance, provided the arrangement otherwise satisfies all of the requirements of an applicable exception.**

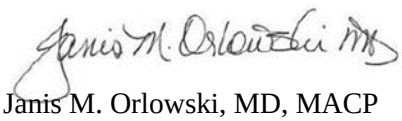
Cybersecurity Technology and Related Services

A new exception to the referral prohibition related to compensation arrangements is proposed for certain arrangements involving donation of certain cybersecurity technology and related services if certain conditions are met. **The AAMC recommends that CMS finalize this exception for cybersecurity with a modification that would allow protection for hardware that is necessary for cybersecurity.** Many cybersecurity products require the use of a particular hardware device to operate. Health care providers are a high value target for cyber criminals and cyber attacks result in patient harm and high costs to the health care industry. This exception would promote interconnected and interoperable health information technology systems by enabling health care providers to mitigate risks posed by cyber-attacks.

We support CMS's decision not to propose a requirement that recipients of cybersecurity software and technology contribute a portion of the costs. We agree that cost-sharing is not necessary for cybersecurity. Cost-sharing would serve as a barrier to participation in value-based arrangements, particularly with respect to small and rural physicians and providers who would be unable to afford the contribution.

CONCLUSION
The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org or Phoebe Ramsey at pramsey@aamc.org.

Sincerely,



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