AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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VIA E-MAIL FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

The American Association of Hip and Knee Surgeons ("AAHKS") appreciates the opportunity to comment on the substantive changes to the Physician Self-Referral law ("Stark law") proposed by the Center for Medicare & Medicaid Services ("CMS") (hereinafter referred to as "proposed rule").

The American Association of Hip and Knee Surgeons ("AAHKS") is the foremost national specialty organization of more than 4,000 physicians with expertise in total joint arthroplasty ("TJA") procedures. Many of our members conduct research in this area and are experts in using evidence based medicine to better define the risks and benefits of treatments for patients suffering from lower extremity joint conditions. In all of our comments, AAHKS is guided by its three principles:

- Payment reform is most effective when physician-led;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus

Our comments focus on the following provisions of the Modernizing and Clarifying the Physician Self- Referral rule:

I. Exceptions for value-based payment program - Section II.A.2.b

a. Full Financial Risk Exception - Section II.A.2.b.1

In the proposed rule, CMS proposed an exception to the physician self-referral law that would apply to value based arrangements that between value based enterprises ("VBE") that has assumed "full financial risk" for the cost of all patient care items and services covered by the

applicable payor for each patient in the target population for a specified period of time on a prospective basis. Prospective basis means that the VBE has assumed financial responsibility for the cost of all patient care items and services convened by the payor prior to providing patient care items and services to patients in the target patient population. A payment is prospective if there can be no additional payment to cover costs for specific patient care items or services furnished, nor can payment be claimed from the payor for such items or services. Full financial risk may take the form of capitation payments or global budget payment. CMS believes that when a value based enterprise is at full financial risk for the costs of all patient services, the incentives to order unnecessary services or steer patients to higher cost sites of service is diminished.

AAHKS Comment - AAHKS believes that this exception as drafted would not be widely utilized. It seems that very few existing arrangements could meet the narrow definition of "full financial risk." The Health Care Learning and Action Network ("LAN") 2019 APM Methodology Report illustrates the types of arrangements being pursued by private payers. The Report finds that only 5.1% of heath care payments were made to providers participating in models that included no FFS payments. CMS's narrow definition is too stringent to break the existing "chill" on innovation under the existing federal fraud and abuse framework.

The restrictive approach to "full financial risk" seems to disallow a payer from making any infrastructural, operational, or administrative investment in the VBE. It is more likely that, during an arrangement, a payer may evaluate a participating entity's performance on certain metrics and determine that provider performance could be improved by the provision of certain resources directed to specific operational areas. Such a payment seems at odds with CMS's current definition of full financial risk.

Full financial risk should be modified to limit VBE responsibility to the cost of only a defined set of patient care services for the target patient population, not all patient care services, to allow for additional flexibility for instances that may require some FFS payments. The exception should allow providers to furnish incentives related to inpatient care, outpatient care, or both, regardless of whether the enterprise is also accountable for other services under Medicare Parts A and B. Such arrangements pose little risk of encouraging inappropriate utilization because hospitals already bear accountability for the cost of these services through Medicare inpatient and outpatient prospective payment rates as well as readmission and other downside penalties.

AAHKS also supports including a protection for a pre-participation period of one year, similar to that offered through the Medicare Shared Savings Program.

b. Meaningful Downside Financial Risk to the Physician - Section II.A.2.b.2

CMS acknowledged that not all providers are prepared to accept full financial risk. As such, in the proposed rule, CMS proposed an exception for value-based arrangements with meaningful downside financial risk, which requires the physician to pay the entity no less than 25

percent of the value of the remuneration he or she receives under the value-based arrangement. CMS explained that they chose 25 percent threshold because it is consistent with the physician incentive plan definition of "substantial financial risk" adopted elsewhere in the proposed regulation.

AAHKS Comment: The 25% threshold for meaningful downside risk is far higher than necessary to discourage overutilization and may instead frustrate broader use of innovative arrangements. The Physician Incentive Plan ("PIP") regulations is an imperfect source from which to draw the 25% standards as PIP regulations are designed to disincentivize *under*utilization, not *over*utilization. Some facilities may be able to bear a 25% threshold but it will prove a disincentive to participation for many physicians.

A 2018 Deloitte survey of American physicians found that most were willing to link 10% of total compensation to quality and cost measures. 10% itself is a much higher threshold than the average amount of physician compensation linked to performance goals presently. The Deloitte survey found that 43% of physicians are eligible for performance bonuses of up to 5% and most of those are tied to productivity, not quality. Only 36% of physicians surveyed were found to have bonuses tied to utilization of resources. This suggests that a 25% threshold is far higher than necessary to motivate physicians in contrast to current practices.

c. Value-based Arrangement without Regard to Financial Risk - Section II.A.2.b.3

In the proposed rule, CMS seeks to create a value exception that would apply without financial risk. The proposed exception also brings safeguard requirements from the value based financial risk exception: (1) the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, (2) the remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population, (3) the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement, (4) the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided, and (5) records of the methodology for determining the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the Secretary of HHS upon request.

AAHKS Comment: We support this exception as essential to driving the transition to more utilization of value-based models. This exception seems tailor-made for many small practices that wish to participate in value-based care but that are not in a financial position to accept down-side risk. We appreciate that this exception does not include some of the traditional requirements for compensation exceptions – i.e., that the compensation be fair market value and not determined in a manner based on volume of value of referrals. In doing so, CMS acknowledges that these traditional requirements are impeding the transition to value-based care.

CMS seeks comments on the third safeguard, the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement. CMS instead may require, broadly, that remuneration specifically not be conditioned on referral of any patients to the entity or the volume or value of other business generated by the physician.

CMS proposes several additional safeguards on which it seeks comment. One is requiring a fully executed writing, in contrast with the two risk-sharing proposed exceptions. Such a requirement would be unreasonable and unhelpful. In light of the substantial difficulties providers currently face with the "signed written agreement" requirements of the physician self-referral law, resulting in voluminous self-disclosures under CMS protocol, many of which are now years-old without settlement, one wonders why CMS would import a "signed written agreement" requirement into this new exception. This is especially confusing since providers may wish to make a value-based arrangements part of an already existing compensation methodology, such as for a group practice or for certain employed physicians, which would not otherwise require a signed writing. Although a writing can be proven through a collection of documents under CMS's existing approach, the signature requirement often is more difficult to substantiate even where it is apparent through available documentation and the parties' course of performance that the arrangements was "set in advance" in a meaningful way.

Another more cumbersome proposed safeguard requires that the performance or quality standards that trigger remuneration be objectively measured and tracked using a prospective methodology. Not protected would be payment tied to quality standards set today for yesterday. As with the writing requirement generally, standards often are articulated prospectively, but it takes some time for the parties to reduce the metrics to writing or determine the measurement methodology with particularity. CMS is also considering whether to require that performance or quality standards be designed to "drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery." It is entirely unclear how CMS expects such an ambiguous standard to be measured or what would be reasonable and not reasonable. This also seems potentially redundant since presumably a qualifying value-based activity (for any of the proposed exceptions) would have one or more of these criteria already.

In this proposed exception, CMS also specifically states that it expects parties to monitor their arrangement to determine whether "they are operating ***as intended*** and serving ***their intended purposes***, regardless of whether the arrangements are value-based, and have in place mechanisms to address identified deficiencies, as appropriate" (emphasis added). While not wholly unreasonable on its face, this safeguard may present a complexing morass of subjectivity for which no real standards exist. Although the physician self-referral law is a strict liability law for which intent is mostly irrelevant, CMS is injecting concepts that examine not only the reasonableness and defensibility of acts, but also, literally, the intent of the parties.

CMS also is considering whether to require that:

(1) The value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination.

There are interesting parallels between this proposal and the 60-day overpayment rule. Although CMS seems to have been very careful so as not to propose the creation of an intent or reasonableness-of-action standard, this proposal certainly mirrors a number of common *facts and circumstances* themes more commonly found in False Claims Act and AKS litigation. For example, if adopted, these requirements would lead to the following questions: Were the entity's monitoring and oversight activities reasonable? Did the entity know, or should it have known, that the value-based activity was not achieving its intended purpose? When did the physician become aware? If one party conceals the failure of the program from the other, will both be held accountable? Such a "moving target" standard will present challenges and disincentives to providers looking for bright-line protection before undertaking value-based care arrangements.

Finally, CMS is also seeking comments on whether requiring physician participants to an arrangement to contribute some percentage (e.g., 15%) towards non-monetary remuneration (aka cost-sharing) would be consistent with the stated goals of the exemption. Such a requirements would preclude a host of innovative arrangements and take a disproportionate toll on small and rural practices. Especially for arrangements involving only infrastructure assistance, participants are sometimes without the financial incentive to front any part of the costs.

II. Price Transparency - Section II.A.2.b.5

CMS notes that health care consumers may lack meaningful access to pricing information that could potentially help them choose providers. Therefore, CMS says it is committed to "ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest."

In almost a non-sequitur, CMS solicits comments regarding (1) the availability of pricing information and out of pocket costs to patients (including information specific to a particular patient's insurance, (2) the appropriate timing for dissemination of information such as whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time; and (3) the burden associated with the compliance with a requirement in an exception of the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred.

AAHKS Comment: It is unclear how, or more importantly why, price transparency would be tackled in the dogmatic strict-liability maze of the physician self-referral law. Nevertheless,

CMS has one specific proposal under consideration with regard to price transparency—that it attaches as a requirement to all of the value-based exceptions. Although CMS does not have a specific proposal as to the content, form, or definition of "price transparency," it suggests examples, such as the provision of a public notice that alerts patients that out-of-pocket costs for DHS referred by the physician may vary based on the provider and the patient's insurance.

CMS states that a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients might be acceptable. Requiring something more than a public notice, which has questionable utility, would likely operate like a lead balloon to the value-based exceptions and render them unusable. Price transparency has wide-reaching legal implications related to antitrust, consumer protection, and contracts, not to mention significant logistical and operational challenges inherent in the dynamic nature of patient costs because of unmet deductibles, in- or out-of-network provider status, and other complications, all of which are relevant irrespective of whether the physician making a referral has a financial relationship with the DHS entity. If CMS finalizes more specific and less generic transparency requirements applicable only to entities engaging in value-based arrangements, entities that seek to enter into beneficial value-based cost-reduction activities may be subject to a major disincentive to do so.

Further, any such requirements are likely to cause confusion because the prices may not accurately reflect all the costs affiliated with services. Additionally, it creates a burden for the provider to consistently communicate with insurers to make sure prices are updated and that the provider has every insurance provider their patients use. This would run counter to CMS's efforts to reduce unnecessary paperwork that benefits neither patients nor providers. The new burdens would be yet another thing to draw physician attention away from patient care.

III. Group Practice - Section II.C.

In the proposed rule, CMS clarifies special rules for profit shares and productivity bonuses by allowing downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. CMS also proposes clarifying the interpretation of the overall profits that can be distributed to physicians in a group to make clear that "overall profits" means either "the profits derived from all the unrelated designated health service ("DHS") of any component of the group that consists of at least five physicians, which may include all physicians in the group" or "if there are fewer than five physicians in the group, the profits derived from all the DHS of the group."

AAHKS Comment: CMS's proposal would protect only the distribution of profits, as opposed to revenue, from DHS that are directly attributable to a physician's participation in a value-based enterprise, and CMS requests comment as to whether distribution of revenues should be protected as well. Because physicians who participate in value-based arrangements through group practices may not be partners or otherwise share in the group's profits, only group practice owners would be able to benefit from participation in value-based arrangements under

CMS's proposal. Since CMS acknowledges that value-based enterprises want to reward the particular physicians who have brought value to the enterprise under the arrangement, this omission of group practice employees and independent contractors is inexplicable.

IV. Limited Remuneration to a Physician - Section II.E.1

CMS proposed an exception for limited remuneration to a physician where the amount of or formulary for calculating remuneration is not set in advance, provided that, among other things, (1) the arrangement is for items or services actually provided by the physicians, (2) the remuneration does not exceed an aggregate amount of $3,500 in calendar year (3) the remuneration does not vary with the volume or value of referrals or other business generated, and (4) the remuneration does not exceed fair market value..

AAHKS Comment: Similar to the non-monetary compensation exception, the monetary limitation will be adjusted for inflation. However, unlike the non-monetary compensation exception, this proposed exception must be for actual items and services provided. This exception would be very helpful, if adopted, to eliminate inadvertent, procedural physician self-referral law violations. We recognize that in proposing this exception, CMS acknowledges that this exception can be used in conjunction with other exceptions. As such, the proposed exception may provide relief for providers that may begin an arrangement for items or services before squarely fitting into another exception.

V. Modifications to Certain Definitions - Section II. B.

a. Volume or Value Standards - Section II. B.3

In the proposed rule, CMS proposes codifying regulations defining and interpreting the "volume or value" and "other business generated" standards outside of the context of value-based arrangements. CMS provided two potential standards for volume or value. The first is that compensation takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family members) compensation includes referrals as a **variable.** As such, CMS proposes to define a positive correlation as existing between two variables when one variable increases as the other variable increases, or when one variable decreases as the other variable decreases. Compensation positively correlates with the number or value of referrals if the physician receives more compensation as the number or value of referrals increases. Likewise, compensation negatively correlates with the number or value of referrals if the physician receives less compensation as the number or value of referrals decreases.

Alternatively, compensation may take into account a predetermined, direct correlation between the physician's **prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined**. As an example, a hospital-employed physician is entering into a renewal employment agreement in which the physician is paid based on personally performed services

via a predetermined tiered compensation system according to the number of outpatient tests that were ordered during the previous year. In this example, the compensation varies based on the volume or value of referrals, even if the physician is paid an unvarying rate per work relative value unit.

AAHKS Comment: AAHKS lauds CMS efforts to determine the best way to clarify the volume or value standard. We support the proposed approach to create an objective test for determining when compensation is determined to take into account volume or value of referrals or other business generated between parties. This distinction likely creates as close to a bright line rule as possible under the statute and may reduce confusion surrounding the meaning if this term, in turn mitigating the burdens associated with meeting this standard.

CMS discusses the inclusion of the volume or value standard or other business generated standard as they apply to the definition of "remuneration" under the statute, exceptions, and indirect compensation relationships, however CMS does not mention the inclusion of this standard in the definition of group practice (84 FR 55792). Qualifying as a bona fide group practice within the meaning of the Stark law is not an exception itself, but rather a *sin qua non* for meeting many exceptions. We suggest that CMS clarify explicitly in the final rule that this interpretation applies for purposes of § 411.352(g) and (i) in the definition of group practice.

b. <u>Commercially Reasonable - Section II.B.2</u>

CMS seeks input on the possible definition for "commercially reasonable". CMS provides two possible definitions. The first is that commercially reasonable is to mean that the "particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements" and specifically states that a financial arrangement can be commercially reasonable "even if it does not result in profit for one or more of the parties." In the second, "commercially reasonable" could also be an "arrangement [that] makes commercial sense and is entered into by a reasonable entity of similar type of size and a reasonable physician of similar scope and specialty."

AAHKS Comment: We support the regulatory text providing that a lack of profitability does not automatically indicate a lack of commercial reasonableness. This could provide clarification for practices and providers that employ or engage physicians at a loss when considering only professional fees, but who serve an appropriate business or mission purpose. However, a rule that says that an unprofitable arrangement "may" still be commercially reasonable is hardly a bright-line standard for providers.

c. <u>Fair Market Value –</u>

CMS proposes to define "general market value" as meaning "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 …." CMS also recognizes that the hypothetical value of a transaction

may not always be "identical to the market value of the actual transaction being considered" as extenuating circumstances may require the parties to veer from identified surveys and theoretical valuation data.

AAHKS Comment: We agree with CMS's statement that the fair market value requirement should be separate and distinct from the volume and value of referrals and other business generated standards. The inclusion of this language in the fair market value definition is superfluous and has led providers and even courts to conflate these distinct rules. We do not agree with CMS's preamble discussion of extenuating circumstances that could require a downward deviation from salary surveys. In the example given, a small hospital should be permitted to rely on salary surveys and good faith bargaining when compensating a physician. This example ignores the physician's value as well as the hospital's need for the physician. That CMS even considers a preamble discussion this granular illustrates how the new fair market value formulation will remain vague and uncertain, like the current one.

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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,

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