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President & CEO

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Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW, Room 445-G  
Washington, DC 20201

**RE:***CMS-1720-P, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations.*

Dear Administrator Verma:

The Federation of American Hospitals (FAH) appreciates the opportunity to submit these comments to the Centers for Medicare & Medicaid Services (CMS) on the above referenced Proposed Rule, published in the *Federal Register* on October 17, 2019 (84 Fed. Reg. 55766). The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute and ambulatory services.

The FAH appreciates CMS' efforts to understand the challenges related to implementing new payment models while operating under the current regulatory provisions of the Physician Self-Referral Law, 42 U.S.C. 1395nn. The following comments offer the FAH's support of CMS and many of its new proposals, revisions, and clarifications. We also offer responses to many of the questions asked by CMS throughout the Proposed Rule and pose some questions as well in an effort to receive greater clarity in future guidance from CMS. We commend CMS' efforts towards reducing regulatory burden and reducing barriers to value-based care transformation while also protecting the integrity of the Medicare program. The FAH supports changes to the Physician Self-Referral Law regulations in the hopes that this will encourage and support innovation and the transformation of the health care system into one that pays for value and rewards high quality care for beneficiaries.

## *General Comments*

The FAH appreciates the effort undertaken by CMS to modernize and clarify aspects of the Physician Self-Referral Law. Although the Law was enacted under a system where most services were paid based on volume, it has become clear to both the industry and government that the law imposes restrictions that are more applicable in a fee-for-service payment system and do not translate effectively to a value-based focus in our evolving payment system. While the Medicare payment system is transitioning towards more value-based payments, hospitals are challenged to manage the evolving forms of their arrangements with physicians. Many of the components of the Proposed Rule offer clarity and simplification. The FAH has also identified areas where further consideration and clarity would be beneficial. We realize the challenge that CMS faces in balancing program integrity for Medicare and the beneficiaries it serves, while also supporting compliance with the Physician Self-Referral Law by those striving to implement new programs and arrangements.

We agree with many of the proposals to delete certain requirements in the regulatory exceptions that have proven burdensome to stakeholders yet offer little impact on the actual or potential risk of Medicare program or patient abuse. Similarly, the proposals to revise existing exceptions or propose new exceptions for non-abusive arrangements is a welcome addition to the Physician Self-Referral Law landscape. It is telling that CMS has received over 1,100 submissions to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) in the last nine years revealing arrangements that violated the physician self-referral law but posed no real risk of Medicare program or patient abuse. With the clarifications provided to the signature and writing requirements in § 411.354(e), the expansion of services unrelated to the provision of designated health services (DHS) at § 411.357(g), and the creation of the proposed new exception for limited remuneration to a physician at § 411.357(z), the FAH is encouraged that CMS recognizes the challenges of complying with a complex strict liability statute.

The proposals related to value-based arrangements offer a large amount of information to digest and understand in the context of this developing area of health care. It is evident that CMS considered the comments received in response to the Request for Information Regarding the Physician Self-Referral Law (RFI) (83 FR 29524) to inform its rulemaking. With the Proposed Rules from CMS and OIG both addressing value-based arrangements similarly, but with notable differences, the task of understanding the true impact of these proposals is compounded. While the FAH appreciates the consideration that CMS has taken in developing proposed definitions and exceptions to address the value-based system we are edging towards, it will take time and experience to understand if the proposals achieve the right balance between ensuring program integrity, making compliance with the Physician Self-Referral Law readily achievable, and providing the flexibility required by participants in the value-based health care delivery and payment systems that CMS endeavors to meet.

As our health care system adopts new value-based models of care, policy and implementation, challenges arise with these models implicating the federal fraud and abuse legal framework more broadly than the Physician Self-Referral Law alone. These changes affect the application of the Federal Anti-Kickback Statute (AKS) and the Civil Monetary Penalties Law

(CMPL) to these arrangements. We are encouraged that CMS and the OIG have worked collaboratively in developing their respective Proposed Rules. The FAH encourages the Agencies to continue to work together and identify additional areas where the terminology and exceptions available for value-based arrangements align more closely in any final rules issued.

### *Facilitating the Transition to Value-Based Care and Fostering Care Coordination*

CMS proposes new exceptions at § 411.357(aa) as well as definitions for the key terms included in the new exceptions to the Physician Self-Referral Law. The proposals are intended to create the set of requirements for protection from the Physician Self-Referral Law's referral and claims submission prohibitions when engaged in a value-based arrangement and focus on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants. The definitions and exceptions discuss the spectrum of value-based arrangements CMS believes will not pose a risk of program or patient abuse. The FAH supports the efforts being made to facilitate the transition to value-based arrangements. Because of the complexity and uncertainty of value-based opportunities, application of revisions to the Physician Self-Referral Law to such opportunities will carry that same uncertainty. Thus, the FAH remains committed to assessing application of any changes to the Physician Self-Referral Law regulations and will appreciate the opportunity to have an ongoing dialogue with CMS in the event that additional changes are needed in the future to maximize the intent of any final regulations.

### *Proposed Exceptions – General Comments*

The experience of our members to date demonstrate that the development of value-based arrangements such as gainsharing, shared savings, and other similar arrangements between hospitals and other providers, take time to develop, including significant effort to address any uncertainties and ambiguities in the applicable regulations. As CMS reviews comments and develops the final rule related to value-based care, the FAH believes it would be beneficial to include examples of how CMS envisions the definitions and proposed exceptions can be operationalized in real life scenarios, as discussed more specifically in the comments below. We agree with CMS that this is a huge sea change for health care and one that is not happening overnight. The FAH hopes that just as the industry's understanding of these arrangements will grow and evolve, the implementing regulations of the Physician Self-Referral Law will likely have to continue to grow and evolve. As stakeholders gain experience with these arrangements and with application of the proposed definitions and exceptions, continued dialogue between the government and industry will become more valuable. We look forward to working with CMS throughout this evolution.

The FAH's comments to the RFI encouraged CMS to create an overarching alternative payment model waiver of the Physician Self-Referral Law and AKS for all gainsharing or similar arrangements, especially those implemented under a CMS-sponsored value-based program. The FAH continues to support such a waiver in an effort to establish certainty and simplification that is not as apparent in the proposed exceptions. We believe that CMS should continue to work with the OIG to implement a long-term solution that will establish legal certainty around permissible

value-based arrangements while encouraging hospital and physician participation in alternative payment models. The proposed exceptions are a beginning in this direction but have presented an entirely new vocabulary that many in the industry are grappling with at this time. The FAH encourages CMS and OIG to continue the dialogue with the industry as stakeholders and the government learn about the practical application of Physician Self-Referral and AKS exceptions and safe harbors to existing and emerging value-based arrangements.

Rather than one overarching waiver or exception for value-based arrangements, CMS and the OIG have proposed multiple exceptions and safe harbors with varying requirements of each. There are multiple exceptions under the Physician Self-Referral Law to understand, and the language of the Physician Self-Referral Law exceptions and the corresponding AKS safe harbors is different. For those already engaged in value-based efforts, this adds an additional level of complexity and challenges to understand the potential impact and meet the varying requirements. The FAH also is concerned that the complexity of the proposals and the new terminology will serve as deterrents to others who have not yet engaged in value-based efforts. We urge CMS to consider the potential chilling effect of rules and definitions that are so complex they are not adopted by the industry on a wide-scale basis. It is possible that a more simplistic approach of broad value-based exceptions or possibly even revisions to existing exceptions, such as the exceptions for risk sharing arrangements and personal services arrangements could support value-based arrangements.

The three proposed exceptions to the Physician Self-Referral Law for value-based arrangements include (i) value-based arrangements involving “full financial risk”; (ii) value-based arrangements with meaningful downside risk to the physician; and (iii) a broad exception for value-based arrangements that do not involve full financial risk or downside risk to the physician. While the efforts undertaken to develop these new exceptions are appreciated, the FAH is hopeful that CMS will consider the questions and requests for clarity when considering final rules.

#### *CMS-Sponsored Models*

In discussing the proposed exceptions for value-based arrangements, CMS notes that the exceptions at § 411.357(aa) would be applicable to compensation arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as a “value-based arrangement”). CMS believes that compensation arrangements between parties in a CMS-sponsored model, program, or other initiative can be structured to satisfy the requirements of at least one of the proposed exceptions at § 411.357(aa). While it may be true that arrangements in a CMS-sponsored model could satisfy one of the proposed exceptions, the FAH believes that an alternate approach would be a more appropriate path forward for these arrangements. Specifically, the FAH urges CMS to reconsider its position and create an exception for value-based arrangements that work in conjunction with the OIG’s proposal for CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives at § 1001.952(ii).

Without a complementary exception to the Physician Self-Referral Law, the OIG’s proposed safe harbor does not provide sufficient guidance for these arrangements on its own. If

parties have to meet both the OIG's safe harbor for CMS-Sponsored Models and then identify the appropriate exception in the Physician Self-Referral Law for the same arrangement, the burden of compliance for these new models increases rather than decreases in most instances from where it stands today. For many CMS-Sponsored Models, the participants have been able to operate under a waiver issued for that specific program. The FAH believes that an exception for CMS-Sponsored Models would operate similarly to the current waivers that are in place for CMS programs.

Because the CMS-sponsored models have already been approved and include safeguards, an exception for these models is appropriate. A lack of such an exception for the Physician Self-Referral Law may impact future voluntary participation in these models. The requirements of these programs are already rather significant, and the additional analysis, uncertainty, and potential for noncompliance only increase the burden. Further, this discrepancy between the laws represents an issue that parties would have to address when trying to comply with both the Physician Self-Referral Law and the AKS. The FAH requests parity between the two rules whenever feasible, particularly with the newly proposed value-based definitions and exceptions. We envision the CMS-sponsored model exception to mirror significantly the proposed OIG safe harbor.

#### *Existing Waivers for CMS-Sponsored Models*

CMS states its intention that the proposed array of exceptions for value-based arrangements, if finalized, would eliminate the need for any new waivers of section 1877 of the Act for value-based arrangements. The FAH likely would agree if there is an exception for CMS-sponsored models. With the possibility of new waivers no longer being issued for CMS-sponsored models, the FAH requests clarification from CMS that all existing waivers for CMS-sponsored models will remain in effect as implemented currently. The FAH is composed of members who actively participate in CMS-Sponsored models, many of whom have implemented arrangements pursuant to these waivers. Even a seemingly small change to the way the waivers are implemented can have a significant impact. These programs often have multiple layers, which are interwoven with each other. One slight change to one layer or component can have a ripple effect throughout the program. The FAH does not believe that early adopters of these programs should be penalized with the burden of complying with a new exception while already active in an approved model with an applicable waiver. The FAH also encourages CMS to consider the potential need for additional waivers in the future if CMS-sponsored models are developed for which the exceptions, when finalized, are not sufficient.

#### *Commercial Payor Exception*

CMS noted in the preamble that the proposed exceptions would apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. The FAH urges CMS to implement a new Physician Self-Referral Law exception to facilitate, with appropriate program oversight, non-CMS advanced payment models such as commercial payer only arrangements. The FAH believes that such an exception is necessary to ensure uniformity in the treatment of CMS-sponsored and non-CMS-sponsored models and further incentivize these innovative models.

Under such an exception, for example, the provision of an incentive payment, directly or indirectly, by a DHS entity to a physician participating in a qualified commercial model would be deemed protected under the Physician Self-Referral Law, provided that the parties adhere to all program and patient safeguards otherwise mandated by the model. The scope of the exception, the inherent protections that come with a formal alternative payment model arrangement, and the applicable program safeguards outlined in such an exception are consistent with CMS's program goals to promote transparency, improve quality, and safeguard against payments for referrals.

*Risk Sharing Arrangements Exception (§ 411.357(n))*

CMS has not proposed any changes to the substance of the Physician Self-Referral exception for risk-sharing arrangements set forth in § 411.357(n). Under this exception, compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization (MCO) or an independent practice association (IPA) and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan would qualify for the exception. However, the exception remains silent as to effect of a DHS entity's ownership of the MCO.

In response to the trend towards value-based care, the FAH has noted a proliferation of enterprises such as clinically integrated networks and accountable care organizations that facilitate physicians' collaboration towards value-based purposes, and which may contract with commercial payors for care provided by the enterprise's providers to their beneficiaries. Given the sizeable investments needed to launch these enterprises, they have frequently been formed by hospitals and health systems. While payments received by an enterprise to its participating physicians may qualify for the exception for risk-sharing arrangements, it is not clear whether the investments made by the DHS entity in the enterprise constitute a separate indirect compensation arrangement between the referring physician and the DHS entity, for which a Physician Self-Referral Law exception would be needed. In considering how this type of arrangement would be analyzed, the FAH asks CMS for guidance regarding the principles that would guide the enterprise's approach to recouping its investment in the enterprise. Determining whether withholds of payments received by commercial payors or by financial contributions from participating physicians in this potential fact pattern can comply with the Physician Self-Referral Law is an example of the uncertainty still present for those innovative models being developed.

*Full Financial Risk (Proposed § 411.357(aa)(1))*

Under the exception for value-based arrangements involving full financial risk, the value-based enterprise (but not necessarily all VBE participants) must be financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. It is unclear if this exception would be available if a DHS entity within the value-based enterprise, such as a hospital, were to guarantee the full risk of the value-based enterprise, or otherwise ensure the repayment of any losses through, by way of example, reinsurance, thereby shielding VBE participants, such as physicians and physician groups, from such risk. Given that physicians often lack the financial means to pursue full financial risk, this exception may have limited utility if each VBE participant

would be required to incur a portion of the risk. However, allowing a DHS entity to incur the risk on behalf of the value-based enterprise would, in our view, accelerate the transition from volume-based models to payment mechanisms based on the quality of care and control of costs.

The proposed exception for value-based arrangements involving full financial risk would protect remuneration paid during the six-month window before the value-based enterprise is contractually obligated to be at full-financial risk. CMS' reasoning was that this period would enable the value-based enterprise to prepare for full financial risk and could be used to implement a shared information technology (IT) resource across the value-based enterprise. However, in our members' experience, many of the activities needed to prepare for success in a value-based arrangement are not limited to those arrangements involving full financial risk. Development of care designs, investments in IT, and deployment of clinical resources, such as care coordinators, may be just as important in arrangements where physicians are at meaningful downside risk or other value-based arrangements without any downside risk. As such, the six-month "preparation period" should be applicable to each of the proposed exceptions for value-based arrangements, and not limited to those involving full financial risk. In addition, an extension of the six-month window may also be beneficial to ensure readiness to engage in the value-based activity. For example, IT implementation efforts or hiring may be delayed. It is possible that all reasonable efforts are undertaken, yet a vendor issue or other unexpected unavailability of a resource occurs that is needed to start the value-based activity. The FAH requests a longer preparation period of at least twelve months to facilitate the myriad of components that must be put into place for a successful value-based arrangement with any level of risk.

*Value-based Arrangements with Meaningful Downside Risk to the Physician (§ 411.357(aa)(2))*

CMS included a proposed exception for value-based arrangements under which the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire term of the arrangement. As we work through the proposed exceptions and related definitions, the FAH has considered certain scenarios to determine how they would interact with both the CMS and OIG proposals related to value-based arrangements. One of the prominent issues that we raise is the difference in terminology proposed in the respective regulations. As we have discussed elsewhere in this letter, the industry is working to decode the proposals and determine how, and if, they support value-based arrangements. The industry is endeavoring to understand each of the proposals individually, and then whether and how they work together.

As an example, the CMS proposal for meaningful downside risk arrangements and the OIG's proposed safe harbor for substantial downside risk arrangements would both protect in-kind and monetary remuneration between a value-based enterprise and its participants. The FAH supports this inclusion of monetary and in-kind remuneration. However, the way that OIG and CMS have proposed to determine what it means to share "meaningfully" in downside risk each have different definitions. CMS proposes that a physician is at meaningful financial risk if he or she is responsible for at least 25% of the value of the remuneration available under the value-based arrangement, or is financially responsible 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 the target patient population

for a specified period of time. To satisfy this proposed exception, the physician would be required to assume meaningful financial risk for the duration of the arrangement.

On the other hand, the OIG proposes that a VBE participant meaningfully shares in the VBE's financial risk if the payment it receives: puts the VBE participant at risk for 8% of the VBE's total risk under the payor agreement (*e.g.*, an 8% withhold, recoupment payment, or shared losses payment); is a partial or fully capitated payment (excluding the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, etc.); or is protected by the corresponding Physician Self-Referral Law exception if the VBE participant is a physician.

The difference between the two is notable for a number of reasons. Establishing the threshold numbers at different reference points, 8% for OIG but 25% for CMS, raises questions of why these are not more aligned. The FAH is interested to learn more about the risk threshold requirements, particularly under the Physician Self-Referral Law, where physicians must agree to up to 25% downside risk in order to be eligible for protection under this newly proposed exception when the existing risk-sharing exception does not have any such threshold.

The FAH also requests additional guidance around what downside risk really means when engaging physicians in value-based activities. An example that raises questions is that of bonus pools for physicians. Some financial arrangements with physicians include a potential bonus pool that the physicians can earn if certain metrics are achieved, possibly related to a value-based purpose such as improving the quality of care for a target patient population in a quantifiable manner or appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population. If the physician does not meet the established metrics, the bonus is not earned. Although it is possible that CMS would view the potential to earn the bonus as an upside risk, to the physicians themselves this is viewed very much as a downside risk. The potential bonus is considered part of the potential aggregate compensation to be paid to the physician and if that bonus is withheld the physician is subject to the downside risk of entering the compensation arrangement. The FAH seeks clear guidance from CMS in applying the proposed exceptions and definitions to practical, real-world scenarios to provide additional clarity going forward if the proposals are finalized.

### *Price Transparency*

In the Proposed Rule, CMS considered whether to include a requirement related to price transparency in every exception for value-based arrangements at proposed § 411.357(aa). As an example, CMS asked if it should require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out of pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have.

Although the FAH continues to support the Department of Health and Human Services' (HHS') goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, the FAH notes the lack of detail in the Proposed Rule on which to comment and strongly opposes CMS' proposal to include price transparency requirements in any of the value-based exceptions proposed. Price transparency does not impact the referral relationship between

physicians and DHS entities and does not belong as a requirement in any exception under the Physician Self-Referral Law. The FAH urges CMS and HHS to work with stakeholders—providers, health plans, employers, and consumers—to identify opportunities to improve consumers’ access to clear, accurate, and actionable cost-sharing information, which is what patients really need to make informed decisions.

The FAH is committed to helping patients understand their cost-sharing and believes that such information should reflect the values and interests of actual patients. In the experience of our members, patients show little interest in the amount a third-party payer will reimburse the provider, and instead are focused on their own copayments, coinsurance, and deductible obligations. Therefore, there is little patient benefit to be derived from providing any information other than an estimate of the patient’s expected cost-sharing obligation, and the provision of additional, unnecessary information creates significant risks of market distortions and patient confusion.

The FAH also notes that, consistent with the goals of value-based care, hospitals and payers are increasingly negotiating risk-sharing agreements. The Proposed Rule provides no information as to how a hospital that accepts full or partial capitation, receives quality bonuses or is subject to withholds, participates in a clinically integrated network, or otherwise enters into a managed care agreement under which payment varies based on quality, volume, acuity, or a broad range of performance metrics that cannot be accurately projected in advance would be expected to comply with the Proposed Rule. For example, it is unclear if the rule would require disclosure of payer-specific negotiated rates that include both partial risk-sharing or value-based payment in addition to a lower fee-for-service payment because no regular payment rate could be identified. Disclosure of only the fee-for-service rates would misleadingly suggest that the negotiated rates are artificially low, which might have unanticipated effects in provider-payer negotiations and might disrupt the marketplace. The FAH urges CMS to not include any price transparency requirements in the proposed exceptions and refers the Agency to the FAH’s previous comments regarding such requirements.<sup>1</sup>

### Fundamental Terminology and Requirements

#### *Commercially Reasonable (§ 411.351)*

Although many of the statutory and regulatory exceptions to the Physician Self-Referral Law include a requirement that the compensation arrangement is commercially reasonable, the regulations do not contain a codified definition of the term. The minimal guidance offered by CMS in the 1998 proposed rules interpreted commercially reasonable to mean that “an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.” While the industry has managed to operate under this guidance, the fact that CMS is opining on a formal definition of the term is a welcome effort towards providing a bright line guide for future financial arrangements. CMS has provided two options for the definition of commercially reasonable.

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<sup>1</sup> See FAH Comment Letter Re: CMS CY2020 OPSS Proposed Rule (September 27, 2019), available at: [https://www.fah.org/fah-ee2-uploads/website/documents/FAH\\_CY2020\\_OPSS\\_Comment\\_Letter\\_FINAL.pdf](https://www.fah.org/fah-ee2-uploads/website/documents/FAH_CY2020_OPSS_Comment_Letter_FINAL.pdf).

Overall, the FAH believes that both proposed definitions for commercial reasonableness are workable. The FAH encourages CMS to consider finalizing both definitions and offering the option to apply either definition to the analysis of an arrangement: if the parties can meet either definition, then the arrangement is commercially reasonable for purposes of the Physician Self-Referral Law. Alternatively, CMS could consider a more straightforward statement that the “arrangement is appropriately designed to meet the parties’ legitimate business goals from the perspective of the parties to the arrangement.”

The FAH applauds CMS’s clarification in regulatory text that an agreement may be commercially reasonable even if it does not result in a profit for one or more of the parties. Our members are committed to providing high quality health care necessary to support the health of the beneficiaries they serve. At times this means entering into an arrangement with physicians for services that are needed. It is not always feasible that these arrangements will be profitable for a hospital entering the arrangement. CMS should clarify in regulation, at a minimum, that the fact that a hospital’s remuneration to a physician may equal or exceed the professional fees generated by the physician on behalf of the hospital does not by itself mean that the employment or contractual arrangement is not commercially reasonable. With this proposed clarification from CMS, our members will be able to provide the services needed in their communities without fear of violating the commercial reasonableness standard.

*The Volume or Value Standard and the Other Business Generated Standard (§ 411.354(d)(5)&(6))*

*Special Rules and Clarification of Change in Policy:* In the Proposed Rule, CMS proposes to institute a policy to clarify when compensation to a physician (or immediate family member) is “determined in a manner that takes into account the volume or value of referrals or other business generated” for purposes of the various exceptions that contain the quoted language. In the Proposed Rule, CMS has included special rules, rather than definitions, at § 411.354(d)(5) and (6) that, if finalized, would constitute the guidance the industry has sought previously.

We understand from CMS officials that it is their view that this proposed policy would be a substantive change, and that some compensation arrangements that previously would have been considered to have taken into account the volume or value of referrals or other business generated (hereinafter, for the sake of brevity, “volume or value of referrals”) now will not be considered so. If we are correct that the proposed policy would be a substantive change, and if the policy is finalized, we recommend that the final rule so state (as the Proposed Rule is not explicit on this point), and that it give multiple examples of arrangements that do and do not take into account the volume or value of referrals. We also recommend that CMS continue to allow (*i.e.*, “grandfather”) arrangements under the current policy for the duration of such arrangements.

In the preamble to the Phase I final rule, CMS stated that “[a] compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated.” 66 Fed. Reg. at 877-78. This

interpretation was reiterated in the Phase II final rule, 69 Fed. Reg. at 16068, and was incorporated into the discussion on “volume or value” in the Phase III final rule, 72 Fed. Reg. at 51026-51031. This standard also is incorporated into the deeming provisions at sections 411.354(d)(2) and (d)(3). We are not aware of any guidance from CMS that deviates from this interpretation.

Although the guidance was framed in terms of when a compensation arrangement does not take into account the volume or value of referrals, the natural reading of the guidance is that when compensation does vary over the term of the arrangement that takes into account referrals, the compensation arrangement does take into account the volume or value of referrals. Or, stated another way, such a compensation arrangement would run afoul of the requirement in various exceptions that the compensation not take into account the volume or value of referrals.

To illustrate, under the current guidance, a personal service arrangement (PSA), whereby a physician is paid \$X per procedure he or she performs at a hospital –regardless of the number of procedures – would not take into account the volume or value of referrals. If, however, the arrangement included a tiered compensation arrangement such that the physician is paid \$X per procedure for the first 50 procedures in a given year, and then \$X+ for procedures 51 – 75, that arrangement would impermissibly take into account the volume or value of referrals.

Our understanding is that, if the proposed policy is finalized, unless referrals for DHS (or other business generated) are an explicit and express component of the formula, the compensation arrangement would not take into account the volume or value of referrals, even if, as a practical matter, the physician’s increase in referrals would result in additional compensation. Thus, where the physician is paid \$X per procedure for the first 50 procedures, and then \$X+ for procedures 51 – 75, the payment arrangement would not take into account the volume or value of referrals according to our understanding of the proposed policy. Similarly, in scenarios where a physician is paid less once a threshold is met, this would be interpreted the same way. For example, if a physician is paid \$X per procedure for the first 50 procedures, and then \$X- for procedures 50-75, the payment arrangement would not take into account the volume or value of referrals. If our understanding is correct, we recommend that the final rule be explicit that tiered payment arrangements like the one described above do not run afoul of the volume or value prohibition.

Further, the FAH supports a regulatory definition that makes clear that the existence of a technical component of a service performed does not trigger a volume or value issue. We agree with the position that with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician’s referrals solely because corresponding hospital services (that is, DHS) are billed each time the employed physician personally performs a service. The FAH appreciates the clarifying guidance that this position is consistent for providers under personal services arrangements as well.

In order to provide the greatest clarity for stakeholders and government agencies alike, the FAH urges CMS also to include this position in regulatory text and not only in the preamble guidance. As CMS is aware, this supporting analysis has come under attack in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, as discussed in the Proposed Rule, as well as

more recent enforcement activity that has caused concern within the industry. For hospitals that have entered numerous financial arrangements with physicians that include a payment rate based on services personally performed by those physicians, the FAH understands that the clarification provided in the Proposed Rule, as well as any future regulatory text, is merely meant to formalize the view that CMS has espoused previously. The additional clarity in the regulations is critical to ensure that compensation arrangements with physicians remain compliant with the applicable exceptions of the Physician Self-Referral Law.

*Existing Deeming Language, If Finalized:* If the proposed policy regarding the volume or value deeming language is finalized in the final rule, we question the continued need for the deeming provision for per unit compensation in section 411.354(d)(2) and (d)(3). At best, this language could be confusing, and the natural reading of the language in the deeming provision is that tiered compensation arrangements take into account the volume or value of referrals. Therefore, the FAH supports removing these provisions should the proposed policy regarding the volume or value deeming language be finalized.

*Existing Deeming Language, If Not Finalized:* In contrast, if the proposed policy is not finalized in the final rule, we have several recommendations. First, current paragraphs (d)(1) – (d)(3) of section 411.354 should be replaced with the following two paragraphs:

(1) Compensation is considered “set in advance” if the aggregate compensation, is calculated using a specific formula (including, for example, time-based, per-unit of service or use based and/or percentage-based compensation, such as a percentage of revenue or billings), that is set out in writing before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) Compensation does not take into account “the volume or value of referrals” or “other business generated between the parties” if the compensation is set in advance, is fair market value for services or items actually provided, and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.

As inferred from the inclusion of only two paragraphs, we also would recommend deleting current paragraph (3) of section 411.354(d) as largely unnecessary given the suggested revision to paragraph (2), and placing a definition of “other business generated” in section 411.351, to read as follows:

Other business generated means any health care business, including private pay business (except for services personally performed by the referring physician, which are not considered “other business generated” by the referring physician).

This definition incorporates the existing parenthetical in paragraph (d)(3) of section 411.354, as well as incorporating language in the Phase II final rule (see 69 Fed. Reg. at 16067 (first column)).

Should CMS not finalize the proposed policy in the final rule, and also not accept the suggested revisions to the regulations above, it should, at the least, add percentage-compensation arrangements to the deeming provisions in current paragraphs (d)(2) and (d)(3) of section 411.354. We discern no good reason to include per-unit compensation in these provisions, while omitting percentage-based compensation. Paragraphs (d)(2) and (d)(3) were added in the Phase I final rule at a time when percentage compensation was not considered to be set in advance. However, CMS changed its position in the Phase II final rule, holding that percentage compensation can be considered set in advance (69 Fed. Reg. at 16068) and reaffirmed that position in the Phase III final rule (72 Fed. Reg. at 51030-31). Given CMS's acknowledgement that "percentage-based compensation arrangements can be considered 'set in advance' if the methodology is fixed at the outset of the contract with sufficient specificity, and not changed during the course of the agreement in a manner that reflects referral volumes or other business generated" (which is identical to the test set forth in the Phase I final rule), 72 Fed. Reg. at 51031, there is no principled basis to not include percentage-based compensation in the deeming provision (which also is identical to the test set forth in the Phase I final rule).

The decision made in the Phase III final rule not to include percentage-based compensation arrangements in the deeming provision is unexplained (CMS says only that it was not persuaded that the deeming provision should be revised to "reference specifically" percentage-based compensation arrangements, see 72 Fed. Reg. at 51031). It is also internally inconsistent with the preamble language in the Phase III final rule quoted above that acknowledges, like per unit compensation (which is referenced specifically in the deeming provision) percentage-based compensation can be "set in advance." Moreover, we note that the OIG proposes to remove the requirement found in several safe harbors that the aggregate compensation must be set in advance, and instead adopt the approach that CMS currently uses for the Physician Self-Referral Law, namely, that formulaic compensation satisfies the set in advance requirement. In this regard, we note that the OIG does not carve out percentage-based compensation in its proposal to adopt a formulaic compensation approach to set in advance. We believe this lack of a carve-out further supports our recommendation that CMS add percentage-based compensation to the Physician Self-Referral deeming provision.

*Indirect Compensation Arrangement Definition and Exception:* The Proposed Rule would remove "varies with" from the phrase "has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS" in the current definition of an "indirect compensation arrangement" found at section 411.354(c)(2)(ii). See 84 Fed. Reg. 55841-42. We understand that the purpose of the proposed change would be to narrow the circumstances in which a physician would satisfy the "aggregate compensation" component of the definition and thus narrow the circumstances in which the physician would have an "indirect compensation arrangement" with a

DHS entity. The FAH applauds this proposed change, but recommends that if it is finalized, the final rule give examples of compensation arrangements that do and do not satisfy the “aggregate compensation” component of the definition of an “indirect compensation arrangement,” and that it also give examples or arrangements that satisfy the “aggregate compensation” component of the definition of an “indirect compensation arrangement” but do not take into account the volume or value of referrals for purposes of the exception for indirect compensation arrangements (regardless of whether the proposed change in policy on what takes into account the volume or value of referrals is finalized). We believe it is necessary to clarify and highlight the differences between the analysis under the indirect compensation definition and the analysis under the indirect compensation exception as they are often conflated.

#### Group Practices (§ 411.352)

##### *Special Rules for Profit Shares and Productivity Bonuses (§ 411.352(i)) – Distribution of Revenue Related to Participation in a Value-Based Enterprise*

As CMS and stakeholders work to incorporate value-based payment models into arrangements with physicians, certain challenges and uncertainties have been identified regarding compensation of physicians in group practices. In an effort to address these concerns, CMS proposed several modifications and clarifications related to the group practice rules. CMS proposes to add to § 411.352(i)(3) a deeming provision related to the distribution of profits from DHS that are directly attributable to a physician’s participation in a value-based enterprise. The FAH believes that is helpful to clarify that when such profits are distributed to the participating physician, they would be deemed not to directly take into account the volume or value of the physician’s referrals. Permitting a group practice to distribute directly to a physician in the group the profits from DHS furnished by the group that are derived from the physician’s participation in a value-based enterprise, including profits from DHS referred by the physician, and clarification that such remuneration would be deemed not to directly take into account the volume or value of the physician’s referrals are needed adjuncts to exceptions for value-based arrangements. Clarifying mechanisms to encourage physicians to participate in value-based arrangements based upon permissible compensation mechanisms supports those entities working to incorporate value-based elements into their practice.

#### 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*

CMS proposes to remove the requirement in the Physician Self-Referral Law compensation arrangement exceptions that the arrangement not violate the AKS. As the FAH noted in previous comments to the RFI, this AKS requirement creates a very unreasonable burden of proof (having to prove a negative (*i.e.*, absence of an illegal inducement)), and awkwardly links a strict liability law to an intent-based law, while not providing any benefit for the Medicare program. It is clear that compliance with the Physician Self-Referral Law is not a substitute for complying with the AKS, and thus this requirement is unnecessary. Additionally, the Proposed Rule would eliminate the requirement that arrangements not violate any federal or state billing and claims submission

rules as this element of the exceptions is equally unnecessary. The FAH appreciates these proposed revisions and believes they offer some burden reduction.

*Definitions (§ 411.351)*

*Designated Health Services*

In the discussion of proposed changes to definitions applicable to the Physician Self-Referral Law, CMS provides a helpful clarification regarding the definition of DHS. As stakeholders have had to calculate actual or potential overpayment amounts when noncompliance is identified, some questions have arisen regarding accurate accounting of the tainted referrals. As many entities have concluded, CMS now affirmatively offers a clarifying revision to the definition that a service provided by a hospital to an inpatient does not constitute a DHS payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). The FAH is appreciative of the proposed revision to the DHS definition. Additionally, we believe this analysis should be extended to analogous services provided by hospitals on an outpatient basis as well as to those that are not paid under the IPPS, such as an IRF PPS, LTCH PPS, or IPF PPS.

Further, the proposed rule provides that if the hospital's payment is affected, such as through an outlier patient under the IPPS, then the inpatient services would be considered DHS. It is unclear how or when the hospital would know whether an outlier patient under the IPPS would affect the hospital's payment such that this proposed caveat may make the exception/exclusion unworkable and operationally difficult to evaluate until long after the referral has been made and the patient has been discharged. As such, the FAH urges CMS to reexamine the treatment of instances in which outlier or other similar payments are affected.

*Transaction (§ 411.357(f))*

CMS' clarification to the definition of transaction is one area where the FAH notes a limiting change in the application of the Physician Self-Referral Law rather than a broadening noted in other proposals. Although CMS stated that it is merely clarifying its longstanding policy regarding application of the isolated transaction exception, there are stakeholders who have understood the exception to apply to arrangements that CMS is now proposing to specifically exclude. The Proposed Rule defines isolated transaction to exclude payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services. While many of the other modifications to the Physician Self-Referral Law provide more flexibility, this restricts the potential application of this exception.

The isolated financial transaction is one of a few exceptions that does not require a writing, making it less burdensome than other similar exceptions. At times, entities have considered this exception for unwritten arrangements that were otherwise fair market value, commercially reasonable, and did not take into account the volume of value of referrals from the physician or other business generated between the parties. As it seems CMS is aware through its administration of the SRDP, health care providers have relied on the isolated financial transaction exception where

they discover that the parties have failed to document a services arrangement with a physician in writing, but the services have already been provided. Without the availability of the personal services or fair market value compensation exceptions because the parties did not have a written arrangement that set the compensation in advance of the services being provided, the parties have limited options to address the arrangement.

Based upon the language of the isolated transaction exception and the preamble guidance provided previously, the plain language of the exception allows a single payment for multiple services. If this revision is finalized, CMS will be adding to the burden of Physician Self-Referral Law compliance and likely increasing SRDP submissions as well. The FAH asks CMS to reconsider the need for this clarification and what abusive arrangements it is meant to prevent. The FAH does not see this limited application of the isolated financial transaction exception as necessary to prevent any potential of program or patient abuse when a physician has provided services and a DHS entity has made payment for those services based on terms agreed upon between the parties but simply not condensed to a writing. Particularly with the proposed new exception at § 411.357(z) for limited remuneration to a physician, discussed elsewhere in this comment letter, even CMS has acknowledged that arrangements not in writing or signed by the parties to the arrangement can be permissible under the Physician Self-Referral Law.

*Denial of Payment for Services Furnished Under a Prohibited Referral – Period of Disallowance (§ 411.353(c)(1))*

When a financial arrangement is identified as noncompliant with the Physician Self-Referral Law, particularly if a self-disclosure will be submitted, the parties must determine the period of time the arrangement was noncompliant. This analysis establishes the period of time during which a physician may not make referrals for DHS to an entity and the entity may not bill Medicare for the referred DHS when a financial relationship between the parties failed to satisfy the requirements of any applicable exception. Previously CMS offered guidance in making this determination with the intent of establishing outside parameters that offered certainty for the conclusion of the period of disallowance.

In the FY 2009 IPPS Final Rule, CMS stated that the period of disallowance would begin when the financial relationship failed to satisfy the requirements of any applicable exception. Where the noncompliance is unrelated to the payment of compensation, the period of disallowance would be deemed to end no later than the date that the financial relationship satisfies all requirements of an applicable exception. Alternatively, where the noncompliance is related to the payment of excess or insufficient compensation, the proposed rule provided that the period of disallowance would be deemed to end no later than the date on which the excess compensation was repaid, or the additional required compensation was paid, and the arrangement satisfied all the elements of an applicable exception. CMS highlighted that this was one way to ensure the period of disallowance would be deemed to have ended but that parties could argue that the period ended earlier.

This was a cumbersome provision to apply and raised questions for parties deciding whether the period of disallowance ended. In response to comments received as well as SRDP submissions, CMS proposes to delete its rules on the period of disallowance entirely as the Agency now believes

they are overly prescriptive and impractical. The FAH appreciates this modification proposed by CMS and believes it will help parties in establishing the end of the period of disallowance on a case-by-case basis without concern of having to defend why an arrangement is believed to have ended prior to the deeming provision in the regulations. We appreciate CMS' clarification that the proposal would not impact parties who have relied on the period of disallowance regulations in the past.

In additional guidance, CMS advised parties on remedying compensation problems that occur during the course of an arrangement, and if the arrangement cannot be fixed, how to determine the end of the period of disallowance. The FAH agrees with CMS that if a party identifies an unintended discrepancy (*e.g.*, an administrative or operational error) during the course of the arrangement, the parties are able to remedy it. Ideally the impact of an effective compliance program will be the identification of unintentional errors in financial arrangements within the term of the arrangement, providing the parties the opportunity to cure the error.

The FAH is concerned with those arrangements with unintentional errors that are not discovered during the term of the arrangement. With the guidance provided by CMS, if the error is identified one day after the term of the arrangement ended, the parties are unable to cure an arrangement that, if identified 24 hours earlier, could have been remedied without issue. The fact that an arrangement ended does not make it any more abusive than an arrangement that is ongoing when the error is discovered. The FAH asks CMS to reconsider its position on "turning back the clock" or retroactively curing a noncompliance. The timeline seems somewhat arbitrary, and we believe that even entities with effective compliance programs may not identify all errors within the term of the arrangement. A grace period to correct unintentional errors once an arrangement ends would enable entities with active compliance programs that, for example, review arrangements on a rolling schedule, to take appropriate corrective action for nonabusive arrangements. Moreover, the Proposed Rule indicates that an operational error can be cured during the term of the arrangement regardless of how long that term may be. This leads to the anomalous result that parties could discover an error in the third month of a five-year arrangement and not cure it until Year 4 and remain in compliance, whereas parties that diligently discover an error near the end of an arrangement but are not able to take any action toward curing it until shortly after the end of the arrangement would be unable to cure it.

Equally concerning is the guidance that states that a DHS entity such as a hospital would need to recover any excess payments it has made or be paid any compensation owed it in order to achieve compliance. It is simply not possible for hospitals and other DHS entities to recover overpayments or collect underpayments in all cases, and it is perhaps more often than not that DHS entities are not able to collect all money owed from a physician or group when an operational error is discovered. For one thing, physicians may refuse to pay compensation owed, either because of a perceived legitimate reason (such as a belief that a hospital has not performed all of its obligations as a lessor), has equitable or legal defenses (such as the statute of limitations), or is unable to or is simply unwilling to make the hospital whole. What should be required instead is that hospitals and other DHS entities make a "reasonable effort" to be made whole, and what is a "reasonable effort" will depend on the facts and circumstances, such as the amount of money at

issue. If a large amount of money is at issue, a reasonable effort might very well require the hospital to sue the physician or group, whereas it would be unreasonable to have to bring suit over a small amount of money, where the costs of the suit could dwarf the amount owed. Also, a compromise of the amount owed may be justified if the physician or group has equitable or legal defenses.

More fundamentally, we question the legal basis on which CMS apparently concludes that a financial relationship is created by an operational error (or why such a financial relationship can be cured during the term of an arrangement but not after the arrangement has expired). We believe a better interpretation of the statute is that the “arrangement” between a DHS entity and a referring physician is what the parties intended (as referenced in a written agreement or otherwise) and that unintentional mistakes (such as a physician writing the incorrect amount on a lease check or the DHS entity writing the incorrect amount on a check for call coverage) does not establish a new and different arrangement. Of course, if a DHS entity discovers that it has overpaid a referring physician or has been underpaid by a referring physician and fails to take reasonable efforts to be made whole, a new financial relationship in the form of a gift (forgiveness of debt) may arise, for which there would be no applicable Physician Self-Referral Law exception. But to take the position that a mistake in the execution of an arrangement can be cured only during the period of a written agreement and can be cured only by actual payment/recovery of payment made is unsupported by the statute and is unfair.

#### *Special Rules on Compensation Arrangements (§ 411.354(e))*

In previous comment letters to CMS, the FAH has expressed concern with the challenges presented by the strict liability nature of the Physician Self-Referral Law when a “technical” or “procedural” error is the cause of noncompliance with the law. CMS has implemented revisions to the regulations over a number of years that have addressed some of the inadvertent errors that can occur, and the FAH appreciates these changes. However, as acknowledged by CMS in the Proposed Rule, stakeholders have submitted numerous compensation arrangements to the SRDP that fully satisfied all the requirements of an applicable exception, including requirements pertaining to fair market value compensation and the volume or value of referrals, except for the writing or signature requirements. In many cases, parties have disclosed short periods of noncompliance with the Physician Self-Referral Law at the outset of a compensation arrangement because the parties begin performance under the arrangement before including all key terms and conditions of the arrangement in a writing.

The clarifications that CMS provided in the CY 2016 Medicare Physician Fee Schedule Final Rule that the “in writing” requirement is satisfied by the “contemporaneous documents evidencing the course of conduct between the parties involved” and that the signature requirement is satisfied by obtaining the required signatures within 90 consecutive days after the arrangement became noncompliant have been appreciated by our members. The subsequent codification of the writing requirement guidance at section 1877(h)(1)(D) of the Act and incorporated into the regulations at § 411.354(e) was helpful in solidifying this clarification. These changes acknowledge the challenges encountered in administering arrangements with physicians and the greater flexibility requested previously regarding the signature requirement.

The FAH commends the proposed change in this Rule addressing CMS' policy on temporary noncompliance with the signature as well as the writing requirements of various compensation arrangement exceptions. We agree that a modification to the Physician Self-Referral Law that permits parties to memorialize an arrangement in writing and sign the written documentation within 90 days, as long as the arrangement otherwise meets all the requirements of an applicable exception, poses no risk of program or patient abuse. We believe that this modification, if finalized, would provide the flexibility in complying with the Physician Self-Referral Law that the FAH requested in our comments to the RFI. We thank CMS for this modification and believe that this will decrease the number of submissions to the SRDP for nonabusive arrangements. A decrease in submissions for these "technical" violations will allow CMS to address those arrangements disclosed that represent meaningful noncompliance with the purpose and intent of the Physician Self-Referral Law.

Although we believe 90 days is a helpful revision, permitting signatures and a writing to be obtained within 120 or 180 days would further cover other low risk situations where the only components that are not met are the writing or the signature requirement. We believe that when the other elements of a Physician Self-Referral Law exception are met and can be demonstrated for the duration of the arrangement with or without a writing, the risk to the Medicare program is very low during a 180-day grace period. Additionally, the clarification provided by CMS regarding the ability to establish the "set in advance" requirement upon practice patterns is also helpful. The set in advance guidance further supports extending the grace period, as an identifiable pattern would need to be present to support the compensation rate paid to the physician.

The FAH also appreciates CMS' clarification of its longstanding policy that an electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in our regulations. We encourage CMS to include specific regulation text at § 411.354(e) to reflect its policy on electronic signatures and documents by explicitly acknowledging that electronic signatures, including assent transmitted via email, are sufficient to meet the signature requirements of the applicable exceptions.

*Exception for Remuneration Unrelated to the Provision of DHS (§ 411.357(g))*

The Physician Self-Referral Law has long held that remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the Physician Self-Referral Law, if the remuneration does not relate to the provision of DHS. Operationally this exception has been interpreted so narrowly that it has been of very little utility for hospitals and physicians. RFI commenters questioned what remuneration, if any, is permissible under the exception, if the exception does not apply to any item, cost, or service that could be allocated to Medicare or Medicaid under cost reporting principles, or to remuneration that is offered in any preferential or selective manner whatsoever. The FAH appreciates CMS reconsidering its analysis of the exception and expanding the application from its previous interpretation.

The proposed revision deletes the current provisions at § 411.357(g)(1) and (2) in their entirety and removes the phrase "directly or indirectly" from the regulation text. In place of the existing § 411.357(g)(1) and (2), CMS proposes language that incorporates the concept of patient

care services as the “touchstone for determining when remuneration for an item or service is related to the provision of DHS.” The clarification notes that remuneration from a hospital to a physician does not relate to the provision of DHS if the remuneration is for items or services that are not related to patient care services.

The majority of financial relationships between hospitals and physicians relate to the furnishing of DHS, in particular, inpatient or outpatient hospital services. However, FAH appreciates the expanded interpretation of this exception. In considering relationships with physicians unrelated to the provision of DHS, the FAH believes this new interpretation will facilitate greater opportunity for hospitals to provide free continuing medical education (CME) to physicians. CMS permits the provision of CME to physicians on the medical staff if it is provided on site and is primarily for the benefit of the hospital’s patients, for example, training on the prevention of nosocomial infection. Now, with this expanded application of this exception, our understanding is that much of the remote CME that hospitals would like to offer to their physicians will qualify for this exception. The revised analysis of this exception will permit hospitals to offer CME training to physicians in a variety of ways that are more compatible with the way CME is often accessed by physicians, without being abusive under a Physician Self-Referral Law analysis. The FAH appreciates the changes made by CMS and requests confirmation that the analysis of CME provided via computer access to a physician not located onsite at the hospital is an example of remuneration that will qualify for this exception under this broadened application proposed by CMS.

*Exception for Fair Market Value Compensation (§ 411.357(l))*

The fair market value exception to the Physician Self-Referral Law has been used for a variety of arrangements, often for those that were not specifically addressed by statutory exceptions. Previously, CMS did not allow the use of the fair market value exception for the rental of office space due to concerns related to abusive practices and not considering it an item or service. In the Proposed Rule, CMS offers a revised analysis of the exception that acknowledges nonabusive and legitimate arrangements for the lease of office space that are unable to satisfy the elements of another exception in some instances due to a term of less than one year. The FAH appreciates the reconsidered analysis for the application of the exception and the additional flexibility it affords short term lease arrangements.

FAH asks CMS to consider another revision to the fair market value exception that would bring it in line with other existing exceptions. Based on revisions finalized in the Calendar Year 2016 Physician Fee Schedule, the fair market value exception allows arrangements for any period of time, including arrangements for more than a year, and allows the arrangement to be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change. While this does afford flexibility for parties entering into these arrangements, the FAH asks CMS to include a holdover provision for the fair market value exception similar to that in the exceptions for rental of office space, rental of equipment and personal services exceptions. Currently an arrangement that meets the fair market value exception must be renewed on the same terms and conditions and must satisfy all the requirements of the exception at the time the physician makes a referral for DHS and the entity bills Medicare for the

DHS. Nothing in the exception requires parties to renew the arrangement in writing; however, the parties must have written documentation establishing that the renewed arrangement was on the same terms and conditions as the original arrangement. This is different than an indefinite holdover of an arrangement on the same terms and conditions. Although CMS did not choose to adopt an indefinite holdover for the fair market value exception in the CY 2016 PFS, the FAH asks CMS to reconsider its position. As many of the changes in this Proposed Rule endeavor to reduce the burden of compliance with the Physician Self-Referral Law, we are unable to identify a benefit from this different extension provision for the fair market value exception.

#### *Electronic Health Records Items and Services (§ 411.357(w))*

The exception for certain arrangements involving the donation of interoperable EHR software or information technology and training services has evolved since its inception in 2006. As technology developed and the EHR being provided under the exception changed, both CMS and the OIG revised and extended the sunset of the exception and safe harbor multiple times. CMS is now proposing to remove the sunset, which the FAH supports. We believe that the continued availability of this exception encourages adoption of EHR technology by continuing the certainty of the cost related to EHR items and services for donors and recipients.

CMS also proposes to add a specific reference to cybersecurity in the introductory text of the exception to clarify that the exception is available to protect the donation of cybersecurity software and services and software that “protects” EHRs. In another portion of the proposed rule, CMS proposes a new exception for cybersecurity technology and related services at § 411.357(bb). The FAH has considerable concerns with the new cybersecurity exception as proposed and has provided separate comments on that proposal below.

The FAH believes the EHR cybersecurity proposal and the separate cybersecurity exception proposal have significant overlap and could lead to confusion were both finalized. As such, should CMS finalize the separate cybersecurity exception, the FAH does not believe the proposed cybersecurity related clarifications to the EHR donation exception are necessary. Should CMS not finalize the separate cybersecurity exception, then the FAH would find it helpful to clarify in the EHR exception that the predominant purpose of the software or service must be cybersecurity associated with EHRs – that is, inclusion of “cybersecurity software and services, necessary and used predominantly to create, maintain, transmit, receive or protect electronic health records if the identified conditions are met.”

#### *Providing Flexibility for Nonabusive Business Practices*

##### *Limited Remuneration to a Physician (Proposed § 411.357(z))*

In a very welcome development to the Physician Self-Referral Law, CMS draws upon its experience in administering the SRDP to propose a new exception that would protect limited remuneration paid to a physician if certain criteria are met. CMS noted that many disclosures involved non-abusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician’s provision of items and services to the entity. In some instances, the arrangements were ongoing service arrangements under which services

were furnished sporadically or for a low rate of compensation; in others, services were furnished during a short period of time and the arrangement did not continue past the service period. CMS acknowledges that despite a hospital's legitimate need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business generated by the physician, the arrangement could not satisfy all requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties. The violations described appear to be very much in line with certain "technical" violations that have plagued hospitals for years and for which relief has been sought.

The proposed exception at 411.357(z) provides an option for many of these arrangements that could not satisfy each and every element of an exception but really posed no risk of program or patient abuse. Certain elements of the exception would need to be satisfied such as: (1) The arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit for either or both of the parties; (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the items or services. These proposed criteria seem reasonable and appropriate as safeguards under the Physician Self-Referral Law and we do not believe that it would be necessary to limit the applicability of the exception to items and services that are personally furnished by the physician. Similarly, it would not be necessary to include a condition that the arrangement must not violate the AKS or other Federal or state law or regulation on billing and claim submission.

CMS proposes to permit the exception to apply only where the remuneration does not exceed an aggregate of \$3,500 per calendar year, which would be adjusted for inflation in the same manner as the annual limit on nonmonetary compensation and the per-instance limit on medical staff incidental benefits. The FAH thanks CMS for its efforts to understand the challenges faced by hospitals in conducting Physician Self-Referral Law-compliant arrangements with physicians and acknowledging that unintentional and often administrative errors should not constitute a violation of the Physician Self-Referral Law. The one element of this exception the FAH urges CMS to reconsider is the aggregate limit of \$3,500 per calendar year. The FAH believes that a higher annual aggregate limit of \$10,000 per year for all arrangements with a physician for items and services provided under this exception is more appropriate to cover the typical range of commercially reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. We are concerned that an aggregate limit set at \$3,500 per year may continue to result in technical violations that are non-abusive but must be reported under the SRDP.

#### *Cybersecurity Technology and Related Services (§ 411.357(bb))*

Our members are very aware of the threat cyberattacks pose in health care and the importance of protecting themselves and their patients' information from such attacks. We appreciate that CMS has proposed a new exception at § 411.357(bb) to protect arrangements

involving the donation of certain cybersecurity technology and related services. Permitting such donations may contribute to improved cybersecurity protection for components of the health care industry by removing a possible barrier to donations to address the growing threat of cyberattacks and can prevent access to health records and other information essential to the delivery of health care. However, the FAH has several concerns, discussed in detail below, about the breadth of the proposed exception, including: the ability of an entity to provide cyber security technology and services that, as a practical matter, result in effective security; potential liability in case of a cyberattack; and fostering a cost-shifting rather than a cooperative environment.

The proposed exception is intended to address the increase of cyberattacks created by the digitization of health care delivery and the increase of interoperability and data sharing in health care. As CMS noted, the cost of cybersecurity technology and related services has increased dramatically, to the point where some providers and suppliers are unable to invest in adequate cybersecurity measures. While entities may have the ability to donate certain cybersecurity technology and related services when it provides additional protection, the parameters for doing so may be more limited than seems contemplated by the proposed exception. Cybersecurity protection can be a whole suite of services, beyond simply providing equipment and involving active management, monitoring, and developing an effective response system if an issue arises. If cyber protection requires the entire suite of services, as a practical matter, this may not be possible for an outside entity to provide. On the other hand, if cyber protection is donated on a more limited basis, it is unclear whether this limited donation would be effective. Further, these arrangements – in any form – raise concerns about liability for the donating entity in the event of a cyberattack.

The FAH also is concerned that the provision of cybersecurity technology and related services to physician practices could increase the risk of fraud and abuse if the donation of cyber protection were become a bargaining chip, this fostering a cost-shifting from entities in need of such services and potential donors rather than a cooperative environment between the entities.

As such, the FAH urges CMS to reconsider this proposed exception and whether cybersecurity protection and its donation is understood sufficiently at this time to proceed with such an exception. If an exception is finalized, the FAH encourages CMS to limit the services and equipment that can be provided under the exception in recognition of the concerns raised above. The FAH also notes the comments provided above regarding the potential for stakeholder confusion regarding the overlap between the EHR-related cybersecurity proposal and this separate cybersecurity exception proposal.

*Payments by a Physician Exception and Clarification that Payment by a Physician or an Entity for Something of Equal Monetary Value does not Create a Compensation Arrangement*

In the Proposed Rule CMS informs that it has revised its interpretation of the statutory payments by a physician exception and acknowledges that the exception is applicable notwithstanding that a regulatory exception is on point, and that the payments by a physician exception is unavailable only in circumstances where there is another statutory exception on point (such as the exceptions for space or equipment leases). The practical effect of the revised interpretation would be to allow parties to rely on the statutory payments by a physician exception,

where it is applicable, instead of having to comply with the requirements of an exception created under the Secretary’s rulemaking authority under the Physician Self-Referral Law (e.g., the exception for fair market value compensation at section 411.357(l)), which by definition must be narrowly tailored. The FAH agrees with CMS’s revised interpretation, which has been urged upon CMS for years, and supports the accompanying proposed changes to regulations text.

In conjunction with its proposal to reverse its position on the use of the payments by a physician exception, CMS also: (1) proposes to retract its prior statements that office space is neither an “item” nor a “service,” thus allowing an arrangement for the lease of space for a term of less than a year to be protected by the exception for fair market value compensation at section 411.357(l), and (2) clarifies that a financial relationship is not created where a physician or entity pays the exact same amount of cash in exchange for a cash equivalent (such as a gift card) or acts as a pure pass-through, taking money from one party and passing the exact same amount of money to another party. The FAH supports the proposal and the clarification.

#### *Cost of Compliance with the Physician Self-Referral Law and Expedited Self-Referral Disclosure Protocol*

It is clear that CMS has drawn from its experience with submissions to the SRDP in developing many of the clarifications in the Proposed Rule. The FAH agrees with CMS that some of the non-abusive arrangements that have been disclosed in large numbers will likely decrease if the new exception for limited remuneration to a physician is finalized as well as the increased flexibility in obtaining a writing and signatures is put in place. However, these modifications do not address other arrangements that also pose a low risk of program or patient abuse and will still be disclosed under the SRDP. Hospitals can expend significant resources and time to identify, report, and resolve Physician Self-Referral Law compliance concerns under the SRDP. They also face financial uncertainty, even after submitting a self-disclosure, as they await their turn in the CMS self-disclosure backlog. Consequently, the FAH has long supported the concept of an expedited SRDP review process.

The FAH requests that CMS consider establishing an expedited SRDP review process for violations of the Physician Self-Referral Law, particularly for Physician Self-Referral Law violations that are “technical” in nature and cannot be resolved as they are beyond the period of disallowance or do not qualify for the additional flexibilities included in this Proposed Rule. In establishing such an expedited process, the current self-disclosure process would be streamlined (thereby lessening the financial burden and uncertainty within the provider community) while reducing the current backlog of CMS self-disclosures. CMS could provide an option for disclosing parties whereby for certain Physician Self-Referral Law technical violations a flat fee would be assessed upon the party (e.g., \$5,000 for technical violations discovered within one year of its occurrence or \$10,000 for technical violations discovered after one year). The FAH believes that CMS has been delegated broad discretion in exercising its authority to compromise amounts owed, but should CMS believe that statutory language is needed to implement the approach recommended here, the FAH urges CMS to support such Congressional action as part of the efforts the government is undertaking to address burdensome regulatory requirements.

Interrelationship Between the Physician Self-Referral Law and AKS

As noted by CMS and the OIG, the proposed revisions to the physician self-referral law and the AKS are issued by separate Agencies within the federal government. However, the interrelationship that exists in analyzing and implementing arrangements between these laws cannot be ignored. The FAH acknowledges the efforts that have been undertaken by CMS and OIG in considering the impact of any proposals or revisions to the application of the fraud and abuse laws and is hopeful the final rules will demonstrate your cooperative relationship and provide more consistent guidance between the respective laws.

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The FAH appreciates the opportunity to comment on these proposed rules. We look forward to continued partnership with CMS to modernize and clarify the Physician Self-Referral Law in ways that ensure compliance is achievable while supporting providers to better collaborate and coordinate care delivery via payment models that reward improved health outcomes for beneficiaries. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Kuntz". The signature is fluid and cursive, with a large, sweeping flourish at the end.