Federation of American Hospitals®
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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

SUBJECT: ***CMS-1720-C, Medicare Program; Request for Information Regarding the Physician Self-Referral Law***

Dear Administrator Verma:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the above referenced Request for Information (RFI), published in the *Federal Register* on June 25, 2018 (83 Fed. Reg. 29524). 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 commends CMS's efforts to understand the challenges related to implementing new payment models while operating under the current regulatory provisions of the Physician Self-Referral Law (Stark Law), 42 U.S.C. 1395nn. The following comments offer FAH's support of CMS in its intent to reduce regulatory burden and dismantle barriers to value-based care transformation while also protecting the integrity of the Medicare program. Such improvements are needed to allow the law to keep pace with the future of health care payment and delivery models aimed at providing patients with coordinated care, while enhancing quality and lowering costs.

OVERVIEW OF NEED FOR STARK LAW IMPROVEMENTS

As our current health care payment and delivery system focuses on value-based care models, including care coordination, it is critical that CMS remove obstacles that prevent hospitals from partnering with physicians and other providers to provide high quality care at lower costs in these models. Flexibility in developing these arrangements will ensure that identified regulatory barriers or prohibitions do not prevent those relationships that may be most beneficial to improving the care provided to patients. The Stark Law was developed in a fee-for-service payment system and, with the transition to value-based payment, it is becoming clear that the existing exceptions are not drafted in a manner that provides adequate certainty to hospitals or physicians that new models of compensation developed in a value-based system will be compliant.

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 Stark Law alone. These changes affect the application of the Federal Anti-Kickback Statute (AKS) and the Civil Monetary Penalties Law (CMPL) to these arrangements. Under a fee-for-service payment system, concerns regarding the potential for improper influences in providing patient care are more readily apparent given the inherent financial incentives to provide more services. To improve quality of care and reduce costs, new care delivery and payment models are designed to encourage greater integration and coordination of care and payment between and among providers and their business partners. In large part, these new models eliminate the financial incentive to provide more services and replace it with an incentive to provide more value-driven care across the care continuum.

While encouraging and considered an improvement over the traditional fee-for-service system, these new value-based care models may get caught up in the existing fraud and abuse legal framework. For example, compensating physicians with savings generated from care plan coordination among clinical and non-clinical partners or the provision of support services to patients at a discounted rate may trigger scrutiny. **While "exceptions" to the Stark Law and "safe harbors" to the AKS exist to protect certain financial arrangements in health care, these protections are narrow in scope. As such, changes to the current framework are needed to make it more compatible with health care delivery system transformation.** Modifying some of these regulatory barriers in a thoughtful manner will help improve patient outcomes through the delivery of more cost-efficient, enhanced-quality care.

Patients deserve a future in which providers are able to better collaborate and coordinate care delivery and utilize payment models that reward improved health outcomes. There is wide support among health care consumers, providers, manufacturers, and payers for modifying the current fraud and abuse framework to make it more compatible with value-based health care while retaining important protections against fraud and abuse.

RECOMMENDED STARK LAW IMPROVEMENTS

The transition to value-based and coordinated care arrangements requires modernizing the Stark Law. The FAH urges CMS to create a single, overarching

alternative payment model (APM) Waiver of the Stark Law for all gainsharing or similar arrangements under CMS-led APMs implemented through its demonstration authority.

Gainsharing, shared savings and other similar arrangements between hospital and other providers (referred to collectively as Incentive Payment Arrangements or Incentive Payments) stand at the heart of many APMs and serve to align participating providers' otherwise disparate financial interests to incentivize improved quality and cost outcomes. Incentive Payment Arrangements are not developed overnight. Rather, they take careful deliberation on the part of numerous stakeholders, involving time-consuming negotiations with potential partners and painstaking drafting of Incentive Payment Arrangements. **Accordingly, the FAH urges CMS to reverse its existing case-specific approach to APM fraud and abuse waivers and develop a single, overarching waiver applicable to all Incentive Payment Arrangements under a CMS-led APM.**

Additionally, and as outlined below, the FAH also urges CMS to implement a new bundled payment program exception to the Stark Law or modify the current Stark Law risk sharing exception at 411.357(n) to permit gainsharing under non-CMS-led APMs, such as commercial payer arrangements. We recognize that CMS has previously noted that certain Stark exceptions can apply to Incentive Payment Arrangements, and we agree with CMS's view. However, to remove any uncertainty for providers and incentivize continued development of innovative models, we encourage CMS to develop a specific Stark exception for non-CMS-led APMs.

Should CMS not move forward with an overarching waiver applicable to all Incentive Payment Arrangements under a CMS-led APM, the FAH would urge CMS to implement a new bundled program exception to the Stark Law or modify the current Stark Law risk sharing exception for CMS-led APMs as well.

APM Waiver

Need for APM Waiver

With the passage of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), Congress signaled to the provider community the value and importance of APMs in fundamentally reshaping the way health care is paid for and delivered. **To achieve this vision, the hospital community must be afforded the flexibility to align physicians' and other providers' otherwise divergent financial interests, while promoting incentives to reduce costs and improve quality on a timely and informed basis. While APMs offer the chance to change this paradigm, the Stark Law stands as an impediment.**

To date, many current CMS-administered APMs that encourage Incentive Payment Arrangements between hospitals and physicians as a tool to promote alignment between hospitals and physicians have included waivers of the Stark Law. However, the FAH respectfully notes that participants were not timely informed of such waivers, leaving considerable legal uncertainty within the provider community. This unfortunately resulted in fewer participants able to take advantage of these arrangements.

For example, for the Bundled Payments for Care Improvement (BPCI) Advanced model, CMS and the Department of Health and Human Services Office of Inspector General (OIG) did not issue any fraud and abuse waivers until several months after announcing the program and were unable to even confirm that waivers would be forthcoming. Likewise, when CMS instituted the Comprehensive Joint Replacement (CJR) model for hospitals, fraud and abuse waivers from CMS and the OIG were not issued at that time but appeared later. As a result of this legal uncertainty and delay, many FAH members lose valuable preparation time with respect to developing and implementing Incentive Payment Arrangements for planned APMs and then must either rush to establish such arrangements prior to program implementation or simply not participate.

Accordingly, the FAH urges CMS to work with the OIG to implement a long-term solution that will establish legal certainty around permissible Incentive Payment Arrangements while encouraging hospitals and physician participation in APMs. **Specifically, CMS and the OIG should develop a single, overarching APM Waiver of the Stark Law and AKS, applicable to all Incentive Payment Arrangements developed and administered pursuant to the terms of any CMS-led APM – with the necessary parity for non-CMS-led APMs, such as commercial payer arrangements**. CMS could also issue program-specific waivers where circumstances warrant a different approach. The development of a single waiver would streamline the process for both CMS and the OIG and create additional legal certainty for program participants.

Proposed APM Waiver Parameters

In adopting a comprehensive APM Waiver, CMS could consider potential waiver parameters, as outlined below. In developing the proposed APM Waiver parameters, FAH has drawn heavily from the existing BPCI Model 2 and CJR model program safeguards, as well as CMS's approach to, and structure of, the Accountable Care Organization (ACO) fraud and abuse waivers. The FAH believes ACO fraud and abuse waivers have achieved a delicate and difficult balance: pairing critical program integrity safeguards with adequate flexibility for program participants.

On this basis, the FAH proposes the following requirements for a new APM Waiver:

- Any amounts shared under an Incentive Payment Arrangement by a participant hospital are earned by the participant hospital: (a) solely pursuant to the terms of the APM; and (b) during the term of the APM, even if the actual distribution or use of the payments occur after the expiration of the APM;
- The participants in the arrangement are selected based upon criteria to promote the quality, cost, and overall care to be delivered to APM beneficiaries; the participant hospital's Incentive Payment Arrangement with each collaborator is set forth in writing and specifies both the care redesign services to be provided by the collaborator and the APM-compliant Incentive Payment Arrangement methodology;
- The participant hospital's Incentive Payment Arrangement methodology is set in advance of any earned amounts from CMS for that specific performance period;
- Any Incentive Payment Arrangement payment made to a collaborator by the participant

hospital is for actual care redesign services provided;

- Only those collaborators who meet quality measures established by the participants in advance of the Incentive Payment Arrangement are eligible to receive an Incentive Payment; such quality measures must be reasonably related to improving quality outcomes for the participants' patient population;
- Any Incentive Payment Arrangement payment made by a participant hospital to a collaborator is not knowingly made to induce the collaborator to reduce or limit medically necessary items or services to APM patients under his or her care.

The FAH acknowledges that, depending on the applicable APM, CMS may wish to add or subtract from the requirements of the above APM Waiver. However, the FAH suggests that the core tenets of the waiver would remain the same across all such APMs. In addition, as noted previously, CMS and the OIG would continue to have the ability to issue program-specific waivers, where warranted.

Timing of APM Distributions

Under the current structure for existing APMs, certain characteristics create challenges to successfully develop effective incentives for physicians participating in an APM Incentive Payment Arrangement. For example: the timing of these payments permitted under some bundled programs are too attenuated to drive behavior; programs that limit the payments to no more than once per calendar year are too restrictive; and the time lag between the performance of activities that result in an Incentive Payment and the time when that payment is made minimizes the impact the potential payment may have on future behavior. Specifically, current participant hospitals in the CJR model choosing to share net payment reconciliation amounts are prohibited from making any payment until after the annual reconciliation process – a time-consuming process that may take up to 18 months from the start of a performance year. **This lengthy process stifles meaningful change, while undermining efforts to improve quality and create cost savings under the CJR model. Accordingly, the FAH urges CMS to permit at least a quarterly, if not monthly, Incentive Payment schedule for all applicable APMs.**

The FAH also requests that CMS consider increasing the total amount physicians and/or physician group practices (PGPs) may be eligible to receive under current and future APMs while remaining eligible for waiver protection. CMS has entrusted hospitals with the responsibility to oversee and implement care redesign. **Accordingly, hospitals should have increased flexibility in designing their respective Incentive Payment Arrangement programs and determining the amount of savings to share with their collaborators while remaining eligible for waiver protection. This should include allowing participant hospitals the opportunity to raise the Incentive Payment cap (*i.e.*, increase the total amount of Incentive Payment dollars a physician or PGP is eligible to receive.)** This increase could be accomplished by applying the cap to the total episode savings up to 50 percent rather than limiting it only to the Medicare physician fee schedule payment. This would promote the effectiveness of any participant hospital's Incentive Payment Arrangement program and provide more meaningful financial incentives with limited additional fraud and abuse risk.

Create a New Stark Exception or Modify Existing Stark Exception

New APM Exception

In addition to an overarching waiver applicable to all Incentive Payment Arrangements under a CMS-led APM, the FAH also urges CMS to implement a new Stark Law exception to facilitate, with appropriate program oversight, non-CMS-led APMs, such as commercial payer arrangements. Such an exception is necessary to ensure parity in the treatment of CMS-led and non-CMS-led APMs and further incentivize these innovative models. Such an exception would also be needed for CMS-led models should CMS choose not to move forward with an overarching waiver.

Under such an APM Exception, for example, the provision of an Incentive Payment, directly or indirectly, by a designated health services (DHS) entity to a physician participating in a qualified APM would be deemed protected under the Stark Law, provided that the parties adhere to all program and patient safeguards otherwise mandated by the APM. The same safeguards and parameters outlined above regarding the APM waiver could apply to the Stark APM Exception. **The scope of the above APM Exception, the inherent protections that come with an APM arrangement, and the substantial program safeguards outlined above will ensure that Incentive Payment Arrangements evolve consistent with CMS's program goals to promote transparency, improve quality, and safeguard against payments for referrals.**

Clarify the Risk Sharing Exception

CMS could also expressly clarify that the existing risk sharing exception at 411.357(n) applies to compensation arrangements between a managed care organization or an independent physician's association and a physician (either directly or indirectly through a subcontractor) and to CMS-led arrangements. That is, compensation arrangements between CMS and an APM-participating physician (either directly or indirectly through a downstream contractor, like a hospital) is protected under the Stark Law risk sharing exception.

The FAH believes this proposed clarification to the risk sharing exception aligns with prior statements made by CMS in the preamble to the Stark Phase II regulations. Specifically, in response to a prior request for clarification relating to the definition of "managed care organization," CMS stated that it "purposefully declined to define the term 'managed care organization' so as to create a broad exception with maximum flexibility." 69 Fed. Reg. 16054, 16114 (March 26, 2005). **CMS's statement regarding "maximum flexibility" supports an expansive risk sharing exception, one that encompasses CMS-led APMs and non-CMS-led APMs, such as commercial payer arrangements.** Hospitals, as the leader and coordinator of any APM, act similarly to that of their managed care organization counterparts from an operations perspective.

We note that here, as with the proposed APM Exception, CMS may wish to consider instituting specific safeguards to protect against patient and program abuse. We refer CMS to

the APM Exception for our discussion of such program safeguards.

Clarify the Volume or Value Standard

If the event that CMS does not develop an APM Waiver (or, at a minimum, an APM Exception), it should clarify the "volume or value" standard for percentage compensation arrangements for qualified APMs. The Stark Phase III rule clearly stated that percentage compensation arrangements can be permissible in this regard, but CMS declined to expressly add that type of arrangement to the special deeming rules in 411.357(d). Due to recent enforcement activity, including a misunderstanding by the Department of Justice as to how the "volume or value" rules work, **we strongly urge CMS to recognize that there is essentially no difference between percentage compensation and per click compensation (which is covered by the special deeming rules).**

CMS was clear in both the Phase II and Phase III rules that percentage compensation can be considered "set in advance." In Phase I, CMS stated that compensation is deemed not to take into account the volume or value of referrals or other business generated, provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. That standard is codified at 411.354(d)(3) for per click compensation. **CMS should clarify that a percentage compensation arrangement involving the distribution of shared savings that is fair market value and in which the percentage does not vary over the course of the arrangement (*e.g.*, the percentage is a flat 50 percent of savings regardless the amount of referrals instead of 50 percent of the savings for the first 100 cases referred and 60 percent of the savings for the next 100 cases referred) does not impermissibly take into account the volume or value of referrals or other business generated**.

Fair Market Value Carve Out for APMs

The FAH also urges CMS to consider whether a fair market value requirement is necessary for APM Incentive Payment Arrangements. Undoubtedly, those APM-participating physicians and PGPs eligible to receive an Incentive Payment will have provided critical care redesign services related to both quality improvement and cost control. However, because the methodology employed for any Incentive Payment Arrangement will necessarily hinge on total savings generated by all participants to the APM, it may often be difficult to conclusively determine that an Incentive Payment meets fair market value. Fair market value concerns are significantly reduced in the context of CMS-led APMs and non-CMS-led APMs, such as commercial payer arrangements.

Other Stark Law Considerations

Commercial Reasonableness

Certain exceptions under the Stark Law utilize several standards to qualify for the exception. Three primary standards used in Stark exceptions require that remuneration under an

arrangement: is consistent with fair market value; does not take into account the volume or value of referrals; and is commercially reasonable. **The fair market value and volume or value of referrals standards generally are well understood and can be objectively determined. If payments to physicians are fair market value and do not take into account the volume or value or referrals, these two standards should satisfy the purposes of the Stark Law. The commercially reasonable standard, however, is vague and not generally well understood or objectively measured, and therefore should be eliminated**.

There is little definitive guidance regarding the relationship between fair market value and commercial reasonableness. Fair market value is more of an objective standard (which can be determined through comparison to what may be generally paid in the industry), while commercial reasonableness is more of a subjective standard without an industry-wide database to consult when considering this element of an arrangement. Further, some interpretations of commercial reasonableness have reached well beyond the language and clear meaning of the statute. These interpretations do not take into account that there are a number of legitimate and appropriate reasons for a hospital to engage in a particular arrangement that may not appear commercially reasonable under a very narrow and improper interpretation of this term, such as community need and access, as well as initiating or continuing a particular service line. As hospitals look to develop systems for implementing coordinated care for patients, ensuring that the proper care is available from the needed practitioners should not be hampered by an unclear standard such as commercial reasonableness that raises the potential for noncompliance and carries high financial penalties. At a minimum, CMS should clarify 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.

The FAH is concerned that the commercially reasonable standard also may impede the development of new APMs. These newer models are highly complex, especially considering Incentive Payment Arrangements between hospitals and physicians and other downstream providers that must be undertaken for the models to be implemented effectively. **Attempting to apply a vague and poorly understood standard such as commercial reasonableness to these models creates more uncertainty and is a significant barrier that continues to unnecessarily chill development and implementation of these new models.**

Overall, the commercially reasonable standard creates substantial uncertainty. Commercial reasonableness is a question of whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions "typical" of similar arrangements between similarly situated parties. Asking whether the amount of the purchase is reasonable is the subject of fair market value determinations, not commercial reasonableness, and information about what is "typical" is not readily available in the market. **The law would be strengthened if this standard were removed, with the more objective and understandable standards of fair market value and volume or value of referrals remaining.**

Signature Requirement

CMS has previously acknowledged the challenges and related administrative burden associated with the strict application of signature requirements related to the Stark Law exceptions requiring a writing. The FAH appreciates the clarification provided by CMS in the CY 2016 Medicare Physician Fee Schedule Final Rule that the "in writing" requirement is satisfied by "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 calendar days after the arrangement became noncompliant. More recently, in Section 50404 of the *Bipartisan Budget Act of 2018*, Congress indicated its desire that the signature requirement should be relaxed. Accordingly, the regulatory proposal in the CY 2019 Medicare Physician Fee Schedule Proposed Rule would clarify and simplify the temporary noncompliance with signature requirements set forth at 42 C.F.R. § 411.353(g) and would remove the regulatory provision limiting the use of the temporary noncompliance signature rule to once every three years per referring physician, allowing for the unlimited use of this provision. The FAH believes that these changes are appropriate and beneficial.

Although these changes acknowledge some of the challenges encountered in administering arrangements with physicians, CMS could create greater flexibility in implementing the signature requirement. **To that end, CMS could modify the signature requirement to provide that clear evidence of assent between the parties to the terms of the arrangement is sufficient to meet the Stark Law signature requirement.** CMS itself has effectively acknowledged that, in situations where the terms of an arrangement are clearly outlined, all that is required to continue the arrangement is the clear assent of the parties. This was evidenced by previous CMS regulatory action that allowed for indefinite contractual holdovers when the parties continue to operate under the existing terms of the arrangement. The FAH supports this expanded interpretation and requests that CMS adopt this approach in place of the current signature requirement.

We also urge CMS to explicitly allow electronic signatures, including clear electronic expressions of assent, to satisfy the signature requirement. In the digital age, most communications take place electronically; for example, often a series of electronic writings establishes the terms of the arrangement and clearly indicates the assent of the parties to those terms. Therefore, CMS should revise the signature requirement to reflect that reality by explicitly acknowledging that electronic signatures, including assent transmitted via email, are sufficient to meet the signature requirements of the applicable exceptions. This approach also would be consistent with the application of state commercial law.

An additional benefit to changes acknowledging assent between the parties is likely to be a reduction in the number of "technical violations" to the Stark Law reported under the Self-Referral Disclosure Protocol (SRDP). As CMS has been addressing a backlog of these submissions, reducing the number of arrangements disclosed would assist the Agency in focusing on issues disclosed that represent meaningful noncompliance with the purpose and intent of the Stark Law, rather than a technical violation.

Cost of Compliance with the Stark Law and Expedited Self-Referral Disclosure Protocol

While applying the Stark Law to the more common types of arrangements with physicians, as well as the newer arrangements under APMs, hospitals can expend significant resources and time to identify, report, and resolve Stark 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.**

Accordingly, the FAH recommends that CMS establish an expedited SRDP review process for violations of the Stark Law, particularly for Stark Law "technical violations." 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 Stark 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.

Stark Law Requirement of Compliance with AKS

We urge CMS to eliminate the requirement in Stark Law compensation arrangement exceptions that the arrangement not violate the AKS. This 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 Stark Law is not a substitute for complying with the AKS, and thus this requirement is unnecessary. Further, the requirement that arrangements not violate any federal or state billing and claims submission rules is equally unnecessary and should be eliminated.

Interrelationship Between the Stark Law and AKS

Although the Stark RFI was issued by CMS and focuses on possible changes and improvements to the Stark Law, it is critical that CMS keep in mind the impact of any resulting proposals or revisions to the application of other fraud and abuse laws, such as the AKS. To make changes under one component of the fraud and abuse laws without a correlating revision to the other may render the change of little to no utility to the providers working to implement coordinated care efforts.

As such, the FAH is pleased that OIG just released an RFI entitled, *Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties* [RIN: 0936-AA10] to address concerns with the AKS not covered by this RFI and hopefully ensure a harmonious application of the fraud and abuse laws in any future proposed

rulemaking that may result from this process. One such example that falls under the AKS is the importance of the discount and Group Purchasing Organizations (GPO) harbors at 42 C.F.R. §§1001.952(h) and (j). These are important tools that allow hospitals and other providers and suppliers to receive lower prices on goods and services while ensuring that legitimate arrangements do not pose any risk under the AKS. The discount safe harbor applies to price discount and rebate arrangements between purchasing hospitals and providers and their suppliers (typically, a manufacturer or distributor). The GPO safe harbor, meanwhile, applies to the arrangement between the GPOs, hospitals and other providers, and suppliers. Aside from the fact that the statute contains exceptions to the AKS for discounts and GPOs, and Congress did not provide the HHS Secretary with authority to narrow these statutory exceptions through regulatory safe harbors. If the OIG were to consider changes to these safe harbors, we caution that the OIG should consider that various stakeholders across the health care supply chain rely on these safe harbors to provide legal certainty for certain business arrangements that achieve lower costs for providers and Medicare beneficiaries.

Physician Self-Referral to Physician-Owned Hospitals

It is critical that improvements to the Stark Law ultimately result in increased flexibility essential to clinically and financially integrate hospitals, physicians, and other providers in new payment and delivery models that promote coordinated, high quality of care at lower costs**. At the same time, it is important that CMS continues to reject efforts by those who would seek to weaken the Stark Law ban on self-referral to physician-owned hospitals.** Such arrangements are mired in conflicts of interest, and years of independent data show such arrangements result in over-utilization of Medicare services at significant cost to patients and the Medicare program. The issue of self-referral to physician-owned hospitals, and the inherent conflicts of interest it presents, stands in significant contrast to thoughtful improvements to the Stark Law aimed at lowering costs and improving outcomes in developing payment models.

The FAH appreciates the opportunity to emphasize once again the limited role physician-owned hospitals should play in the delivery system. There is a substantial history of congressional policy development and underlying research on the impact of self-referral to physician-owned hospitals. The empirical record is clear that these conflicts of interest arrangements of hospital ownership and self-referral by owner physicians result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns. This policy development includes 15 years of work by Congress, involving numerous hearings, as well as analyses by the HHS OIG, the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC). Seven years ago, after a decade of studies and congressional hearings showing the adverse impact of these arrangements, Congress acted to protect the Medicare and Medicaid programs and the taxpayers that fund them by imposing a prospective ban on self-referral to new physician-owned hospitals.

The FAH strongly believes that the foundation for the current law must be fortified, not weakened. It is noteworthy that Congressional Budget Office scoring of proposals to modify existing law consistently demonstrates that self-referral to physician-owned hospitals increases utilization, which increases Medicare costs and health care costs generally. **We are unable to identify reasons within the context of value-based care and advancements in care**

coordination that would justify any modification to the long-supported ban on self-referral to physician-owned hospitals. The law as it stands protects patients, businesses, and taxpayers. It also helps ensure that full-service hospitals can continue to meet their mission to provide quality care to all of the patients in their communities. Expanded physician-owned hospital opportunities would not facilitate better avenues to coordinated care and should not be included in any future proposed rulemaking.

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The FAH appreciates the opportunity to comment on the RFI. We look forward to continued partnership with CMS to modernize the Stark Law in ways that permit and support the development and success of pathways where providers are better able to 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,