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President & CEO

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Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

RE: *OIG–0936–AA10–P, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.*

Dear Acting Inspector General Chiedi:

The Federation of American Hospitals (FAH) appreciates the opportunity to submit these comments to the Office of Inspector General (OIG), Department of Health and Human Services (HHS) 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 the OIG's efforts to understand the challenges related to implementing new payment models while operating under the current safe harbors of the anti-kickback statute (AKS) and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of remuneration. The following comments offer the FAH's support of the OIG's new proposals and revisions. We also offer responses to many of the questions asked by the OIG throughout the Proposed Rule and pose some questions as well, in an effort to receive greater clarity in future guidance from the OIG. We commend the OIG's efforts to strike a balance between flexibility for beneficial innovation and safeguards to protect patients and federal health care programs. The FAH supports changes to the AKS and CMP regulations in the hopes that they 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 the OIG to design safe harbors that permit innovation to health care delivery and are useful for a broad range of individuals and entities engaged in the coordination and management of patient care. Although the AKS 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 as effectively to a value-based focus in our evolving payment system. While the Medicare payment system is transitioning towards more value-based payments, entities are challenged to manage the evolving forms of their arrangements with providers. The FAH has identified areas in the Proposed Rule where further consideration and clarity would be beneficial for a new value-based environment. We realize the challenge that the OIG faces in balancing program integrity for federal health care programs while also supporting compliance with the AKS and CMP laws by those striving to implement new programs and arrangements.

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 healthcare. It is evident that the OIG considered the comments received in response to the Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP (RFI) (83 FR 43607) to inform its rulemaking. With the Proposed Rules from the OIG and the Centers for Medicare & Medicaid Services (CMS) 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 the OIG has taken in developing proposed definitions and safe harbors 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 and providing the flexibility required by participants in the value-based health care delivery and payment systems that OIG 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 AKS and the CMP. These changes affect the application of the Physician Self-Referral Prohibition (Physician Self-Referral Law) to these arrangements. We are encouraged that the OIG and CMS have worked collaboratively in developing their respective Proposed Rules to foster arrangements that promote care coordination and advance the delivery of value-based care while also protecting against fraud and abuse against patients and federal health care programs. The FAH encourages the Agencies to continue to work together to identify additional areas where the terminology and safe harbors and exceptions available for value-based arrangements align more closely with each other in any final rules issued.

Anti-Kickback Statute Implications of Care Coordination and the Value-Based Framework

The OIG proposes new value-based terminology (§1001.952(ee)(12)) and safe harbors at §1001.952 (ff), (gg), (hh), and (ii). The proposals are intended to create a set of requirements for protection from the AKS' 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

safe harbors discuss the spectrum of value-based arrangements the OIG believes will pose a low risk of abuse of federal health care programs. 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 the AKS revisions to such opportunities will carry that same uncertainty. Thus, the FAH remains committed to assessing the application of any changes to the AKS safe harbor regulations and will appreciate the opportunity to have an ongoing dialogue with the OIG in the event that additional changes are needed in the future to maximize the intent of any final safe harbors.

Proposed Safe Harbors – General Comments

The experience of our members to date demonstrates 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 safe harbors. As the OIG reviews comments and develops the final rule related to value-based care, the FAH believes it would be beneficial to include examples of how the OIG envisions the definitions and proposed exceptions can be operationalized in real life scenarios, as discussed more specifically in the comments below. We agree with the OIG and CMS that this is a huge sea change for healthcare and one that is not happening overnight. The FAH hopes that, just as the industry's understanding of these arrangements will grow and evolve, 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 safe harbors, continued dialogue between the government and industry will become more valuable. We look forward to working with the OIG throughout this evolution.

The FAH's comments to the RFI encouraged the OIG and CMS to create an overarching alternative payment model waiver of the AKS and Physician Self-Referral Law 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 safe harbors. We believe that the OIG should continue to work with CMS to implement a long-term solution that will establish legal certainty around permissible value-based arrangements while encouraging participation in alternative payment models. The proposed safe harbors 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 the OIG and CMS to continue the dialogue with the industry as stakeholders and the government learn about the practical application of AKS exceptions and Physician Self-Referral Law safe harbors to existing and emerging value-based arrangements.

Rather than one overarching waiver or exception for value-based arrangements, the OIG and CMS have proposed multiple safe harbors and exceptions with varying requirements of each. There are multiple safe harbors under the AKS to understand, and the language between the AKS safe harbors and the Physician Self-Referral Law exceptions is different. This adds an additional level of complexity and challenges for those already engaged in value-based efforts 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 the OIG to consider the potential chilling effect of rules and definitions that are so complex they may not be adopted by the industry on a wide-scale basis. It is possible that a more simplistic approach of broad value-based safe harbors could support value-based arrangements.

The three proposed safe harbors to the AKS for value-based arrangements include (i) care coordination arrangements; (ii) value-based arrangements with substantial downside financial risk; and (iii) value-based arrangements with full financial risk. While the efforts undertaken to develop these new safe harbors are appreciated, the FAH is hopeful that the OIG will consider the concerns and requests for clarity when considering final rules.

CMS-Sponsored Models

The OIG is proposing a separate safe harbor at 1001.952(ii) for care delivery and payment arrangements as well as beneficiary incentives pursuant to certain CMS-sponsored models. The OIG defines the term “CMS-sponsored models” as payment models and initiatives being tested by CMS through the Innovation Center and the Medicare Shared Savings Program (under sections 1115A and 1899 of the Act, respectively). The proposed safe harbor is meant to standardize protection of CMS-sponsored model arrangements by permitting: remuneration between and among parties to arrangements under CMS-sponsored models and remuneration in the form of incentives and supports provided by model participants to patients covered by the model. This new safe harbor, if finalized, would be beneficial in providing clarification to participants in CMS-sponsored models as it would replace the model-by-model process that has been applied to date.

This simplified and standardized approach to protecting CMS-sponsored model arrangements under the AKS and beneficiary inducement CMP is a welcomed proposal. With a clear safe harbor that will apply to models that have already been vetted by CMS, participants will have the benefit of uniformity and predictability of the waivers. To date, the waivers issued for the specific models did not provide participants with timely notice. This left considerable legal uncertainty within the provider community, which unfortunately resulted in fewer participants able to take advantage of these arrangements.

While the OIG is proposing a safe harbor for CMS-sponsored models, surprisingly CMS has not proposed a complementary exception to the Physician Self-Referral Law. Without a similar exception explicitly drafted under the Physician Self-Referral Law regulations, the OIG’s proposed safe harbor alone does not provide sufficient protection for these arrangements. 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, as CMS suggests they do, 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, and we urge the OIG and CMS to finalize a corresponding safe harbor and exception.

Existing Waivers for CMS-Sponsored Models

The OIG and CMS have jointly issued fraud and abuse waivers of certain provisions of the Federal AKS, the Physician Self-Referral Law and, for OIG only, certain CMP law authorities for numerous payment models established and tested by CMS under section 1115A(d)(1) of the Act (pertaining to models tested by the Innovation Center) and section 1899 of the Act (pertaining to the Medicare Shared Savings Program). These waivers have been made available for the participants in specified programs and with applicable safeguards in place.

The OIG notes that the proposal of a safe harbor for CMS-sponsored models, if finalized, would eliminate the need for any new waivers of the AKS or beneficiary inducements CMP for value-based arrangements. With the possibility of new waivers no longer being issued for CMS-sponsored models, the FAH requests confirmation from the OIG that all existing waivers for CMS-sponsored models will remain in effect as implemented currently. The preamble does note that, “to the extent that an arrangement under a CMS-sponsored model implicates the AKS or beneficiary inducements CMP, parties within CMS-sponsored models for which a fraud and abuse waivers have been issued may continue to use applicable CMS-sponsored model waivers to protect their arrangements.” This point should be included in the final rule discussion as well to ensure that the OIG’s consideration of this point does not change between the proposed and final rule. FAH members already actively participate in CMS-Sponsored models, and many of them have implemented arrangements pursuant to these waivers. Even a seemingly small change to implementing the waivers can have a significant impact. These programs often have multiple layers which are interwoven with each other. One slight change to a layer or component can have a ripple effect throughout the program. Early adopters of these programs should not be penalized with the burden of complying with a new safe harbor while already active in an approved model with an applicable waiver.

Commercial Payor Safe Harbor

The OIG employed a guiding principle in constructing proposed safe harbors useful for a range of individuals and entities engaged in the coordination and management of patient care, including large and small practices and health systems, rural and urban providers and suppliers, primary care physicians and specialists, providers and suppliers contracting with public and private payors, clinically integrated networks, and looser affiliations of providers and suppliers collaborating to coordinate care for patients across the continuum of care. The FAH urges the OIG to implement a safe harbor to facilitate, with appropriate program oversight, non-CMS advanced payment models such as commercial payor only arrangements. The FAH believes that such a safe

harbor is necessary to ensure uniformity in the treatment of CMS-sponsored and non-CMS-sponsored models and further incentivize these innovative models.

Under such a safe harbor, for example, the provision of an incentive payment, directly or indirectly, to a physician participating in a qualified commercial model would qualify for safe harbor protection from the AKS, provided that the parties adhere to all program and patient safeguards otherwise mandated by the model. The scope of the safe harbor, the inherent protections that come with a formal alternative payment model arrangement, and the applicable program safeguards outlined in such safe harbor, drawing on protections included in previous innovative payment models, are consistent with the OIG's program goals to promote accountability, quality of care, clarity, transparency, and ease of implementation.

Common Ownership

Each of the OIG's proposed safe harbors at 1001.952(ee), (ff), and (gg) requires that the protected arrangement include value-based activities that directly further the first of the four value-based purposes: the coordination and management of care for the target patient population. The OIG proposes to define "coordination and management of care" and "coordinating and managing care" synonymously to mean, for purposes of the AKS safe harbors, the deliberate organization of patient care activities and sharing of information between two or more "value-based enterprise" (VBE) participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.

With the goal of supporting providers' coordination and management of care for patients that leads to better outcomes for patients, the OIG is concerned about distinguishing between referral arrangements, which would not be protected, and legitimate care coordination arrangements. These arrangements, though, will involve referrals across provider settings but include beneficial activities beyond the mere referral of a patient or ordering of an item or service. It is important to permit arrangements that will contribute to coordinating and managing patient care transitions for the purpose of improving the quality of patient care or appropriately reducing costs. However, the OIG raises the concern of parties who establish referral arrangements that are less focused on patient coordination and more on "churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue." In response to this concern, the OIG has considered the possibility of revising the definition of the "coordination and management of care" or additional elements that could be included in the definition to protect against fraudulent and abusive practices that parties attempt to characterize as the coordination and management of patient care.

One option posed in the Proposed Rule is to preclude some or all protection under the proposed safe harbors for arrangements between entities that have common ownership. We are concerned that this may be too aggressive to address what is, at this point, a *potential* concern. Value-based arrangements focus on the coordination of care and this often occurs among different entities and care settings in order to provide the care needed by patients throughout the spectrum of care. The simple fact of common ownership is not sufficient to preclude protection of coordination and management of care. As the proposed value-based definitions and proposed safe

harbors are not yet in place, it is difficult to say what changes are needed to balance the concern the OIG has expressed with the actual integrated health systems that have been developed and will continue to provide care to patients, hopefully with the option of safe harbor protection under these proposals, as applicable. These networks are able to achieve positive results for their patients through the use of some of the activities included in their definition of coordination and management of care – the sharing or use of health information technology and data to identify a target patient population, coordinate care, or measure outcomes. The FAH believes it would be a mistake to outright remove these entities with common ownership based on that factor alone, and we encourage the OIG to reconsider this proposed restriction or to add safeguards as necessary to permit these entities to continue providing value-based care.

Full Financial Risk (Proposed 1001.952(gg))

Under the proposed safe harbor for value-based arrangements involving full financial risk, the VBE (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. The proposed safe harbor would protect only remuneration between a VBE that has financial responsibility and a VBE participant. The OIG would not protect remuneration among VBE participants, or between a VBE participant and a downstream contractor. This is in contrast to the similar CMS proposed exception, which is more permissive. The proposed Physician Self-Referral Law exception would protect payments to physicians not only from the VBE, but also from other VBE participants. We ask that the OIG consider applying the same standard as CMS has considered in its proposal.

The OIG looks to balance the need to protect start-up arrangements with its program integrity concerns and proposes that the safe harbor would protect arrangements between the VBE and the VBE participant only during the six months prior to the date by which the VBE must assume full financial risk. The OIG believes that this period would enable the VBE 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 participants are at substantial 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 safe harbors 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 Substantial Downside Risk (1001.952(ff))

The OIG includes a proposed safe harbor for value-based arrangements under which the participant is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the arrangement. As we work through the proposed safe harbors and related definitions, the FAH has considered certain scenarios to determine how they would interact with both the OIG and CMS 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 endeavoring to understand each of the proposals individually, and then whether and how they work together.

As an example, the OIG's proposed safe harbor for substantial downside risk arrangements and CMS' proposal for meaningful 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. 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.

On the other hand, 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. The difference between the two is notable for a number of reasons. Establishing the threshold numbers at different reference points, 8% for the OIG but 25% for CMS, raises questions of why these are not aligned.

The proposed safe harbors largely focus on the assumption of downside financial risk, yet participants in value-based arrangements may assume certain types of risk other than downside financial risk for items and services furnished to a target patient population (*e.g.*, upside risk, clinical risk, operational risk, contractual risk, or investment risk). The FAH also requests additional guidance around what downside risk really means when engaging participants in value-based activities. An example that raises questions is that of bonus pools for participants. Some financial arrangements include a potential bonus pool that the participants 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 participant does not meet the established metrics, the bonus is not earned.

Although it is possible that the OIG would view the potential to earn the bonus as an upside risk, to the participants themselves this is viewed very much as a downside risk – particularly if they do not earn the incentive. The potential bonus is considered part of the potential aggregate compensation to be paid to the participant and if that bonus is withheld the participant is subject to the downside risk of entering the compensation arrangement. The FAH seeks clear guidance from the OIG in applying the proposed safe harbors and definitions to practical, real-world scenarios to provide additional clarity going forward if the proposals are finalized.

Electronic Health Records (1001.952(y))

The safe harbor for certain arrangements involving the donation of interoperable electronic health record (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 safe harbor changed, both the OIG and CMS revised and extended the sunset of the safe harbor and exception multiple times. The OIG is now proposing to remove the sunset, which the FAH supports. The continued availability of this safe harbor encourages adoption of EHR technology by continuing the certainty of the cost related to EHR items and services for donors and recipients.

The OIG proposes to amend the safe harbor to clarify that certain cybersecurity software and services have always been protected under this safe harbor. The proposed safe harbor modification will now include certain cybersecurity software and services that “protect” electronic health records. In another portion of the proposed rule, the OIG proposes a new safe harbor for cybersecurity technology and related services at 1001.952(jj)). The FAH has considerable concerns with the new cybersecurity safe harbor as proposed and provides separate comments on that proposal below.

The FAH believes the EHR cybersecurity proposal and the separate cybersecurity safe harbor proposal have significant overlap and could lead to confusion were both finalized. As such, should CMS finalize the separate cybersecurity safe harbor, the FAH does not believe the proposed cybersecurity related clarifications to the EHR donation safe harbor are necessary. Should CMS not finalize the separate cybersecurity safe harbor, then the FAH would find it helpful to clarify in the EHR safe harbor that the predominant purpose of the software or service must be cybersecurity associated with the electronic health records – 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.”

Cybersecurity Technology and Related Services (1001.952(jj))

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 the OIG has proposed a new safe harbor § 1001.952(jj) 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

safe harbor, 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 safe harbor 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 the OIG 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 safe harbor. 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 is also 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 to become a bargaining chip, thus 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 the OIG to reconsider this proposed safe harbor and whether cybersecurity protection and its donation is understood sufficiently at this time to proceed with such a safe harbor. If a safe harbor is finalized, the FAH encourages the OIG to limit the services and equipment that can be provided under the safe harbor 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 safe harbor proposal.

Beneficiary Engagement Considerations

Local Transportation (1001.952(bb))

To ensure patients have proper access to health care services, the FAH previously requested an expansion to the local transportation safe harbor. In response to the comments received, the OIG proposes revisions to this safe harbor that address some of the challenges with the previous analysis related to local transportation. The FAH appreciates these changes and urges the OIG to consider expanding the final safe harbor. As noted in the Proposed Rule, experts are recognizing the important role transportation plays in patient access to care, quality of care, healthcare outcomes, and effective coordination of care for patients, particularly for patients who lack their own transportation, live in “transportation deserts,” or who need special considerations due to their clinical conditions. Efforts to enhance patient access to care contribute to value-based goals.

The creation of the local transportation safe harbor to the AKS in 2016 provided greater access to care needed by beneficiaries. Although this new safe harbor has provided protection for entities to assist beneficiaries in reaching this care, the FAH believes the safe harbor was too limited for certain patient populations who need access to services, often in emergent situations, but who do not satisfy the elements of the safe harbor currently in place. Even with the proposed expansion in the Proposed Rule, the FAH is concerned that it does not provide for all patients in need. While the proposal to increase the limit on transportation of residents of rural communities to 75 miles is beneficial, we believe that in some areas, often where patients need it most, this will still not be sufficient for safe harbor protection. Without any proposal to expand the 25-mile threshold for local transportation in non-rural areas, the safe harbor remains too limited.

The FAH agrees that free transportation should be permitted for “local” transportation. However, there are situations, particularly for “special patient populations” where an extended distance is needed to find those services locally. Examples of patients who might need to travel further for necessary care include patients undergoing cancer treatment, behavioral health treatment, or rehabilitation treatment. These special patient populations often need transportation services to care facilities over a much greater distance than 25 or even 75 miles in order to access safely the quality medical care needed to best treat their medical condition. For these ‘extended distance’ local transportation services providers, “reasonable measures” could be required. These measures would serve as a safeguard and could assess whether a patient’s medical condition requires such transportation, and the measures (*e.g.*, a shortage of appropriate medical facilities or health care professionals in a geographic area) could be evaluated on the totality of the circumstances for each individual patient’s condition, with deference given to support patient safety and access to care. With these principles in mind, the FAH believes that free or discounted transportation can be provided to patients in a reasonable manner, above and beyond the proposed safe harbor, that achieves a higher quality of value-based care, while minimizing the risk of triggering concerns under the AKS.

Transportation can be a challenge for patients, not only when trying to access needed care, but also upon their return home – particularly after an inpatient stay. The OIG proposes to remove the distance limitation for patients who are being transported home from an inpatient facility regardless of whether the patient resides in an urban or rural area, if the transportation is to the patient’s residence, or another residence of the patient’s choice (such as the residence of a friend or relative who is caring for the patient post discharge.) Expanding this further to permit transportation to locations other than the patient’s home acknowledges the reality of many patients who are discharged from an inpatient facility and need further care and support at home or another location where a caregiver resides. This analysis also would be beneficial when applied to treatment received by patients beyond an inpatient admission but more significant than a simple office visit. Patients may still travel a significant distance to reach treatment that does not require an admission, and the FAH believes that transportation home for these patients, without a limitation on distance, would be appropriate. The OIG could provide parameters for when this would be permissible so that it is not used as a workaround for local transportation limits applicable to more routine visits.

Access to Care CMP

In analyzing how the AKS and CMP apply concurrently, the FAH continues to be concerned about the analysis of an arrangement under the access to care CMP exception and the local transportation safe harbor. The access to care CMP exception permits providers to assist beneficiaries in overcoming barriers that prevent their access to care in relation to long-distance transportation, yet the OIG seemingly undermined, or greatly limited, the access to care exception by stating previously that compliance with the CMP exception does not assure AKS compliance:

We note, however, that this exception does not apply to the anti-kickback statute. Entities desiring to enter into transportation arrangements that do not meet the requirements of the anti-kickback safe harbor may wish to seek an advisory opinion. For activities and arrangements that are not addressed by a more specific safe harbor or exception, anyone asserting this exception as a defense will have the burden of presenting sufficient facts and analysis for OIG to determine that the arrangement promoted access to care and posed no more than a low risk of harm to patients and the Federal health care programs, as described in this Final Rule. (81 Fed. Reg. 88391).

Per the OIG, any transportation provided outside the local transportation safe harbor is “unlikely to be low risk under [the CMP Access to Care] exception” (81 Fed. Reg. 88391). The FAH remains concerned that this narrow interpretation of “low risk” arguably means that compliance with the requirements of the access to care CMP exception has limited value under the AKS safe harbor and would thus undermine or limit the very access to care the CMP exception was created to promote.

The FAH notes that there are other considerations the OIG should take into account when deeming arrangements that pose low risk of fraud and abuse. We continue to believe that the needs of patients requiring specialized care should not be limited due to an overly restrictive set of criteria. Rather than focusing on the distance the patient must travel to obtain the needed services, turning the focus onto the type of practitioner or facility the patient needs to see may increase the utility of the exception. Situations that could be limited by the current criteria often involve behavioral health patients, oncology patients, and rehabilitation patients. In these cases, the needs of the patient can be urgent, and the initial care setting may be unable to provide the services the patient needs. The entity seeking the ability to provide the transportation services is looking to do so to ensure that the patient receives the needed care in the appropriate care setting as quickly and efficiently as possible. The FAH believes that permitting a facility to provide free transportation to specialized populations will improve coordination of care, access to needed care, as well as quality outcomes. Behavioral health patients, in particular, are likely to require repeat services if they cannot travel to the appropriate care setting. We again urge that the OIG more expansively recognize the patient’s circumstances when evaluating potential AKS liability and enhance alignment of the AKS safe harbors and CMP exceptions.

The FAH urges the OIG to consider the needs of specialized patient populations separately without applying local transportation restrictions. Providers should be permitted to take reasonable measures as indicated by the patient’s condition to accomplish such transportation. The measures should be evaluated on the totality of factors involved with consideration given to accommodations

for patient safety and support.

Personal Services and Management Contracts and Outcomes-Based Payment Arrangements (1001.952(d))

In our comments to the RFI, we highlighted the challenges faced in applying the OIG's policy on compensation that is set in advance as well as its position on what it means for compensation to be determined in a manner that takes into account the volume or value of referrals. With the efforts underway to facilitate innovative payment arrangements, the safe harbor requirements limited the opportunity for many of the typical value-based arrangements to qualify for protection under this safe harbor. The OIG has proposed to modify certain elements of the personal services and management contracts safe harbor in a way that offers greater flexibility.

Rather than requiring that the aggregate compensation is set in advance, the safe harbor focuses on the methodology for determining compensation as what must be set in advance. This is a beneficial change because, as a practical matter, incentive compensation in a co-management arrangement, bundled payment arrangement, internal cost savings arrangement, etc., needs to be structured in a formulaic manner. Hospitals and physicians cannot know at the beginning of the arrangement whether, and to what extent, the physicians will meet the requirements for earning incentive compensation, or potentially the actual amount of compensation available. This change also more closely aligns with CMS' "set in advance" standard, which helps to simplify the analysis when both laws apply.

Although the proposed change will be potentially helpful if it is finalized, hospitals and physicians will not be fully confident that a co-management arrangement, bundled payment arrangement, internal cost savings, or other arrangement will meet the personal services and management contracts safe harbor without clarification as to what it means for compensation not to be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties. For example, it would be very helpful for the OIG to clarify that incentive compensation paid to a physician under a co-management, bundled payment, or internal cost savings arrangement does not take into account the volume or value of referrals simply because the physician is paid a percentage of savings per case. For one thing, more cases performed may result in more savings, more losses, or somewhere in between. We believe that under CMS' current, as well as proposed policy, paying a percentage of savings per case performed does not take into account the volume or value of referrals. Although the standard for the volume or value prohibition proposed by CMS may not fully align with OIG's view, the volume or value standard should be consistent to the extent possible, given the differences in the Physician Self-Referral Law and the AKS.

As a practical matter, the FAH appreciates the OIG eliminating the requirement that, if an agreement provides for the services of an agent on a periodic, sporadic or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals. In the past, it has proven to be difficult to establish the precise schedule for part-time services for the duration of the arrangement when it was entered, particularly if the services would only be needed on an occasional basis. This proposed revision in the safe harbor would afford parties additional flexibility in designing bona fide business arrangements, including care coordination and quality-

based arrangements, where parties provide legitimate services as needed.

Interrelationship Between the AKS and the Physician Self-Referral Law

As noted by the OIG and CMS, the proposed revisions to the AKS and the Physician Self-Referral Law are issued by separate Agencies within the federal government, each with its own priorities to uphold, but also with a close nexus between the two. 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 the OIG and CMS 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.

The FAH appreciates the opportunity to comment on these proposed rules. We look forward to continued partnership with the OIG to modify the AKS to foster arrangements that promote care coordination and advance the delivery of value-based care while also protecting against fraud and abuse related to patients and federal health care programs. 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,

