Federation of American Hospitals®
Charles N. Kahn III
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October 26, 2018

Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

***RE:*** ***OIG-0803-N, Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP***

Dear Mr. Levinson:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Office of Inspector General, HHS (OIG) on the above referenced Request for Information (RFI), published in the *Federal Register* on August 27, 2018 (83 Fed. Reg. 43607). 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 the OIG's efforts to understand and address 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 in its intent to reduce regulatory burden and dismantle barriers to value-based care transformation while also protecting the integrity of federal health care programs. 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.

The FAH also submitted comments to the Centers for Medicare & Medicaid Services (CMS) in response to its RFI published in the Federal Register on June 25, 2018, and we take the opportunity to share many of the same concerns and recommendations herein, as alignment between the goals and actions taken by the OIG and CMS must occur in order for these new payments to succeed. No matter what decisions the OIG ultimately settles upon, the **FAH supports the OIG addressing a number of AKS and CMP related issues through regulations, as opposed to guidance documents, in order to afford the industry, the time and opportunity to review and offer comment on any such proposed changes.**

## OVERVIEW OF NEED FOR ANTI-KICKBACK STATUTE IMPROVEMENTS

**As our current health care payment and delivery system focuses on value-based care models, including care coordination, it is critical that the OIG remove obstacles that prevent collaborations and partnerships among hospitals, physicians and other providers to provide high quality care, delivered more efficiently, and 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 AKS 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 and safe harbors are not drafted in a manner that provides adequate certainty to hospitals, physicians, and other participants that new models of compensation developed in a value-based system will be compliant.

**The FAH believes that this burgeoning shift in payment policy is hindered by the existing fraud and abuse regime.** 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 AKS and CMPs alone. These changes affect the application of the physician self-referral law (Stark Law) to many of 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.

Unfortunately, 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 "safe harbors" to the AKS and "exceptions" to the Stark Law 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 better able to collaborate and coordinate care delivery and utilize payment models that reward improved health outcomes for patients. 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 ANTI-KICKBACK STATUTE IMPROVEMENTS

**The transition to value-based and coordinated care arrangements requires modernizing the AKS. The FAH urges the OIG to create a single, overarching alternative payment model (APM) waiver of the AKS for all gainsharing or similar arrangements under CMS-led APMs implemented through its demonstration authority.**

Gainsharing, shared savings and other similar arrangements between hospitals 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 the OIG 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.**

**The FAH also urges the OIG to create a new bundled payment program safe harbor under the AKS to permit gainsharing under non-CMS-led APMs, such as commercial payer arrangements.** Should the OIG not move forward with an overarching waiver applicable to all Incentive Payment Arrangements under a CMS-led APM, the FAH would urge the OIG to implement a new bundled program safe harbor to the AKS for CMS-led APMs in addition to the non-CMS-led APMs. By implementing these recommended changes, we believe that the OIG will not only assure the health care community of a consistent approach across all APMs, but also will provide to hospitals and physicians the confidence necessary to move forward with meaningful alignment strategies that further quality, reduce waste, and improve patient outcomes.

### 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 AKS 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 AKS. 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, the OIG and CMS 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 prior to that date. Likewise, when CMS instituted the Comprehensive Joint Replacement (CJR) model for hospitals, fraud and abuse waivers from the OIG and CMS 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 the OIG to work with CMS to implement a long-term solution that will establish legal certainty around permissible Incentive Payment Arrangements while encouraging hospital and physician participation in APMs. **Specifically, the OIG and CMS should develop a single, overarching APM Waiver of the AKS and Stark Law (APM Waiver), 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**. The OIG and CMS also could issue program-specific waivers where circumstances warrant a different approach. The development of a single waiver would streamline the process for both the OIG and CMS in addition to providing additional legal certainty for program participants.

*Proposed APM Waiver Parameters*

**In adopting a comprehensive APM Waiver, the OIG could consider potential waiver parameters, as outlined below.** In developing the proposed APM Waiver parameters, the FAH has drawn heavily from the existing BPCI Model 2 and CJR model program safeguards, as well as the OIG and 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, the OIG 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, the OIG and CMS 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 OIG to permit at least a quarterly, if not monthly, Incentive Payment schedule for all applicable APMs.**

The FAH also requests that the OIG 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. The OIG 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 AKS Safe Harbor**

**In addition to an overarching waiver applicable to all Incentive Payment Arrangements under a CMS-led APM, the FAH also urges the OIG to implement a new AKS safe harbor to facilitate 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 the OIG choose not to move forward with an overarching waiver.

Under such an APM safe harbor, for example, the provision of an Incentive Payment, directly or indirectly, by a hospital to a physician participating in a qualified APM would be provided safe harbor protection from the AKS, 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 AKS APM safe harbor. **The scope of the above APM safe harbor, 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 HHS's program goals to promote transparency, improve quality, and safeguard against payments for referrals.**

**Clarify the Volume or Value Standard**

**The FAH recommends that the OIG revise its policy on compensation that is set in advance, and revise or clarify its policy on what it means for compensation to be determined in a manner that takes into account the volume or value of referrals or other business generated, to align with CMS's policy.** This would provide opportunity for the safe harbors for personal services and management contracts to be met in APM arrangements.

CMS's policy provides that formulaic compensation that is sufficiently specified in a written agreement (*e.g.*, a percentage of internal cost savings) is set in advance. The OIG, however, does not consider formulaic compensation to qualify as set in advance for purposes of the safe harbor. This is unfortunate 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 simply will not 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**. Provided that the compensation to be received is fair market value, does not take into account the volume or value of referrals, and is commercially reasonable, the arrangement should be deserving of safe harbor protection.** Of course, the set-in-advance requirement

performs a valuable function as it guards against parties adjusting the compensation up or down in order to reflect referrals. However, formulaic compensation that is sufficiently specified in the agreement between the parties serves that purpose, and, conversely, even fixed rate compensation could be adjusted frequently to reflect the volume or value of referrals. The key to avoiding the gamesmanship by parties lies in the requirement that the arrangement must be for a year or more in order to qualify for safe harbor protection. "The 1-year term requirement ensures that protected leases or contracts cannot be readjusted frequently based on the number of referrals between the parties" (*See* 64 Fed. Reg. at 63526). Allowing incentive compensation arrangements to qualify for safe harbor protection is important because some physicians and hospitals have not entered, and will not enter, into such an arrangement without such protection.

**The FAH also recommends that the OIG adopt the same meaning for compensation that is determined in a manner that takes into account the volume or value of referrals or other business generated, as does CMS.** CMS's stated position is that compensation 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. *See* 66 Fed. Reg. at 879-80; *see* also 42 C.F.R. § 411.354(d)(2).

The OIG does not appear to have a definition or specific regulatory guidance on compensation that takes into account the volume or value of referrals for purposes of the safe harbors, however. **It would be helpful for parties to APMs to operate under a single standard for the prohibition on taking into account the volume or value of referrals and to have clarity, for example, that compensation based on a percentage distribution of shared savings does not take into account the volume or value of referrals provided that the percentage does not fluctuate up or down based on referrals.** For example, if a hospital pays 50 percent internal cost savings to physicians, and that percentage remains at 50 percent regardless of the number of referrals or the amount of revenue generated by the referrals, the compensation would not take into account the volume or value of referrals or other business generated for purposes of the Stark exceptions for personal service arrangements and fair market value compensation, as well as the safe harbors for personal services and management contracts.

**Fair Market Value Carve Out for APMs**

**The FAH urges the OIG to consider whether a fair market value requirement is necessary for APM Incentive Payment Arrangements.** To receive an APM incentive payment, 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. Moreover, fair market value concerns may be further alleviated with the implementation of various program safeguards, like making the receipt of any Incentive Payment contingent upon participants

meeting quality targets and/or capping Incentive Payments made to physicians and physician practice groups.

**Other Anti-Kickback Statute Considerations**

*Commercial Reasonableness*

Certain safe harbors within the AKS utilize several standards to qualify for the exception. Three primary standards used in the AKS safe harbors 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 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 AKS. 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 and other penalties. At a minimum, the OIG 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 or other financial arrangement 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 safe harbors 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.**

*Discount and Group Purchasing Organization Safe Harbors*

Pharmacy Benefit Managers (PBMs) assist buyers (such as insurers and large employers) to procure lower drug prices and help sellers (drug manufacturers) pay rebates to secure placement on health plan formularies. **It is not clear what authority the OIG has or would employ to regulate PBMs, and how it would do so, but to the extent the OIG considers making any changes to the discount safe harbor and the group purchasing (GPO) safe harbor, the FAH urges OIG to proceed carefully to avoid unintended consequences.**

The discount and GPO harbors at 42 C.F.R. §§1001.952(h) and (j) 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. It is important to recognize that, whereas the OIG has published these safe harbors, the statute contains exceptions to the AKS for discounts and for GPOs. *See* sections 1128B(b)(3)(A), (C) of the Social Security Act. Congress did not give the Secretary the authority to narrow the statutory exceptions through regulatory safe harbors, and courts have found that regulated parties may rely on either a statutory exception or a corresponding regulatory safe harbor. Indeed, there is a long line of precedent that administrative agencies have no authority to interpret criminal statutes.

**The FAH cautions that the OIG should consider that various stakeholders across the health care supply chain, not simply PBMs, rely on these safe harbors to provide legal certainty for certain business arrangements that achieve lower costs for providers and Medicare beneficiaries.** Virtually all of the country's hospitals use at least one GPO, and on average, hospitals belong to 2-4 GPOs, which compete with one another for hospital business.[1] According to the same data, GPOs reduce healthcare costs by up to $55 billion annually and save each hospital an average of 10 percent to 18 percent compared to direct purchases. As such, we encourage the OIG to consider the impact any suggested changes may have on the health care supply chain, generally.

*Signature Requirement*

The FAH requests that the OIG create greater flexibility in implementing the signature requirement. **We suggest that the OIG modify the signature requirement to provide that**

[1] Healthcare Supply Chain Association, https://www.supplychainassociation.org/about-us/faq/

**clear evidence of assent between the parties to the terms of the arrangement is sufficient to meet the AKS signature requirement.**

**We also urge the OIG 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,** the **OIG should clarify 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.

The FAH submitted comments to CMS noting the challenges and related administrative burden associated with the strict application of signature requirements related to the Stark Law exceptions requiring a writing. **We ask that the OIG and CMS consider the needed alignment between the AKS and Stark law when implementing clarifications and changes to these laws. Changes to one law without the correlating change in the other for areas in which they overlap will only increase the complexity and challenges faced in this era of evolving APMs**.

*Cost of Compliance with the Anti-Kickback Statute*

Many of our members are actively participating in some of the newer payment models but would like to expand their participation and others are interested in beginning to do so. However, the uncertainty regarding how the AKS applies to some innovative payment arrangements can be costly. For participants in these programs, ensuring that all relationships related to the payment model do not violate the AKS is a challenging an expensive proposition. Performing the applicable legal analysis and implementing safeguards that are believed to offer protection without an applicable waiver are costly endeavors. Without assurance of AKS compliance, the concern of financial penalties for a misstep – determined by the Federal government after the fact – can be disastrous. For those who determine that the risk is too great to even participate due to the potential consequences that can be imposed under both the AKS and the False Claims Act, not participating in an APM can be costly for the participants and patients who never benefit from these savings and improvements in quality**. The FAH encourages the OIG to develop an overarching bundled payment waiver to alleviate the concerns that exist and allow participants to focus efficiently on implementing the necessary safeguards as the programs are developed and implemented.**

*Interrelationship Between the AKS and Stark Law*

**Although the RFI was issued by the OIG, and it focuses on possible changes and improvements to the implementation of the AKS and CMP laws, it is critical that the OIG keep in mind the impact of any resulting proposals or revisions to the application of other fraud and abuse laws, such as the Stark Law.** 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. **We also wish to reiterate that the changes that result from the responses the OIG and CMS received should be issued as proposed rulemakings to allow the industry to review and offer comment before changes are set in place.**

## BENEFICIARY ENGAGEMENT CONSIDERATIONS

### Flexibility Needed for Special Populations

Efforts to enhance patient access to care contribute to the goals of APMs. Ensuring that beneficiaries are able to access the care that is needed was improved by the creation of the local transportation safe harbor to the AKS in 2016. Although this new safe harbor has provided protection for efforts of entities to assist beneficiaries in receiving the proper care, the FAH believes the safe harbor as currently drafted is too limiting 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.

The FAH agrees that free transportation should be permitted for "local" transportation, but the 25-mile threshold is too limited and ultimately undermines the purpose of the safe harbor. Even the 50-mile threshold is insufficient in rural and underserved areas for certain populations. **In considering the permitted radius for local transportation, FAH asks that free transportation be permitted for "special patient populations," including for example, patients undergoing cancer treatment or who need behavioral health treatment.** These special patient populations often need personalized transportation services to care facilities over a much greater distance than 25 or even 50 miles in order to access safely the quality medical care needed to best treat their medical condition. Providers could be required to have in place "reasonable measures" to assess whether a patient's medical condition requires such transportation, and these 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 manner that achieves a higher quality of value-based care, while minimizing the risk of triggering concerns under the AKS.**

Although 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, the OIG seemingly undermined the access to care exception by stating in the rule finalizing the exception 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). This narrow interpretation of "low risk" arguably means the access to care CMP exception has limited value under the AKS safe harbor. 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. 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 will increase the utility of the exception.** The situations that are critical yet limited by the criteria in place currently often involve behavioral health patients as well as other special patient populations, such as oncology. 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 access to care, continuity of 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 ask 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 needs of specialized patient populations should be considered 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 deference given to accommodations for patient safety and support.

**Patient Care Coordination**

Care coordination is a term that encompasses a broad range of items and services that contribute to the goals of APMs in enhancing quality and efficiency for beneficiaries, hospitals, and physicians. Many resources are being developed to facilitate the transition of patients from an acute care setting to the appropriate post-acute care setting – whether that is a skilled nursing home, a rehabilitation facility or the patient's home. These resources include software products that process quality data, create algorithms to identify the highest quality and appropriate setting for post-acute care services for a patient, or identify resources for patients in the community. **The compliance concerns that persist around AKS liability have stifled development and implementation of tools that support clinical collaboration and care coordination.** The OIG has noted its position on the provision of free or below-market goods or services to actual or potential referral sources – such arrangements are suspect and may violate the AKS, depending on the circumstances. The OIG's analysis of such arrangements has focused on the degree to which the item or service provided is primarily for the benefit of the provider of the item or service and its patients (with no more than incidental benefit to a referring provider), or primarily for the benefit of the potential referring provider and would therefore be viewed as a potential kickback.

Another area that bolsters care coordination efforts are care navigators. These individuals can also assist in care coordination for patients preparing for discharge from an acute care hospital, particularly those with complex conditions such as stroke or orthopedic patients who require a range of post-acute care services. The responsibilities of such clinician navigators could include the coordination of beneficiary care throughout a defined post-acute period or episode, by working closely with the case managers and discharge planners within the acute care hospital, as well as with case managers of inpatient rehabilitation facilities, skilled nursing facilities, home health agencies, outpatient therapy providers, urgent care clinics, and other healthcare providers and suppliers from which the specified patients may receive care during the post-acute period.

**To facilitate and encourage implementation of these care coordination tools, the FAH requests that the OIG use its discretionary authority to create a safe harbor under the AKS for care coordination activities that consist of evidence-based, data-driven care coordination, even when provided independent of specific CMS-led APMs.** An additional point to note as the OIG considers an expansion to include care coordination between facilities and practitioners, is to keep in mind the coordination needed between the OIG and CMS in order for increased care coordination efforts to work. **Due to CMS requirements and limitations related to discharge planning, it is critical that any OIG safe harbor be coordinated with CMS efforts to offer similar flexibility in support of care coordination.**

**Incentives to Promote Access to Care**

With a focus on increasing access to care for a broad range of beneficiaries, the FAH encourages the OIG to consider a broad range of services and activities that can contribute to improved quality of care and better health outcomes for beneficiaries. These items and services may not always be categorized directly as health-related but can play a part in achieving the goal of improved care for patients both at home and in the community. The range of services that can assist patients are wide-ranging and include transportation, counseling, telecommunication for patient education, and even meal preparation, and can contribute to improved health outcomes and reduced health care costs. With the implementation of innovative payment models, the FAH believes that the OIG should encourage innovative mechanisms to support access to care and compliance with care services by patients. Hospitals, patients, and federal health care programs benefit if these small activities promote good health and access to care while decreasing unnecessary hospitalizations.

**The FAH recommends that the OIG develop a new safe harbor for assistance to patients that promotes access to care or is based on financial need.** For the new safe harbor to be most effective, we suggest that the OIG is not overly prescriptive for these non-direct health related items to avoid the limitation of medically necessary items or services. For example, any definition of items or services that "promote access to care" should be broad-based and support ease of patient access to care, whether for an individual or for a patient population. Further, the term "care" should be defined broadly to include many services, such as social services and non-clinical services that are related to a patient's health. Hospitals need flexibility to determine what services best contribute to and promote a patient's overall health.

Additionally, the FAH suggests that incentives to beneficiaries for compliance with treatment regimens be permitted to allow innovation in promoting patient-centered care tailored to particular patient characteristics or patient populations in certain localities. While safeguards are needed to ensure these incentives are provided for meaningful reasons and do not steer patients to a particular provider, these safeguards should not be so restrictive as to undermine the ability of hospitals to promote patient compliance with needed medical care. **Patients, hospitals, and federal health care programs benefit when beneficiaries are provided with the tools needed to access care and comply with care plans that address their need and improve their health.**

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The FAH appreciates the opportunity to comment on the RFI. We look forward to continued partnership with the OIG to address AKS and CMP provisions 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,