Federation of American Hospitals®
Charles N. Kahn III
President & CEO

February 26, 2018

Daniel R. Levinson
Inspector General
Office of the Inspector General
Department of Health and Human Services
Attention: OIG–127–N
Room 5541C, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Attn: OIG-127-N; Patrice Drew; Office of the Inspector General, Regulatory Affairs
Re: Solicitation of New Safe Harbors and Special Fraud Alerts; 82 Fed. Reg. 61,229 (December 27, 2017)

Dear Inspector General Levinson:

The Federation of American Hospitals (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 include teaching and non-teaching, short-stay, inpatient rehabilitation (IRF), long-term care (LTCH), psychiatric, and cancer care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH appreciates the opportunity to provide comments to the Office of Inspector General (OIG) regarding its *Solicitation of New Safe Harbors and Special Fraud Alerts.*

A. Current fraud and abuse laws pose barrier to alternative payment models

Federal and private payers alike are increasingly embracing alternative payment models (APMs) that improve quality, lower cost, and further hospital and physician alignment across the care spectrum. As these new payment models shift the nation away from a payment methodology dominated by traditional fee-for-service (FFS), they are fundamentally reshaping the way health care is paid for and delivered.

APMs recognize the importance of aligning otherwise divergent financial interests between hospitals (subject to a medical severity diagnosis related group (MS-DRG) payment methodology, with payment based upon the average resources used to treat Medicare patients in

that DRG) and physicians (compensated on a largely volume based, *i.e.*, per procedure, basis), as well as other downstream providers who are compensated based on different types of payment structures.

Nowhere is this shift in payment policy, and the embrace of physician and other provider alignment strategies, more apparent than at CMS' Center for Medicare & Medicaid Innovation (CMMI), which has spearheaded numerous APMs. In addition, with passage of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), Congress signaled to CMS and the provider community the integral role of APMs in fundamentally reshaping our health care payment and delivery system. As such, APMs often emphasize bundled payments and/or value-based payments, with a focus on alignment strategies among hospitals, physicians, and other providers and achieving higher quality and lower total expenditures for individual Medicare beneficiaries and the Medicare program.

The FAH believes that this ongoing and wholesale shift in payment policy has been and will continue to be materially hindered by the existing fraud and abuse regime. The fraud and abuse laws, including the federal anti-kickback statute, are designed to require strict financial separation, both on a direct and indirect basis, between providers who are in a position to refer to or even recommend one another. Nevertheless, in order to successfully implement APMs, providers must integrate and coordinate care in ways that potentially implicate these statutes. With appropriate patient and program safeguards in place, providers participating in APMs must be afforded the flexibility to enter into financial arrangements that align both clinical and financial incentives, such as risk-sharing, gainsharing, and/or shared savings arrangements (collectively, Incentive Payment Arrangements). Without clearly applicable fraud and abuse waivers, providers participating in such arrangements have been faced with uncertainty as to whether the arrangements may be found to violate the anti-kickback statute or other fraud and abuse laws.

Accordingly, and as outlined below, the FAH urges the OIG to consider creating a new regulatory safe harbor to the anti-kickback statute, or to modify existing safe harbors, such that Incentive Payment Arrangements between hospitals and other providers are protected when operating within the confines of an APM as designated by CMS (a "qualified APM"). By doing so, we believe that the OIG will not only assure the health care community of a consistent approach across all APMs, but also will provide hospitals, physicians, and other providers the confidence necessary to move forward with meaningful economic and clinical alignment strategies that further quality, reduce waste, and improve patient outcomes, without threatening overutilization, decreased quality, or unnecessary costs, factors which gave rise to the relevant limitations at their inception.

B. A new alternative payment model safe harbor

In light of shifting payment policies, and the legal uncertainty currently faced by providers contemplating (or subject to) participation in qualified APMs, the FAH urges the OIG to consider a new APM safe harbor (APM Safe Harbor). Such a safe harbor may apply not only to current or proposed APMs, but also to all future qualified APMs.

Specifically, the FAH submits to the extent that a qualified APM departs or deviates from the traditional Medicare FFS payment structure, the provision of direct or indirect monetary remuneration (Incentive Payment) by a hospital to a physician, physician practice group, or other providers will be deemed protected by the APM Safe Harbor. This protection is contingent on meeting certain program and patient safeguards, to be set forth in the safe harbor and based on those contained in current CMMI bundled payment programs. In addition, the safe harbor should protect arrangement start-up costs and support contributions. For the OIG's consideration, such safeguards may include the following requirements:

- The Incentive Payment Arrangement is set forth in writing, signed by the parties, and specifies the care redesign services to be provided and the Incentive Payment Arrangement compliant methodology;
- The Incentive Payment compensation methodology is set in advance;
- Any Incentive Payments made to a participating physician (or other provider) by a designated health services (DHS) entity is for actual care redesign services provided;
- Only those physicians (or other providers) who meet objective, evidence-based quality measures are eligible to receive an Incentive Payment; furthermore, such quality measures must be reasonably related to the DHS' entity's practices and patient population**;**
- The receipt or payment of any Incentive Payment is not conditioned by either party on the volume or value of referrals (*e.g.*, economic value rather than improved value of care provided) or other business generated between the parties; and
- Any Incentive Payment made directly or indirectly from a DHS entity to a physician or physician practice group (or other provider) must not be made knowingly to induce a physician (or other provider) to reduce or limit medically necessary items or services to patients under the direct care of the physician.

The FAH believes that the focused scope of the above APM Safe Harbor, the inherent protections that come with a CMS defined program, and the substantial program safeguards outlined above, will ensure that Incentive Payment Arrangements evolve consistent with CMS' program goals to promote transparency, increase quality, and safeguard against payments for referrals.

C. Modifications to the Personal Services and Management Contracts Safe Harbor

In the alternative, if the OIG chooses not to rely upon a new APM Safe Harbor, it should consider modifying existing safe harbors to facilitate and encourage APM Incentive Payment Arrangements. As the OIG has recognized in past advisory opinions on gainsharing arrangements, the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), would be potentially applicable to such arrangements. *See, e.g.*, OIG Advisory Opinion No. 08-09. Nevertheless, arrangements that include variable payments cannot meet the safe harbor requirements that the *aggregate* compensation be set in advance, be consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or business otherwise generated between the parties. Thus, the safe harbor does not

offer the sufficient flexibility necessary for implementing and administering Incentive Payment Arrangements.

1. Set in Advance and Volume and Value Standard

The FAH urges the OIG to consider carving out qualified APMs from the safe harbor requirements that the *aggregate* compensation be set in advance and not determined in a manner that takes into account the volume or value of referrals or business otherwise generated between the parties. The *aggregate* payment amount under an APM Incentive Payment Arrangement will not, by definition, be set in advance because such payments are earned only if objective, evidence-based quality measures are met, and if cost savings are achieved.

The OIG could accomplish this carve out by amending the safe harbor to state that for APM Incentive Payment Arrangements, the *aggregate* compensation will be deemed to be set in advance if the compensation *methodology* is set in advance. Moreover, Incentive Payment Arrangements would be deemed not to take into account the "volume or value of referrals" or "other business generated between the parties," provided that the compensation is for actual care redesign services provided, and the compensation *methodology* does not vary over the course of the arrangement in any manner that *directly* takes into account the volume or value of referrals or other business generated by the parties.

The FAH recognizes that the OIG has historically viewed the "aggregate" and "volume or value" standards as necessary to "limit the opportunity to provide financial incentives in exchange for referrals," 56 Fed. Reg. 35,952 (July 29, 1991). The FAH, nonetheless, believes that the concerns regarding any potential *improper* incentives to refer can be both addressed and alleviated with adequate program and patient safeguards.

For example, and as outlined in the above, were the OIG to require that all Incentive Payment Arrangement compensation methodologies not be based *directly* on the volume or value of referrals, physicians' incentives to unnecessarily refer patients, and/or increase the utilization of particular items or services would be significantly lessened. Furthermore, the OIG could cap the total amount of available Incentive Payments, and limit eligibility for such payments to only those participating physicians or providers that meet objective quality metrics. Moreover, with patient disclosure requirements relating to the Incentive Payment Arrangement, patient choice would continue to be respected. And, provided that patient and program safeguards were put in place as part of the safe harbor, the playing field among hospitals would be leveled, as all competitors participating in an APM would be subject to the same program parameters.

In addition, the FAH notes that the risk of program fraud and abuse is limited since hospitals participating in APMs are reimbursed on a DRG basis for inpatient services, which the OIG recognizes as a payment methodology that places a hospital at substantial financial risk. *See* 42 C.F.R. § 1001.952(u)(1)(i)(C). Given the purpose of APMs, and the requirements under such programs that are carefully designed to reduce overutilization and increase quality of care,

including such programs under the safe harbor would be unlikely to increase costs to federal health care programs provided certain safeguards are adopted.

We note that additional program and patient safeguards that the OIG may wish to consider are set forth in the above Section B, "A new alternative payment model safe harbor."

2. Fair Market Value

In addition, we urge the OIG to consider whether a fair market value requirement is necessary for APM Incentive Payment Arrangements. Undoubtedly, those APM participating physicians and physician practice groups or other providers that are 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, and the arrangements may not have a ready market and the attendant data available for easy comparison, it may often be difficult to conclusively determine that an Incentive Payment meets fair market value.

We note that in the context of APMs, fair market value concerns are significantly reduced in light of the simple fact that APMs are CMS defined and/or administered. 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 the Incentive Payments.

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We appreciate the opportunity to provide input regarding the need for safe harbor protection for APMs. If you have any questions about our comments or need further information, please contact me, Katie Tenoever or Erin Richardson of my staff at (202) 624-1500.

Sincerely,