



**CALIFORNIA  
HOSPITAL  
ASSOCIATION**

*Providing Leadership in  
Health Policy and Advocacy*

December 30, 2019

Joanne Chiedi  
Acting Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Wilbur J. Cohen Building  
330 Independence Avenue, S.W., Room 5527  
Washington, D.C. 20201

***SUBJECT: 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; Federal Register (Vol. 84, No. 201), October 17, 2019***

Dear Acting Inspector General Chiedi:

On behalf of our more than 400 member hospitals and health care systems, including post-acute care providers, the California Hospital Association (CHA) welcomes the opportunity to respond to the recent Office of Inspector General (OIG) proposed rule to modify the Anti-Kickback Statute (AKS) and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of “remuneration.”

Our country’s current health care delivery system is undergoing significant transformation. California’s hospitals are leading this transformation in adopting innovative care delivery and payment models that improve the quality of care, make patients’ needs central, and reduce health care costs per capita. Clinical integration with aligned incentives among hospitals, physicians, and other providers working as a team across sites of care, along with alternative payment models, are critical to achieving our shared goals of moving from a fee-for-service delivery system that rewards volume to a value-based delivery system that prioritizes patient outcomes.

To be successful, it is critical that both the statutory and regulatory framework provide sufficient flexibility to accommodate the rapid pace at which providers are asked to innovate and transform through these models. Current federal fraud and abuse laws — which were enacted and primarily developed in a fee-for-service, hours-based environment — not only currently fail to accommodate these new models but serve as a difficult, if not insurmountable, barrier to utilizing them. CHA applauds the administration’s recognition of these challenges and is encouraged by many of the changes proposed to modernize the physician self-referral laws.

Federal law does not create the only barrier to clinical integration for California hospitals and health systems. California also has state laws designed to prevent health care fraud and abuse that, while similar to their federal counterparts, differ both in scope and the specifics of the prohibited conduct. This necessitates any arrangement be separately analyzed for compliance with California law. Further, California law prohibits all but a handful of hospitals from employing physicians. This eliminates most

hospitals' ability to align incentives with physicians through the terms and conditions of their employment.

When these additional burdens imposed by state law are combined with the current challenges imposed by federal fraud and abuse laws, California hospitals' cost of doing business is substantially increased. The need for complex business arrangements that appropriately navigate the current multifaceted regulatory framework presents an added cost that does not improve either patients' health outcomes or their health care experience. This impact can be especially severe for rural and small providers, with their limited financial and staffing resources to devote to managing complex compliance issues. Thus, it is especially important to California hospitals that barriers and burdens at the federal level that impede improved care coordination be reduced to the greatest extent possible.

CHA appreciates the thoughtful approach that OIG has taken to propose various revisions and introduce new provisions to the AKS and CMP for the purpose of "remov[ing] potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency." CHA generally supports many of the provisions outlined in the proposed rule. However, we believe additional changes are needed to advance our shared goals of care coordination and reduced administrative burden. Our detailed comments are noted below.

#### **Value-Based Terminology and Safe Harbors**

CHA appreciates OIG proposals to facilitate the development of desirable and innovative value-based arrangements. CHA encourages OIG to consider the following important refinements to eliminate unintended obstacles that some providers, **especially in California**, will likely experience in attempting to satisfy the proposed safe harbors as currently drafted.

##### *Full Financial Risk Safe Harbor*

For purposes of the value-based arrangements with the full financial risk safe harbor, "full financial risk" would be defined to mean the value-based enterprise (VBE) is financially responsible for the cost of all items and services covered by the applicable payer for each patient in the target patient population and is prospectively paid by the applicable payer.

However, it **might not be possible to satisfy this standard in California**. California has an advanced and well-developed model for delivering health care services in a managed care environment, often referred to as the "delegated model" because California health plans *delegate* financial risk to physicians and hospitals. Health plans generally delegate risk by paying providers a fixed per-member, per-month "capitated" amount, in exchange for which providers agree to accept responsibility for providing or arranging for the covered services required by those members. Another variant is the accountable care organization-type (ACO) model, in which providers are paid fee-for-service, but actual expenditures are compared to a per-member, per-month budgeted amount, and the providers receive a share of savings (or owe a share of costs overruns) based on periodic comparisons of the actual expenditures to the budgeted amounts.

**Importantly, however, under both of these models, providers are permitted to accept risk only for the services for which the providers are licensed.** In other words, physicians may accept financial risk only for professional services, and hospitals may accept risk only for institutional services. This is because

under California's Knox-Keene Health Care Services Plan Act of 1975 and its implementing regulations, any party that accepts risk for both institutional and professional services (referred to as "global risk"), must be licensed as a health care services plan. Securing a health care services plan license, however, is complex, time-consuming, and expensive and is well beyond the reach of most hospitals, physician groups, or even advanced ACOs or provider networks. For this reason, we request some refinements that will permit advanced, at-risk California provider networks to qualify for these exceptions.

**Due to these state law limitations, a value-based enterprise, even consisting of providers that had banded together, would be unable to satisfy this safe harbor without becoming a licensed health plan, which is an enormously expensive and time-consuming process, well beyond the reach of most hospitals, and would entail a fundamental restructuring of the parties' arrangements.**

A secondary issue in this definition is the phrase "*all* patient care," which potentially forecloses the possibility of excluding certain high-cost or specialty services. It is very common, however, even in the most advanced value-based arrangements, for provider-organized, value-based arrangements to forgo financial responsibility for selected services (e.g., organ transplant or pharmacy benefits). **In other words, the "full financial risk" exception unreasonably limits the range of "at risk" arrangements that it protects.**

Therefore, as an alternative to the current wording, CHA urges OIG to modify the definition to clarify that the value-based enterprise and its participants may be "collectively" responsible for the cost of "substantially" all patient care items and services (not all), and clarify that each provider participant (or provider type) can be responsible for services it is licensed to provide as long as they are collectively at risk for "substantially all" patient items and services. CHA suggests defining "substantially all" to mean at least 75% of the cost of all patient care items and services.

If a value-based enterprise is collectively at risk for substantially all services furnished to the target patient population, there should be little risk of program or patient abuse, compared to being at risk for all services. If a hospital is at risk for hospital services, it has an enormous stake in a value-based enterprise, as all its potential revenue is at risk. There is no need to have it also financially at risk for services furnished by professionals.

**In addition, an arrangement should qualify for full risk if the value-based enterprise or its participants are at full financial risk for the items and services to which the protected remuneration relates.**

#### *Full Financial Risk and Substantial Downside Financial Risk Safe Harbors*

These proposed safe harbors would protect remuneration only between a VBE and VBE participants, not between or among VBE participants. In contrast, the care coordination arrangements safe harbor would more broadly protect remuneration "pursuant to a value-based arrangement."

It is unclear why the safe harbors, which require additional risk, also contain this additional restriction – when otherwise these safe harbors include fewer restrictions, with more risk, in recognition of the fact that the more financial risk taken, the less risk there is for overutilization or other abusive arrangements. In addition, restricting the protection to remuneration between a VBE and VBE participants is too limiting, given the realities of how VBEs may be structured. In many instances, a VBE will not be a separate, independent legal entity. Rather, the VBE could be a formal or informal network of individuals

and entities that are the VBE participants collaborating to achieve one or more value-based purposes. Thus, the VBE participants will need to be able to provide remuneration between and among each other.

This may have been the intent of OIG given the broad definition of a VBE, but for purposes of eliminating compliance uncertainty, CHA urges OIG to revise these safe harbors to make clear that remuneration is protected between or among VBE participants.

#### *Interplay with Stark Law Exceptions for Value-Based Arrangements*

CHA appreciates the efforts of OIG and CMS to coordinate on developing value-based safe harbors for purposes of the AKS and the value-based exceptions to the federal physician self-referral law (the “Stark Law”). CHA also recognizes that the purview and consequences for violation of the AKS and the Stark Law are different. **However, CHA is concerned that the differences in the proposed safe harbors and exceptions will chill innovation, as providers may be reluctant to enter into value-based arrangements that meet a Stark Law exception but do not meet a safe harbor. Therefore, CHA urges OIG to include a safe harbor for any arrangement to which the Stark Law applies and that meets a Stark Law exception. This would provide more certainty for hospitals and physicians that are seeking to align incentives and coordinate care in value-based arrangements.**

#### *OIG Solicitation of Comments on Miscellaneous Topics*

CHA greatly appreciates that OIG has solicited comments on numerous topics as part of what is clearly a thoughtful approach to engage stakeholders prior to adding additional restrictions to proposed safe harbors that are intended to provide more flexibility. Responses to certain solicitations of comments follow.

- Definition of Target Patient Population. OIG has inquired whether this definition should be limited to patients with a chronic condition, or whether the value-based safe harbors or other definitions should be similarly limited. CHA urges OIG not to further narrow this definition or other related provisions in this manner. Limiting the definition to patients with chronic conditions would be too restrictive. For example, such a restriction could curtail value-based arrangements that promote the provision of preventive care or important coordination of care efforts, including, without limitation, for patients with behavioral and mental health needs or women with high-risk pregnancies, to name a couple examples.
- Definition of Value. OIG has inquired whether a definition should be added for the term “value,” including whether the term should be defined with reference to financial arrangements under advanced alternative payment models (whether HHS or other payer models). CHA urges OIG not to define “value” in such a manner, as it would be too limiting and could defeat the purpose of giving providers the flexibility needed to experiment with different value-based models.
- Accountable Body. OIG has inquired as to the benefits, burdens, and challenges of imposing a standard requiring either independence or a duty of loyalty as a criterion for accountable bodies of VBEs, and/or requiring a separate compliance program. CHA urges OIG not to impose these additional standards, as they would impose additional, unnecessary burdens that would be challenging to implement from a practical perspective when the VBE is comprised of a network

of hospitals and other participants, as opposed to a separate legal entity with its own governing body.

- Common Ownership. OIG is considering precluding some or all protection for arrangements between entities with common ownership, and has requested feedback on the extent to which integrated health systems believe they need new safe harbor protection for care coordination arrangements in light of currently available protections. CHA urges OIG not to preclude protection under the safe harbors for entities under common ownership. In California, it is very common for affiliated hospital entities and affiliated nonprofit medical foundations under common ownership or control to be closely aligned, and for such entities to be affiliated with other entities that provide patient care. Currently, there are not robust available protections for value-based models in an integrated health system, as there is no safe harbor or express affirmation that there cannot be a kickback between affiliates under common ownership or control. When such systems have the resources and ability to experiment with value-based models to coordinate care, given their close alignment, the absence of such protections for value-based models in integrated health systems could significantly limit how many entities enter into value-based arrangements, particularly ones that take on substantial or full financial risk.
- Exclusivity. OIG has requested comments on whether to preclude protection for value-based arrangements that include exclusivity requirements. CHA urges OIG not to include such a limitation. Alternatively, OIG could provide that to the extent there is an exclusivity requirement, there would be an exception “if the patient expresses a preference for a different provider, practitioner, or supplier; the patient’s insurer determines the provider, practitioner, or supplier; or the provision of items or services by the VBE participant with an exclusivity arrangement is not in the patient’s best medical interests in the physician’s judgment.”
- Submitting Data Regarding Value-Based Arrangements. OIG has stated that it is considering requiring the submission of information identifying the VBE, the VBE participants, and the value-based arrangements, as a requirement for safe harbor protection. CHA urges OIG not to require such submissions because they would be unduly burdensome and could discourage implementation of such arrangements or full compliance with the safe harbors. For example, each time VBEs with a large network of participants and a variety of value-based arrangements modify their structure or have a change in participant, they would presumably fall outside of the safe harbor if they fail to update OIG. In addition, CHA notes that hospitals are already subject to significant oversight by accrediting organizations and state licensing agencies regarding quality of care, and other Medicare program oversight includes hospital inpatient and outpatient quality reporting programs, a readmissions program, and value-based purchasing programs, with corresponding significant operational and compliance requirements.

#### **Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency Safe Harbor**

CHA supports including a safe harbor for the provision of patient engagement tools or supports by value-based enterprise participants to members of a target patient population. However, CHA strongly urges OIG to expand the proposed safe harbor to apply it more broadly, regardless of whether an entity

is participating in a value-based enterprise, or at the very least, expand the safe harbor to apply to hospitals whether or not participating in a value-based enterprise.

To further the goal of population health, hospitals are expanding their roles beyond providing direct patient care in a hospital setting and are helping ensure that people can access needed care in the first instance. To do this, hospitals must be able to provide assistance that addresses a wide range of needs specific to their various communities. For example, ***in California, much attention is currently being given to the complex issues around medical care for individuals experiencing homelessness, including the need to provide a safe discharge following hospitalization despite the dearth of community resources. Unfortunately, current federal fraud and abuse laws inhibit hospitals' ability to help patients achieve and maintain health beyond a hospital's four walls*** by, for example, providing in-kind or financial support, such as transportation vouchers or meal preparation, providing social services to help maintain health, and otherwise offering free or discounted items to help address social determinants of health.

Importantly, the proposed safe harbor has significant protections embedded to safeguard against abusive arrangements, which would equally serve to safeguard arrangements outside of a value-based care enterprise. These include, without limitation, the following requirements: the patient tools or supports must be in-kind, directly related to coordination and management of care, recommended by the patient's licensed healthcare provider, and used to advance specific care-related goals. In addition, the patient supports or tools cannot be used for recruiting or marketing.

Separately, OIG has solicited comments on whether this safe harbor should make distinctions among categories of social determinants of health, such as protecting some types of tools and supports related to social determinants but not others, as well as whether the regulations should specify a list of permissible tools and supports. CHA appreciates the opportunity to provide input, and ***strongly urges OIG not to limit permissible tools and supports***. As referenced above, California hospitals face significant challenges given the complex issues around medical care for certain patient populations, including without limitation individuals experiencing homelessness, individuals with behavioral and mental health needs, and individuals who lack an adequate support system at home to assist in achieving and maintaining health outcomes.

California hospitals need the flexibility to provide the individualized tools and supports needed by patients, which may change over time; these may include, without limitation, addressing food insecurity or otherwise assisting with shelter, safety, clothing, or transportation needs.

#### **Local Transportation Safe Harbor**

CHA appreciates OIG's statements about the important role transportation plays in patient access to care, quality of care, and effective coordination of care, particularly for patients who lack their own transportation or who do not otherwise have reasonable access to transportation options. Accordingly, CHA strongly supports the proposed revisions to the local transportation safe harbor, but urges OIG to further increase the mileage limit for patients in rural areas and to remove the mileage limits upon discharge from hospital outpatient departments.

*Expanding the Mileage Distance Limits*

While CHA appreciates OIG's recognition that the mileage limit for transportation of patients who reside in rural areas needs to be increased, changing the limit from 50 to 75 miles is insufficient to meet the needs of certain California patients or provide sufficient protection to California hospitals providing transportation services to such patients. For some hospitals in California in rural communities, a 75 mile limit would continue to be an obstacle to providing access to medically necessary care. For example, one member hospital reports that the nearest site for its oncology patients to receive necessary radiation treatment is 100 miles away. Another member hospital is more than 115 miles away from the nearest hospital capable of providing specialty care required by the member's patients.

CHA urges OIG to revise the safe harbor as follows:

(B)(i) Within 25 miles of the healthcare provider or supplier to or from which the patient would be transported, or (ii) if the patient resides in a rural areas, as defined in this paragraph (bb), within the greater of 75 miles or the actual distance to the nearest hospital to the patient that has the capability of providing medically necessary items or services to the patient. The mileage limits set forth in this paragraph (bb)(1)(iv)(B) shall not apply if the patient is being discharged from an inpatient facility and transported to the patient's residence, or another residence of the patient's choice.

In the alternative, CHA urges OIG to revise the safe harbor as follows:

(B) Within 25 miles of the healthcare provider or supplier to or from which the patient would be transported, or within 75 miles if the patient resides in a rural area, as defined in this paragraph (bb), except that the mileage limits set forth in this paragraph (bb)(1)(iv)(B) shall not apply if the patient is being discharged from an inpatient facility and transported to the patient's residence, or another residence of the patient's choice, or if transportation is furnished to the patients based on a good faith, individualized determination that the transport is necessary to facilitate the patient's access to medically necessary items or services.

Including such a safeguard would prevent against abusive arrangements by requiring individualized assessments, while providing the flexibility to assist patients with accessing the transportation needed to receive medically necessary care. CHA notes that OIG proposes a similar approach in the patient engagement tools, supporting a safe harbor limiting the aggregate retail value of tools and supports to \$500 unless based on a good faith, individualized determination of the patient's financial need.

*Removing Any Mileage Limit on Transportation on Discharge from a Health Care Facility*

CHA strongly supports the proposed removal of a mileage limit if a patient is being discharged from an inpatient facility and transported to the patient's residence or other residence of the patient's choice.

**Importantly, in California, hospitals are currently required to offer transportation upon discharge up to 30 miles under certain circumstances.** In particular, California Health & Safety Code Section 1265.2(o) requires documentation that, prior to discharge of a homeless patient, the hospital has offered the homeless patient transportation to a specified destination if that destination "is within a maximum travel time of 30 minutes or a maximum travel distance of 30 miles of the hospital." CHA urges OIG to consider expressly expanding this safe harbor to include any discharge from a hospital, including from an outpatient department.

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### **Electronic Health Records (EHR) Items and Services Safe Harbor**

As a general matter, CHA greatly appreciates the removal of the sunset date for this safe harbor and the added flexibility regarding replacement technology to help protect against physician practices or other recipients being locked in to a vendor that may be providing subpar services.

CHA also appreciates the opportunity to comment on the requirement that a recipient contribute 15% of the cost for the donation of the EHR technology and related services. CHA has provided feedback in its comment letter to CMS with respect to the Stark Law proposed rule on this topic. CHA understands that OIG and CMS are coordinating closely in the rulemaking process and respectfully requests that OIG refer to CHA's comments to CMS.

### **Personal Services and Management Contracts and Outcomes-Based Payment Arrangements Safe Harbor**

Under the proposed revisions to the personal services and management contracts safe harbor, "outcome-based payments" are payments that "(A) [r]eward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across settings; or (B) [a]chieve one or more outcome measures that appropriately reduce payer costs while improving, or maintaining, the improved quality of care for patients." OIG has proposed to include an express requirement in this safe harbor that parties rebase the benchmark for the outcome-based measure periodically where feasible, to prevent parties from inadvertently carrying over savings from prior periods that do not reflect legitimate achievement of outcomes.

CHA urges OIG to remove the requirement to "rebase" each outcome-based measure periodically. Per OIG's statements in the preamble, the intent is to reset the benchmark to take into account improvements already achieved, and to prevent against payments that reward referrals. However, the issue with such a proposal is that if parties are successful in achieving outcomes initially, there will be significantly less margin for improvement over time, and instead the challenge is more likely to be maintaining the new and improved status quo. The danger in requiring rebasing, given that margins for improvement against benchmarks will be significantly more challenging or impossible to meet over time, is that parties will be disincentivized to enter into these arrangements in the first place, or incentivized to unwind them after initial improvements, due to concern with having a business structure that does not squarely meet a safe harbor. In addition, CHA notes that the proposed safe harbor expressly acknowledges that a payment is appropriate to "maintain" improvement, and requiring a periodic rebasing of benchmarks contradicts that concept.

As an alternative, CHA urges OIG to revise this provision to require the parties to "periodically re-evaluate whether an outcome measure should be rebased throughout the term," and/or otherwise expressly state that under some circumstances it may be appropriate upon review to maintain an existing outcome-based measure in order to incentivize the behavior needed to continue to achieve the improved outcomes as compared to the commencement of the arrangement.

OIG also requests comments on the appropriate timeframe to require for a periodic rebasing of benchmarks, noting a concern about "evergreen" arrangements where outcome measures are not properly monitored or assessed. CHA urges OIG not to define a specified timeframe, as the appropriate timeframe could vary based on facts and circumstances and the parties to the arrangement are in the



best position to make that determination. Alternatively, CHA urges OIG to adopt a period of five years or longer for the applicable benchmark period, to encourage parties to enter into agreements that reward quality and cost-savings over quantity with some security regarding compliance with the AKS. Parties may be disincentivized to enter into such agreements if rebasing is required at more frequent intervals, given the time and resources needed to identify valid evidence-based outcome measures, negotiate related outcomes-based payments, and otherwise implement and monitor the arrangement – with the knowledge that the agreement may need to be unwound within a short period if the parties cannot agree to an appropriate re-basing of any particular outcome measure.

**Compliance with the AKS and Beneficiary Inducement CMP**

CHA appreciates OIG’s receptiveness to stakeholder comments and respectfully urges OIG to consider the addition of a new safe harbor. 42 U.S.C. § 1320a-7a(i)(6)(B) and 42 C.F.R. § 1003.110 currently provide an exception to the definition of “remuneration” for purposes of the beneficiary inducement CMP if an arrangement meets a statutory or regulatory safe harbor under the AKS. However, there is currently no corollary safe harbor under the AKS for arrangements that meet an exception to the definition of “remuneration” under the beneficiary inducement CMP. This disparity causes some compliance uncertainty and potentially chills the offering of certain supports or tools to patients, which would help to promote the goals of the proposed rule and the overall Regulatory Sprint to Coordinated Care.

For example, although the beneficiary inducement CMP provides a broad exception to remuneration for items or services that improve a beneficiary’s ability to obtain items or services payable by Medicare or Medicaid and that pose a low risk of harm to beneficiaries and the Medicare and Medicaid programs, there is currently no corollary under the AKS. Further, the proposed safe harbor for the provision of patient engagement tools and supports – a similar concept to this particular CMP exception – is currently contemplated as being available only to participants of VBEs (see comments to that safe harbor above).

CHA, therefore urges OIG to adopt a new safe harbor to expressly state that, as used in the AKS, “remuneration” does not include the offer or payment of anything of value to the extent such offer or payment falls within an exception to the definition of “remuneration” under the beneficiary inducement CMP.

CHA appreciates the opportunity to provide OIG with our comments on the proposed rule. If you have any questions, please contact me at [akeefe@calhospital.org](mailto:akeefe@calhospital.org) or (202) 488-4688, or my colleague Jackie Garman, vice president, legal counsel, at [jgarman@calhospital.org](mailto:jgarman@calhospital.org) or (916) 552-7636.

Sincerely,

/s/

Alyssa Keefe  
Vice President, Federal Regulatory Affairs