CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

October 26, 2018

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Room 5513
330 Independence Avenue, SW
Washington, D.C. 20201

SUBJECT: ***OIG-0803-N: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP***

Dear Ms. Edwards:

On behalf of our more than 400 member hospitals and health care systems, the California Hospital Association (CHA) welcomes the opportunity to respond to the Office of Inspector General's (OIG) recent request for information (RFI) seeking public input on the Anti-Kickback Statute (AKS) and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of "remuneration." Specifically, the RFI seeks input on how the OIG might modify or add new safe harbors to the AKS, and whether it should develop exceptions to the beneficiary inducements CMP to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.

CHA and its member hospitals and health systems — which comprise a range of provider types, from large, urban facilities and academic medical centers to small, rural and critical access hospitals and post-acute care providers — appreciate the OIG's efforts to advance the Department of Health and Human Services' Regulatory Sprint to Coordinated Care. We especially appreciate the OIG's recognition that the broad reach of the AKS and beneficiary inducements CMP potentially impedes beneficial arrangements that would advance the delivery of higher quality, more cost-effective care with better outcomes.

Our country's current health care delivery system is rightfully being asked to make significant changes in its delivery and payment models to improve the quality of care and better meet patients' needs while, at the same time, reducing health care costs per capita. California's hospitals are committed to these goals. Clinical integration with aligned incentives between hospitals, physicians and other providers working as a team across sites of care, along with alternative, value-based payment models, are critical to achieving the administration's goals. It is important 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 fail to accommodate these new models but also present difficult, if not insurmountable, barriers to utilizing them.

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Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

For these reasons and more, CHA supports the addition of regulatory safe harbors to the AKS and beneficiary inducements CMP to foster arrangements that would promote care coordination and advance the delivery of value-based care while protecting against harms caused by fraud and abuse. CHA urges the OIG to consider the following recommendations and rationale for proposed changes.

Fraud and Abuse Laws, in Their Current Form, Impede Clinical Integration, Care Coordination and Accountability for Patients' Health in the Community

Achieving clinical integration depends on hospitals, doctors, nurses and other caregivers working as a team to ensure that patients get the right care, at the right time, in the right place. This requires mechanisms that align providers' interests to improve quality while decreasing health care costs. Further, as the health care industry transitions from volume- to value-based payment, new reimbursement models extend hospital accountability for patients' health beyond inpatient or outpatient care by effectively making hospitals responsible for encouraging and furthering patients' access to care in their homes and communities. However, current federal fraud and abuse laws create serious barriers to achieving these goals.

The OIG RFI encourages the resubmission of relevant comments previously submitted in response to CMS' RFI on the physician self-referral law (RIN 0938-AT64), also known as the Stark Law. In the following discussion, we have included key points from our response to CMS.

Changes Needed to Federal Fraud and Abuse Laws

It is well recognized that the federal fraud and abuse laws, as currently formulated, impede current efforts to transform our health care delivery system to a value-based system of coordinated care and improved patient outcomes. The OIG itself has identified the broad reach of the AKS and beneficiary inducements CMP as a potential impediment to beneficial arrangements that would advance coordinated care. Similarly, as CHA pointed out in its response to the CMS Stark RFI, Congress itself has recognized that the Stark Law — which was originally enacted to ban physicians from referring patients to facilities in which the physician has a financial interest (self-referral) — has developed and expanded over the years so that it now bans or impedes arrangements that encourage hospitals and doctors to work together in a clinically integrated model designed to improve patient care at reduced cost.

Examples abound of the impediments created by these laws. Providers are reluctant to utilize innovative payment models based on the delivery of high-quality, cost-effective care for fear of running afoul of the broad definition of "remuneration" in the beneficiary inducements CMP, given the potentially ruinous consequences for being wrong. The Stark Law's requirement that compensation be fixed in advance and based only on hours worked, similarly creates substantial barriers to — if not effectively prevents — payments tied to achievements in quality and efficiency. Many care coordination activities and innovations are currently prohibited, limited or complicated by the AKS or the Stark Law, including activities such as assisting physician practices with making phone calls to patients to schedule well visits, routine diagnostic tests and follow-up visits; and providing patients transportation to physicians' offices for care. These laws also prevent or impede hospitals from providing to a potential referral source (such as physicians participating in the value-based delivery model) resources such as cybersecurity, telehealth, electronic health record (EHR) or other data analytic technology or support to assist in making treatment decisions for patients if an imputed purpose for the transfer — coordinated care that

improves patients' health and well-being — could encourage referrals as a result of the benefit of better outcomes resulting from the value-based model implemented by the hospital.[1]

If efficiencies and outcomes are to be improved, the financial interests of members of the health care team need to be aligned. Hospitals also need to be given the flexibility necessary to improve care outcomes and the health of their communities while reducing unnecessary expenditures on inpatient services. There should be protection for these efforts across the fraud and abuse laws.

Admittedly, federal law is not the only source of barriers to clinical integration for California hospitals and health systems. California has its own set of 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 conduct prohibited. This necessitates that any arrangement be separately analyzed for compliance with California law. Further, California law prohibits almost all hospitals from employing physicians, thereby depriving them of the ability to align their incentives with physicians through the terms and conditions of their employment.

When these additional burdens imposed by state law are combined with the challenges imposed by the federal fraud and abuse laws, California hospitals' cost of doing business is substantially increased. The need for complex business agreements 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, therefore, proposes the following changes to reduce the regulatory barriers to care coordination that result from current federal fraud and abuse laws.

Proposed New Safe Harbors for AKS

CHA supports the creation of the following new AKS safe harbors that will remove barriers to clinical integration and care coordination:

- **AKS safe harbor for clinical integration/value-based payment arrangements:** CHA supports the creation of a new AKS safe harbor, promulgated by the American Hospital Association (AHA) and others, for clinical integration/value-based payment arrangements. To achieve the goals of improved quality, increased efficiency and controlled costs, hospitals, physicians and other health care providers must have aligned interests — which are achieved by sharing resources, rewards and risks. Building clinically integrated networks and relationships requires substantial investment in coordination of care and information systems; hospitals have both the capability and incentives to make this investment. However, such asymmetric investment by hospitals in systems and structures utilized by physicians and other providers constitutes a transfer of remuneration between referral sources, in conflict with existing law.

[1] While there is a Stark Law exception addressing EHR technology and support, the current rules do not allow hospitals to bear the full financial cost of the EHR and instead require physicians to bear a portion of the financial costs regardless of their time, effort and expertise contributions to the collaborative effort. Further, the existing exception is not universally applicable.

Therefore, CHA supports the creation of a safe harbor to protect such arrangements and any transfer of remuneration for which a principal purpose is the achievement of care coordination underpinning a value-based system. Bearing in mind the goal of preventing actual fraud and abuse, this safe harbor should focus on the purpose of the arrangement, protecting those with a declared objective of meeting one or more of the following pillars of coordinated care: promoting accountability for the quality, costs and overall care for patients; managing and coordinating care for patients across and among other providers; or encouraging investment in infrastructure and improved processes for high-quality and efficient patient care delivery. Such a safe harbor should be designed to ensure transparency with respect to the use of incentives or other assistance; utilize performance standards for improving care delivery processes that are consistent with accepted medical standards and reasonably calculated to improve patient care; and be subject to internal monitoring to guard against adverse effects. The latter two aspects should be implemented without supplanting, duplicating or recreating existing quality improvement processes or mechanisms for monitoring quality of care in hospitals.

CHA submitted a companion exception for clinical integration/value-based payment arrangements in our response to the CMS Stark RFI. We believe that an intersecting AKS safe harbor and Stark exception should be aligned.

- **AKS safe harbor for cybersecurity:** CHA supports the creation of a new safe harbor to allow the sharing of cybersecurity-related items and services, as recommended by the U.S. Department of Health and Human Services Office in its *2017 Health Care Industry Cybersecurity Task Force Report to Congress*. Cybersecurity is a patient care issue, as increasing amounts of health care data are being collected for the good of patients and used to develop treatment; interrupted access to such data may adversely impact patient care. Further, care coordination has pushed health care providers to use EHR and other technologies to exchange patient information. The increasing digitalization of health records has resulted in cyberattacks in the health care industry increasing in both numbers and sophistication. Providers need cybersecurity tools to protect patient information and care, but — as noted above — hospitals are in the best position to make the necessary investments. Unfortunately, hospitals' asymmetric investment in such resources and supplying of the tools to other providers constitutes a transfer of remuneration. As the report indicated, "often organizations want to provide [cybersecurity] technology to ensure smaller business partners [such as physicians] do not become a liability in the supply chain." In the health care field, such arrangements are constrained by the fraud and abuse laws. Creating a safe harbor for the sharing of cybersecurity-related items and services will empower health care providers to actively and efficiently manage and share their cybersecurity technology without fear of violating AKS.

- **AKS safe harbor for patient assistance:** To further the goal of population health, hospitals are expanding their roles beyond providing direct patient care in a hospital setting. Hospitals are doing so by helping ensure that people can access needed care in the first instance, can do so easily and can be safely maintained in the community after care is provided. But 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 homeless individuals, including the need to provide a safe discharge following hospitalization, despite the dearth of community resources to assist

these patients. The fraud and abuse laws' prohibition on providing anything of value to induce the use of Medicare services interferes with hospitals' ability to provide necessary assistance. CHA, therefore, supports the creation of an AKS safe harbor, promulgated by AHA and others, that will allow hospitals to help patients achieve and maintain health beyond a hospital's four walls. Such a safe harbor should help patients access care or make access more convenient; permit financial or in-kind support, such as transportation vouchers or meal preparation; and permit the social services (such as counseling) that help maintain health. Providing these services is essential, as many patients reside in economically challenged communities where there is limited access to services upon discharge. Thus, this safe harbor should protect the assistance patients need to realize the benefits of their discharge plan and maintain their health and independence — to the extent possible — in the community by protecting efforts and resources to encourage, support or help patients access care (including making access more convenient); recognizing that access to care includes addressing the social determinants of health; and permitting both financial support, such as transportation vouchers, and in-kind support, such as meal preparation.

CHA submitted a companion exception for patient assistance in our response to the CMS Stark RFI. We believe that an intersecting AKS safe harbor and Stark exception should be aligned.

Other Proposals Relevant to AKS Included in CHA Response to CMS Stark RFI
The following proposal made by CHA in its response to the CMS Stark RFI is also relevant to this RFI:

Remove compensation provisions from the Stark Law. CHA supports returning the Stark Law to its original focus of regulating self-referral to physician-owned entities by removing its compensation provisions, as advocated by AHA and others. This would permit compensation arrangements to be regulated by the AKS, which has both civil and criminal penalties and is far better suited to combatting payment for referrals. Removing the compensation provisions from the Stark Law is consistent with the law's original intent and would minimize the burden placed on hospitals and health systems, which are currently forced to comply with excessive, overlapping and redundant rules and regulations.

CHA appreciates the opportunity to provide CMS with our proposals on how to improve the AKS. If you have any questions, please contact me at akeefe@calhospital.org or (202) 488-4688, or my colleague Jackie Garman, vice president, legal counsel, at jgarman@calhospital.org or (916) 552-7636.

Sincerely,

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs