CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, D.C. 20201

SUBJECT: CMS–1720–NC, Request for Information Regarding the Physician Self-Referral Law; Federal Register (Vol. 83, No. 122), June 25, 2018

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health care systems — representing 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 — the California Hospital Association (CHA) welcomes the opportunity to respond to the recent Centers for Medicare & Medicaid Services (CMS) Request for Information seeking public input on ways to address the undue impact and burden of the physician self-referral law, also known as the Stark Law. Among other things, this request focuses on how the law may impede care coordination, which is critical to delivering high-value care.

CHA appreciates CMS' interest in improving the Stark Law and reducing the regulatory burden and costs it imposes on the nation's health care system. CHA also supports a more aggressive approach to address the challenges. Many have called for repealing this law, noting that it has become too complicated. The Stark Law is a maze that can trap not only the unwary but also the reasonably wary and well intentioned, as even those knowledgeable about the law cannot always agree on whether a particular scenario violates it. While combatting true fraud and abuse is undeniably necessary, we believe this would be best effectuated by wiping the slate clean and developing a new statutory and regulatory framework that creates fewer barriers to the delivery and payment models that facilitate care coordination.

However, knowing that amending the existing Stark Law and related regulations — rather than replacing them — is the preferred and more expedient option, CHA urges CMS and its partners to move quickly to make changes that achieve the law's intent and objectives in a fair and equitable manner, while reducing its unnecessary compliance burdens and risks.

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, center around patients' needs and reduce 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 payment models, are critical to achieving the administration's goals. To be successful, 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. The Stark Law — which was enacted and primarily developed in a fee-for-service, hours-based environment — not only fails to accommodate these new models but serves as a difficult, if not insurmountable, barrier to utilizing them.

For these reasons and more, CHA believes that both legislative action and regulatory action are necessary to effectively address these issues. CHA urges CMS to consider the following recommendations and rationale for proposed changes.

The Stark Law, As It Currently Exists, Impedes Clinical Integration

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. Shared savings and gainsharing provide important mechanisms for aligning providers' interests to improve quality while decreasing health care costs, as the health care industry transitions from volume- to value-based payment.

However, current federal law creates serious barriers to achieving these goals. As Congress has recently recognized, 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. By requiring that compensation be fixed in advance and based only on hours worked, the Stark Law effectively prevents — or, at best, creates substantial barriers to — payments tied to achievements in quality and efficiency. In addition, the anti-kickback statute and civil monetary penalties create further barriers and complications. Many care coordination activities are currently prohibited, limited or complicated by the Stark Law. These include care coordination activities such as assisting physician practices with making phone calls to patients to schedule well visits, routine diagnostic tests and follow-up visits; providing patients transportation to physicians' offices for care; providing electronic health record (EHR) technology or support; and providing other data analytic tools to assist physicians in making treatment decisions for patients[1]. While the Stark Law impacts all California hospitals' clinical integration strategies, this impact can be especially severe for rural and small providers, with their limited financial and staffing resources to devote to complex compliance issues.

If efficiencies and outcomes are to be improved, the financial interests of members of the health care team need to be aligned. There should be protection for these efforts across the fraud and abuse laws.

Admittedly, federal law does not create the only such 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 all but a handful of hospitals from employing physicians;

[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 may not be utilized in all situations.

this deprives most hospitals 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 Stark Law and other 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. 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.

Proposed Legislative Changes
CHA urges CMS to work with hospitals and Congress on a number of legislative reforms that will more fully address the issues that cannot be addressed through administrative regulatory change. Specifically**:**

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 the American Hospital Association (AHA) and others. This would permit compensation arrangements to be regulated by the Anti-Kickback Statute (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.

Create New AKS Safe Harbors. CHA supports proposals, promulgated by AHA and others, that Congress create the following new AKS safe harbors that will remove barriers to and facilitate clinical integration:

- **AKS safe harbor for clinical integration arrangements:** CHA supports the creation of a new AKS safe harbor for clinical integration arrangements that are designed to meet one or more of the following objectives: promote accountability for the quality, costs and overall care for patients; manage and coordinate care for patients; or encourage 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.
- **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 supports the creation of an AKS safe harbor 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 (e.g., counseling, etc.) 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.

Proposed Regulatory Changes

Congressional action is not the sole solution to reducing or eliminating the Stark Law's impediments to care coordination: CMS can make changes to the related compensation regulations that would substantially reduce these barriers and the burdens they cause. **We applaud the administration's prioritization of these important regulatory burdens by issuing this Request for Information to obtain additional provider input and specific recommendations.**

Many of the Stark Law compliance challenges faced by hospitals and other providers arise from uncertainty surrounding several of its key concepts. Ambiguity about exactly what is required, coupled with the enormous penalties that can result from noncompliance, make hospitals reluctant to implement innovative care coordination programs and value-based arrangements. In the best scenarios, this uncertainty increases transaction costs and burdens of trying to structure such programs to ensure compliance. At worst, the chilling effect of the **threat** of financial penalty halts innovation and clinical integration. This ambiguity with respect to the Stark Law's concepts can be eliminated or reduced by:

Creating a new innovative payment exception for value-based payment arrangements. This proposed exception would protect remuneration that is provided or received pursuant to a clinical integration arrangement between hospitals and physicians (or physician practices), including incentive payments, shared savings based on actual cost savings, infrastructure payments or in-kind assistance reasonably related to and used in the implementation of clinical integration arrangements. For innovative payment arrangements involving such relationships to be fully successful, the ability to make investments in care coordination — which can improve quality of care and decrease program costs — is essential. By clearly protecting value-based incentive programs, such an exception can promote care management and coordination; accountability for quality, cost and overall care of patients; and investment in infrastructure and care processes that will improve the quality and efficiency of care delivery. Adequate protections from abuse can be provided by having objective, measurable and transparent performance standards as a condition of this exception.

Adopting "bright line" rules for core concepts. The concepts of fair market value (FMV), commercial reasonableness and "takes into account" are included in virtually all Stark Law compensation exceptions. The first two — FMV and commercial reasonableness — are not suited to the collaborative models that reward value and outcomes. Moreover, there is significant confusion surrounding each concept's requirements. The resulting ambiguities not only substantially increase both the transaction costs and regulatory burden on the parties to affected transactions, but they also create obstacles to developing value-based arrangements. While the proposed new exception for alternative payment models would offer some relief, implementing clear and objective standards for these core concepts would provide broader and more valuable relief.

Specifically:

- **Fair market value:** First, FMV should be defined as an objective, not subjective, standard: the range of value that two hypothetical parties, negotiating in good faith, would agree upon as the price. Considering either party's state of mind as part of the FMV assessment introduces

subjectivity and, consequently, uncertainty; therefore, such consideration should not be a factor. Similarly, whether the parties to an arrangement are in a position to generate business for each other should not be relevant to the determination of FMV. Second, there should be a **presumption that the price is FMV.** Currently, the presumption is just the opposite — a transaction is presumed not to be FMV unless the provider can prove it is. The current policy reflects an outdated view that all relationships between hospitals and physicians are suspect and has served to encourage meritless lawsuits by permitting qui tam relators to survive motions to dismiss based on groundless allegations of compensation in excess of FMV.

- **"Takes into account":** The "takes into account" standard in various exceptions prohibits compensation from considering the volume or value of a physician's referrals. We recommend that CMS adopt a new "deeming" provision to the effect that any compensation that does not fluctuate with a physician's referrals is deemed not to take into account the volume or value of a physician's referrals. Further, the provision should state that if a physician's compensation is concluded to be within the range of FMV, it is deemed to have not taken into account the volume or value of the physician's referrals. We also recommend that CMS formally affirm that compensation based on a physician's personally performed services does not take into account the volume or value of the physician's referrals even if the physician's services generate a corresponding facility fee.
- **Commercial reasonableness:** Economic elements of the Stark Law, such as compensation and purchase price, are most appropriately evaluated under an objective FMV standard and not a "commercial reasonableness" standard. CHA proposes that CMS adopt a clear standard that the commercial reasonableness concept applies only to the non-economic elements of the arrangement; for example, whether the items or services being purchased are useful and included in terms and conditions of similar arrangements.

Finally, we want to call attention to one area that should not be subject to change — regulations implementing the Stark Law's physician ownership ban. That carefully crafted policy is working as Congress intended and should not be altered.

CHA appreciates the opportunity to provide CMS with our proposals on how to improve the Stark Law. 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