

Response to RFIs: EBG Submits Comments to CMS on Stark Law Reforms and Is Preparing Comments to OIG on Anti-Kickback Statute and Beneficiary Inducement CMP Modifications

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As addressed in a previous Epstein Becker Green (“EBG”) [Client Alert](#), earlier this summer, the Centers for Medicare & Medicaid Services (“CMS”) published in the *Federal Register* a [“request for information”](#) (“RFI”) regarding potential reforms to the federal physician self-referral law (or the “Stark Law”). The impetus for the RFI was an effort by the U.S. Department of Health and Human Services (“HHS”) to accelerate the government’s transformation from a fee-for-service system to a value-based system focused on care coordination (referred to as the “Regulatory Sprint to Coordinated Care”).

On the heels of CMS’s Stark Law RFI, on August 27, 2018, the HHS Office of Inspector General (“OIG”) issued its own [RFI](#) pertaining to the federal Anti-Kickback Statute (“AKS”). In the AKS RFI, OIG is soliciting comments on the ways in which it might modify or adopt new safe harbors to the AKS and modify or add new exceptions under the beneficiary inducements civil monetary penalty provisions of the Social Security Act (“CMP”). The OIG states that its goal in this process is to evaluate the AKS and, in doing so, 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.

EBG’s Comments to the Stark Law RFI

Turning first to the Stark Law RFI, on behalf of a number of firm clients and based on our collective representation of numerous health industry stakeholders on Stark Law issues over recent decades, EBG submitted comments in response to this RFI. A copy of EBG’s response letter to CMS can be found at https://www.ebglaw.com/content/uploads/2018/08/CMS-RFI-Submitted-8_24_18.pdf.

In our response letter to CMS, EBG provided examples and descriptions of instances in which the current Stark Law regulatory exceptions are not broad enough to allow the industry to align incentives among all stakeholders and protect cost-reduction measures that can reduce medical spend in both Medicare and commercial pay programs.

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As part of our letter, we offered a number of suggestions for CMS. The following are some of our suggestions:

- Create new regulatory exceptions for: Arrangements Unrelated to Federal Health Care Program Business; Services Furnished by a Clinically Integrated Network or Accountable Care Organization (“ACO”); Services Furnished by an Integrated Delivery System; and Incentive Payments, Shared Savings Programs, and Other “Gainsharing” Type Arrangements;
- Expand the prepaid plan exception to include licensed health maintenance organizations, preferred provider organizations, and insurers that manage care;
- Expand the current risk-sharing exception and eliminate from this exception both the word “enrollee” and the reference to managed care organizations;
- Expand the special rule for compensation under a physician incentive plan to all relevant compensation exceptions;
- Scale back the expansive interpretations of the Stark Law from 2009 that transformed services that were not previously on the list of designated health services (“DHS”) when provided pursuant to a contractual relationship with a hospital and billed by a hospital, i.e., so-called *under arrangements*;
- Eliminate from the definition of “DHS” the professional component of certain imaging services;
- Clarify further CMS’s position on what constitutes commercial reasonableness;
- Confirm that the definition of “fair market value” is flexible;
- Recognize that fee schedules and other payment methodologies are set in advance and are not based on the volume or value of referrals so long as the payment rate does not fluctuate based on referrals during the contract term;
- Modify a number of limitations that CMS has placed on the ability of physician groups to qualify as “group practices”;
- Revise the exceptions related to remuneration unrelated to the provision of DHS and payments by a physician;
- Impress upon CMS that it lacks the statutory authority to create a hierarchy of exceptions or require that certain exceptions be used exclusively for specific situations;
- Urge CMS to address (and finalize in regulations) that the Stark Law itself does not impact Medicaid payments to particular providers because states have the ability to choose whether or not to seek federal financial participation dollars; and

- Request that CMS consider the ways in which it might provide Stark Law protection for various arrangements recognized under the Anti-Kickback Statute safe harbors.

Overview of the AKS RFI

Regarding the AKS RFI, as noted above, OIG is soliciting comments on the ways in which it might modify or adopt new safe harbors to the AKS and modify or add new exceptions to the beneficiary inducement CMP provisions. This RFI was prompted, in part, by OIG's recognition that the broad reach of the AKS and the beneficiary inducement CMP may be impeding beneficial arrangements that could facilitate the coordination of patient care.

The AKS RFI identifies several specific areas of input and information that OIG is seeking from the public, including:

- Detailed information regarding potential arrangements that the industry is interested in pursuing, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements that may implicate the AKS and beneficiary inducement CMP;
- Suggestions for additional or modified safe harbors or exceptions to the definition of "remuneration" under the beneficiary inducement CMP to protect care coordination and value-based care arrangements;
- Comments on how "value" could be defined and applied to safe harbors or exceptions such that OIG could evaluate "value" within an arrangement;
- Suggestions for definitions for critical terminology, including, but not limited to, "alternative payment model," "care coordination services," "clinical integration," "incentive payments," "risk-sharing," etc.;
- Clarification on whether there are opportunities where OIG could issue guidance, as opposed to regulations, to articulate its position;
- Detailed information regarding the types of incentives that providers, suppliers, and others are interested in providing to beneficiaries;
- Information on how relieving or eliminating the beneficiary cost-sharing obligation might improve care delivery, enhance value-based arrangements, and promote quality of care;
- Feedback on the current fraud and abuse waivers for testing models by the CMS Innovation Center and carrying out the Medicare Shared Savings Program, including information on whether compliance with the waiver programs has been challenging, what requirements are particularly burdensome, what conditions or structures have worked well, feedback on how the ACO governing body concept

is working, and feedback on the pros and cons of fraud and abuse protections that are uniform across different types of CMS-sponsored initiatives;

- Information regarding how fraud and abuse laws may pose barriers to donating or subsidizing cybersecurity-related items and services to providers and others with whom information is shared;
- Information related to two new statutory exceptions for ACO beneficiary incentive program incentive payments and telehealth, as added by the Bipartisan Budget Act of 2018, Public Law 115-123, 115th Cong. (2018) (enacted); and
- Feedback regarding the intersection of the Stark Law and the AKS.

Responses to the AKS RFI are due by October 26, 2018.

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Given the importance of these issues, Epstein Becker Green is working with our clients to organize and submit comments and information in response to the AKS RFI. If you are interested in participating in this submission, please contact the Epstein Becker Green attorney with whom you regularly work, or any of the authors of this Client Alert—**Jason E. Christ, Anjali N.C. Downs, Leonard Lipsky, David E. Matyas, Bonnie I. Scott, Victoria Vaskov Sheridan, and Carrie Valiant**—who are among our team of attorneys focused on these fraud and abuse laws.

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