

CMS Request for Information: Reforming the Stark Law to Facilitate the Transformation to Value-Based Care

By Jason E. Christ, Anjali N.C. Downs, David E. Matyas, Victoria Vaskov Sheridan, and Carrie Valiant

June 2018

On June 25, the Centers for Medicare and Medicaid Services (“CMS”) published in the Federal Register a [“request for information”](#) regarding potential reforms to the federal physician self-referral law (or the “Stark Law”). The request for information: (i) acknowledges that the current Stark Law regulations may create barriers to implementing alternative payment models focused on value and coordinated care and (ii) seeks information from the public on how the Stark Law regulations should be revised or modified to permit and incentivize payment reform.

The request for information reflects ongoing efforts by the Department of Health and Human Services 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”). Moreover, the request follows a number of other recent administrative actions and announcements focused on reforming the current regulatory environment, including the formation of an interagency group to review the regulatory barriers to alternative payment models created by the Stark Law and a proposal in the Trump Administration’s 2019 budget to reform the Stark Law to “better support and align with alternative payment models and to address overutilization.” These more recent actions continue to build on concerns and recommendations identified in a white paper released by the Senate Finance Committee in 2016 that recommended improvements to the Stark Law to encourage new payment models.

The request identifies several specific areas of input and information that CMS is seeking from the public:

1. Detailed information regarding existing or potential arrangements between designated health services (“DHS”) entities and referring physicians that participate in alternative payment models with any type of payer—public or private.

2. Issues related to the applicability of the existing Stark Law exceptions to a particular alternative payment model and/or the ability of the alternative payment model to satisfy an existing exception.
3. Suggestions for additional exceptions to the Stark Law that may be necessary to protect financial relationships between DHS entities and referring physicians who participate in the same alternative payment model, or that relate to payments for integrating and coordinating care outside of alternative payment models.
4. Suggestions for definitions of new key terminology, or revisions to current terminology, to help effectuate changes necessary to permit alternative payment models to operate within the Stark Law's restrictions.
5. Comments on the role of transparency in the context of the Stark Law and whether transparency surrounding a physician's financial relationships has the potential to reduce or eliminate harm to the Medicare program.

The request for information is a unique method for obtaining stakeholder input on regulatory activity. Prior rulemaking efforts under the Stark Law utilized the typical notice and comment process, whereby the agency developed proposed regulations before formally seeking public input. By soliciting public comment before the regulations are drafted, CMS has presented stakeholders with a significant opportunity to collaborate and pursue mutual objectives as the health care system transforms into payments based on value and coordinated care. In particular, the following types of arrangements may benefit from participating in the response to the request for comment:

- Hospitals that desire to pay physicians for assisting the hospital in achieving certain quality benchmarks.
- Hospitals and physician groups that receive care coordination, shared savings, or similar value-based payments from commercial payers and that desire to pass a portion of those payments to downstream referring physicians.
- Accountable care organizations that do not participate in the Medicare Shared Savings Program and, therefore, are unable to rely on waivers implemented under that program to protect remuneration provided among the accountable care organization and its participants.
- Remuneration provided among members of an integrated health care delivery system that does not qualify as an "academic medical center."
- DHS entities that desire to provide physicians with infrastructure, tools, and/or related services for the purpose of encouraging and achieving care coordination, quality, and efficiency.

- Joint ventures involving ownership and participation by both DHS entities and referring physicians who desire to distribute revenue associated with both fee-for-service and alternative payment models to referring physicians.
- Multi-specialty physician groups focused on care coordination that provide ancillary services but may not qualify as a “group practice” under the Stark Law.

Responses to the request for information are due by August 24, 2018.

* * *

Given the importance of these issues, Epstein Becker Green is working with our clients to organize and submit comments and information in response to this request for information. 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, David E. Matyas, Victoria Vaskov Sheridan, and Carrie Valiant**—who are among our team of attorneys focused on the Stark Law.

This document has been provided for informational purposes only and is not intended and should not be construed to constitute legal advice. Please consult your attorneys in connection with any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your company.

About Epstein Becker Green

Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973 as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in locations throughout the United States and supporting domestic and multinational clients, the firm’s attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

If you would like to be added to our mailing list or need to update your contact information, please contact Lisa C. Blackburn at lblackburn@ebglaw.com or 202-861-1887.