

## Proposed 2016 Medicare Physician Fee Schedule Includes Changes to Stark Regulations

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**SUMMARY**

The Centers for Medicare & Medicaid Services (“CMS”) recently released the proposed 2016 Medicare Physician Fee Schedule (the “Proposed Rule”), which includes a number of proposed revisions to the regulations under the federal physician self-referral law (commonly referred to as the “Stark Law”), as well as the solicitation of comments on other potential revisions to these regulations. The Proposed Rule, if implemented, will affect the implementation of health care delivery and payment reform initiatives.

While these proposed changes are not yet final, the Proposed Rule provides guidance as to potential changes in the Stark Law regulations and provides health care entities and physicians with an important opportunity to comment on these prospective changes before they become effective. A detailed analysis of the Stark Law issues in the Proposed Rule, prepared by George W. Bodenger and Karilynn Bayus of the Firm’s Health Law Practice, is available at <http://tinyurl.com/2016Stark>. Comments to the Proposed Rule must be received by CMS no later than 5:00 PM on September 8, 2015. Saul Ewing can assist in preparing comments to CMS.

The Proposed Rule is published in its entirety at <http://federalregister.gov/a/2015-16875>. Some of the significant changes to the Stark Law regulations contemplated under the Proposed Rule include:

### Recruitment/Retention of Non-Physician Practitioners

CMS proposes a new exception for assistance in employing “non-physician practitioners” (“NPPs”), as well as clarifications for Federally Qualified Health Center (“FQHC”) and Rural Health Clinic (“RHC”) service areas. This proposed new exception was prompted by the shortage of available primary care services, and represents a significant opportunity for hospitals, FQHCs and RHCs to assist medical practices in hiring non-physician practitioners to enhance primary care services delivery.

### Revisions to “In Writing” Requirements

CMS clarifies that Stark Law exceptions that require writings for compliance do not require a formal agreement or a single document. Instead, “a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.” This is a significant relaxation of current Stark Law requirements for compensation arrangements and makes compliance with such exceptions less burdensome to entities that provide designated health services (“DHS”) and physicians.

## Timeshare Arrangements

CMS proposes a new exception that would protect timeshare arrangements in which a hospital or physician organization licenses the use of space, equipment, personnel, items and supplies to a physician licensee. The proposed exception would require that substantially all of the services furnished to patients on the licensed premises are not DHS, and that only DHS that is incidental to the patient's evaluation and management visit, and furnished contemporaneously with that visit, are permissible.

## Solicitation of Comments: Perceived Need for Regulatory Revision or Policy Clarification Regarding Permissible Physician Compensation

In this section, CMS discussed the Medicare program's efforts over the past two decades to transition from traditional fee-for-service to value-based payment models. CMS' stated goals in these initiatives are referred to as the "three part aim": (1) improving the experience of care, (2) improving the health of populations, and (3) reducing per capita costs of health care.

To aid CMS in determining whether additional rulemaking or guidance is desirable or necessary, CMS is soliciting comments regarding the impact of the Stark Law on health care delivery and payment reform. CMS is interested in comments regarding perceived barriers to achieve clinical and financial integration posed by the Stark Law. The questions include the following:

- Does the physician self-referral law generally and, in particular, the "volume or value" and "other business generated" standards set out in the regulations, pose barriers to or limitations on achieving clinical and financial integration?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?

- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted?
- Is there a need for new exceptions to the physician self-referral law to support shared savings or "gainsharing" arrangements?

A complete list of the questions raised by CMS in the Proposed Rule is available at <http://tinyurl.com/2016Stark>.

All providers that are affected by the Stark Law should provide comments to CMS regarding the Proposed Rule and reply to the specific questions raised by CMS. Saul Ewing can help interested parties frame responses to ensure that CMS appreciates the perspective of active participants in the health care delivery system.

Members of Saul Ewing's Health Care Practice have significant experience with the Stark Law and its impact on providers and various types of practices. For more information on the Proposed Rule and health law issues generally, please contact the authors or the attorney at the Firm with whom you are regularly in contact.

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