

CLIENT ALERTS

Want to Vent on the Stark Law? Here is a chance.

7.2.2018

The Centers for Medicare & Medicaid Services ("CMS") has issued a request for information seeking input from the public on how to address any undue regulatory impact and burden of the physician self-referral law (the "Stark Law").

Exasperation with the technical and practical restrictions of the complex and intricate Stark Law has been apparent since 1988 when Congressman Pete Stark introduced the "Ethics in Patient Referrals Act," the first of the so-called Stark Law. Now, CMS has issued an invitation to interested parties to comment on them. Here is a link to the Federal Register.

The Stark Law, expanded since the 1988 original legislation, and its regulations prohibit physicians from referring a Medicare or Medicaid patient to an entity providing designated health services ("DHS") if the physician (or an immediate family member) has a financial relationship with that entity. A "financial relationship" includes ownership, investment interest, and compensation arrangements between physicians and DHS entities. DHS includes a wide variety of services: clinical laboratory services; physical and occupational therapy; radiology (including MRI, CT, and ultrasound; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics and orthotics; home health services; outpatient prescription drugs; inpatient and outpatient hospital services; and outpatient speech-language pathology services.

Convoluting and complex, the Stark Law and its regulations were designed to address policy concerns that health care utilization and costs were being driven upward, to the detriment of patients and the Medicare and Medicaid programs paying for DHS. The policy identified an inherent conflict of interest where a physician refers a patient for DHS and also receives financial gain from the referral as a result of an interest in the entity providing the DHS.

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Critics have questioned the policy's foundation that physicians are motivated to act in their self-interest over the best interests of their patients; that (assuming a problem did sometimes exist) the Stark Law and regulations are too complex and, cumbersome; that self-referrals are often essential and inevitable in rural and medically underserved areas; and that DHS entity costs are a fraction of the price of the same services when performed in a high overhead, high-cost hospital setting.

The breadth of the Stark Law led to an initial set of exceptions, which have expanded as new delivery models and systems have evolved. The exceptions, are themselves complex, with additional layers of commentary, Advisory Opinions, educational materials, enforcement actions, and judicial decisions governing the Stark Law's application. Most states have enacted "mini-Stark Law" legislation to extend the Stark Law's prohibitions to state governmental payors and HMOs, PPOs, and insurers regulated by the states.

CMS Administrator Seema Verma said the agency is seeking public comment on the Stark Law, focusing, among other things, on how the Stark Law may impede care coordination. CMS said it is particularly interested in comments regarding the ever-evolving structure of arrangements between providers. "To achieve a truly value-based, patient-centered health care system, doctors and other providers need to work together with patients. Many of the recent statutory and regulatory changes to payment models are intended to help incentivize value-based care and drive the Medicare system to greater value and quality. ... Dealing with the burden of the physician self-referral law is one of our top priorities as we move towards a health care system that pays for value rather than volume."

Verma said CMS will create an interagency group (including CMS, the HHS Inspector General, and the Department of Justice) to review the comments, and that it may require "congressional intervention" as well.

Public comments are due by 5 p.m. EST, August 24, 2018. Interested parties may:

- submit electronic comments on this regulation to <http://www.regulations.gov> by following the "Submit a comment" instructions; or
- mail written comments to: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1720-NC, P.O. Box 8013, Baltimore, MD 21244-8013; or
- send express or overnight mail to: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1720-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Sufficient time must be allowed for mailed comments to be received before the close of the comment period.

The public comment period expires at 5 p.m. EST on August 24, 2018. Expect a deluge.

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If you have questions about the Stark Law and regulations, need assistance in submitting or reviewing comments, or need other information about the self-referral regulation, please contact the authors of this alert, any member of Butzel Long's healthcare industry group, or your regular Butzel Long attorney.

Mark R. Lezotte

313.225.7058

lezotte@butzel.com

Debra A. Geroux

248.258.2603

geroux@butzel.com

Robert H. Schwartz

248.258.2611

schwartzrh@butzel.com