WASHINGTON STRATEGIC CONSULTING

WSC ALERT – ACTION NEEDED

CMS Seeking Comment on Easing Regulatory Burden of Stark Law

On June 20, 2018, CMS issued a request for information (RFI) seeking input from the public on how to address any undue regulatory impact and burden of the physician self-referral law, also known as "Stark Law."

CMS is requesting public comment on 20 specific areas; the full list, along with additional details and context, is listed on the RFI web page. Due to the length and complexity of the CMS request, and in an effort to collect feedback from a diverse cross-section of stakeholders, we have distilled the 20 areas of inquiry into a smaller number of broader categories. Those categories are listed below.

Comments are due to CMS by August 24, 2018.

Stark Law Overview

Enacted in 1989, the physician self-referral law is intended to disconnect a physician's health care decision making from his or her financial interests in other health care providers and suppliers. Specifically, the law:

(1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies;
(2) Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services.

The statute establishes over 30 specific exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

More information on the physician self-referral law can be found by clicking here.

Abridged RFI Questions

Abridged Question	Link to Question
1. Please identify specific concerns regarding the applicability of current Stark Law exceptions to your organization's existing or potential participation in alternative payment models (APMs) or other novel financial arrangements.	1
2. What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physicians who participate in the same APM?	2
3. What additional exceptions are necessary to protect financial arrangements that involve integrating and coordinating care outside of APMs?	3
4. Please share your thoughts on the application and utility of the following current exceptions (see "Exceptions Defined" section, below): a) Risk-sharing arrangements b) Personal service arrangements c) Remuneration unrelated to DHS	4, 5, 14
5. Please share your thoughts on possible approaches to defining "commercial reasonableness" and modifying the definition of "fair market value" in the context of the exceptions to the physician self-referral law.	10
6. Please share your thoughts on when, in each of the below contexts, compensation should be considered to "take into account the volume or value of referrals" by a physician or "take into account other business generated" between parties to an arrangement. a) The physician self-referral law b) Alternative payment models and other novel financial arrangements	11, 12
7. Please share your thoughts regarding whether and, if so, what barriers exist to qualifying as a "group practice" as defined by CMS.	13
8. Please share your thoughts on compliance costs for regulated entities.	18

Exceptions Defined

Risk-sharing arrangements. Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings set forth in § 1001.952(l) of this title.

Personal service arrangements. Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum*

tenens physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

Remuneration unrelated to DHS. To qualify as "unrelated," remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals.

***