Healthcare Law Alert – Summary of 2016 New Stark Exceptions and Clarifications

As previously reported by Hancock Estabrook (Health Care Law Alert July 2015), the Office of the Inspector General for the U.S. Department of Health and Human Services proposed significant, and in many cases welcome, revisions to the federal physician self-referral prohibition or "Stark" law. On November 16, 2015, the final revised regulations were issued, with an effective date of January 1, 2016. The following briefly summarizes the major changes contained in the revised regulations.

Recruitment of Non-Physician Providers

Overview: Under a new exception, hospitals, federally qualified health centers and rural health clinics (DHS entities) can provide financial support to physicians or physician practices (referred to in the regulations as "physician organizations") for the recruitment of certain categories of non-physician practitioners (NPPs), so long as those practitioners will be providing primary care or mental health services to the physicians'/physician organizations' patients. The physicians/physician organizations must either employ or establish direct independent contractor arrangements with NPP recruits. The new exception imposes complex requirements on the support terms (similar, in part, to the requirements of the physician recruitment exception), as well as limits on the amount the DHS entity can pay and the time frames during which such support can be provided.

Specifics:

1. Non-Physician Providers

The NPPs for which a DHS entity may provide support are limited to:

Nurse Practitioners

Physician Assistants

Clinical Nurse Specialists

Certified Nurse Mid-Wives

Clinical Social Worker

Clinical Psychologist

2. Limit on Kinds of Services NPP Can Provide

"Substantially All" of the clinical services the NPP provides to patients of the physician/physician organization must be "primary care services" or mental health services. Primary care services include:

General Family Medicine

General Internal Medicine

Pediatrics

Geriatrics

Obstetrics

Gynecology

Mental Health Care Services

3. Determining “Substantially All”

“Substantially All” means that at least 75% of all NPP’s services to the physicians’/physician organization’s patients must be primary care or mental health services. NPP’s patient care services must be measured by either the total amount of time the NPP spends delivering such services, documented by any reasonable means, or an alternative measure that is:

Reasonable,

Fixed in advance, before services are performed,

Uniformly applied, over time,

Verifiable, and

Documented

4. NPP Must Not Currently Work or Have Recently Worked in Geographic Area

The NPP cannot have practiced within the geographic area served by the DHS entity nor can he/she have been employed/under contract with a physician/physician organization that has an office located within such geographic area (regardless of where the NPP himself/herself practiced) within the 12 months immediately preceding the date upon which he/she begins providing services inside the geographic area.

5. Limit on DHS Entity’s Support

The DHS entity can provide financial support to the physician/physician organization for no more than 2 years and the total support provided cannot exceed 50% of the actual aggregate compensation, signing bonus and benefits paid by the physician/physician organization to the NPP. “Benefits” are limited to health insurance, paid leave and “other routine non-cash benefits offered to similarly situated employees”. “Compensation” can include relocation costs.

6. Limit On Repeat Support to Same Physician/Practice

This exception may only be used once every 3 years for the same physician/physician organization. Supporting a replacement NPP is permitted if the original recruit terminates his/her relationship with the physician/physician organization inside of 1 year, BUT the 2 year support time frame will continue to run from the date the first (unsuccessful) recruit joined the physician/physician organization.

7. No Need to Set NPP's Compensation in Advance

While the NPP's compensation, signing bonus and/or benefits need not be "set in advance" and, therefore, can change over the course of the 2 year period, whatever compensation is paid must be "fair market value".

8. No Staffing Agencies

If the NPP is an independent contractor to the physician/physician organization instead of an employee, the contract must be directly between the physician/physician organization and the NPP. There cannot be a staffing agency as an intermediary.

9. No Practice Restrictions

The physician/physician organization cannot impose practice restrictions on the NPP after he/she leaves physician/physician organization which unreasonably restrict his/her ability to provide patient care services in the geographic area served by the DHS entity.

0. Other Requirements Similar to the Physician Recruitment Exception

- Arrangement must be:

Set out in writing

Signed by the DHS entity

Signed by the physician/physician organization

Signed by the NPP

- Remuneration must not be conditioned on the physician's, the physician organization's and/or the NPP's referrals to the DHS entity.
- Remuneration must not take into account, directly or indirectly, the volume or value of current or anticipated referrals by either the physician/physician organization or the NPP.
- NPP's compensation must be fair market value.
- Arrangement must not violate the anti-kickback laws or any other State or Federal laws governing billing or claims submission.
- Records of (i) the actual amount of support paid by the DHS entity to physician/physician organization and (ii) the compensation and benefits paid by the physician/physician organization to the NPP must be maintained for 6 years.

Timeshare Arrangements

Overview: Arrangements between physicians/physician organizations and hospitals or other physician organizations which provide access to and use of office space, equipment, personnel, items, supplies and/or services but do not convey a possessory leasehold interest in the space in question (a "timeshare") are eligible for this new exception. Previously, such arrangements had to comply with both the space lease exception (including the "exclusive use" component of that exception) and another exception covering the other components of the arrangement (equipment, personnel, services

and supplies, etc.). Now one exception is available for such multifaceted arrangements. The critical distinguishing factor between arrangements that are eligible to use this exception and arrangements that must satisfy the space lease exception is that a timeshare (as CMS uses that term) "does not transfer dominion and control over the premises .... but rather confers a privilege to use [the premises] during specified periods of time." The specific language in the new exception requires that the arrangement, "not convey a possessory leasehold interest in the office space that is the subject of the arrangement." The new exception does not require that the physician/physician organization have "exclusive use" over the space (as required under the space lease exception), nor does it preclude arrangements with terms of less than 1 year. It does, however, impose new and unique restrictions, as well as some of the structural requirements that are common in other Stark exceptions.

Specifics:

1. The arrangement must be between a physician (or the physician organization in the shoes of which that physician stands) and a hospital or another physician organization with which the physician does not have an ownership, employment or contractor relationship.
2. The arrangement need not be for a minimum term of 1 year, nor is it required to confer "exclusive use" over the space, equipment, etc.
3. The space, equipment, personnel, items, supplies or services that are subject of the arrangement must be:

- "Predominantly used" for the provision of evaluation and management ("E&M") services to patients and
- Used on the same schedule.

4. The equipment:

- Must be located in the same building as the space, personnel, items, supplies or services that are also part of the timeshare arrangement;
- Must not be used to provide DHS services other than those which are (i) incidental to E&M services provided to the patient and (ii) provided at the same time as those E&M services are provided to the patient; and
- Must not be advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

5. The compensation cannot be determined using a formula based on

- A percentage of revenue raised, billed or collected by the physician or otherwise attributable to the physician's services provided while accessing the space, equipment, etc. under the arrangement.
- Per-unit of service fees that are not time based, to the degree such fees reflect services rendered to patients referred by the party that retains control over the space, equipment, personnel, items, supplies and services.

6. The arrangement:

- Must be set out in writing;
- Must be signed by the parties;
- Must specify the space, equipment, personnel, items, supplies, and services covered by the arrangement;
- Must be commercially reasonable even if no referrals were made between the parties; and

- Must not violate the anti-kickback laws or any other State or Federal laws or regulation governing billing or claims submission.

7. The compensation over the term of the arrangement:

- Must be set in advance;
- Must be consistent with fair market value; and
- Must not be determined in a manner that takes into account, directly or indirectly, the volume or value of the referrals or other business generated between the parties.

90-Day Grace Period for Securing Signatures

Overview: Prior to the change, the Stark law permitted a signature which was not on the documents at the time the transaction commenced to be added later, under certain circumstances. If the lack of a signature was inadvertent, it could be added up to 90 days after the transaction commenced. If the lack of a signature was not inadvertent – meaning the parties knew the signature had not been secured prior to the commencement of the transaction – a 30-day grace period was granted. The revised regulations grant a 90-day grace period for securing signatures after the commencement of a transaction, regardless of whether or not the failure to secure the signature(s) was inadvertent.

Specifics:

1. This accommodation is available for all exceptions which require a signature.
2. This accommodation is only available if all other requirements of the exception were satisfied at the time the transaction commenced (including, as applicable, having documentation of the agreed-upon transaction, financial terms set in advance, fair market value, commercial reasonability, etc.).
3. This grace period can be used only once every 3 years with respect to the same physician or physician organization.
4. This is not retroactive for any arrangements other than ones that were within the previous applicable holdover periods at the time the new regulations went into effect.

What Constitutes a "Writing", What Constitutes a "Signature" and Who Needs to Sign

Overview: The comments from the OIG accompanying the revised regulations clarified the OIG's position that the "writing" and "agreement" required by various exceptions can be satisfied by a collection of documents; there does not need to be one overarching document containing all critical terms. In addition, the revised regulations changed all references in the regulations to "arrangement" rather than "agreement" or "contract", to make it clearer that there need not be one unified formal "contract". Further, the OIG indicated in comments that not all documents which collectively make up the "writing" need to be signed by both parties and suggested some flexibility as to what constitutes a "signature. Finally, the OIG further clarified that physicians who do not stand in the shoes of a physician organization need not sign the requisite documents

Specifics:

1. The OIG declined to endorse/adopt state law interpretation of what constitutes a contract.
2. The writings required by any exception can be a collection of documents of many types.
3. The writings must have been in existence before the transaction commenced. There is no grace

period for the writing as there is for the signature requirement.

4. If the writings did not exist prior to commencement of the transaction, referrals can be immunized, going forward, once the requisite writings/collection of documents are created. But there is no retroactive immunization for referrals which predated the existence of the writings.
5. All required signatures need not be on every document or writing. The documents which are signed, however, must somehow relate to the whole collection of documents and the overall arrangement.
6. The OIG declined to endorse/adopt state law interpretation of what constitutes a signature. Rather, the OIG indicated that it will consider any reasonable argument about what constitutes a signature and will not preclude, out of hand, using certain things (such as electronic signatures) as signatures, including those which would be acceptable under state law. The key, per the OIG, is that whatever it is, a signature evinces the assent of the parties to the arrangement.
7. Employees and independent contractors of a physician organization need not sign documents detailing the arrangements between physician organizations and DHS entities. While physicians who stand in the shoes of such organizations must sign the documents, the OIG confirmed its previous advice (given via "Frequently Asked Questions") that the OIG will consider a physician who stands in the shoes of a physician organization to have "signed" the document when the authorized signatory of the physician organization has done so. In other words, so long as an authorized signatory of the physician organization has signed the document, physicians who stand in the shoes of the physician organization will be deemed to have signed the document as well.
8. These are retroactive, as they merely clarify what the OIG's position has been all along.

Unlimited "Holdover" Period for Expired Agreements

Overview: Previously, the Stark regulations permitted a 6-month holdover period for expired leases (both equipment and space) and personal services agreements before the arrangement would fall out of compliance with the applicable Stark exception. The new regulations permit expired leases and personal services arrangements to hold over indefinitely on the same terms without falling out of compliance. In addition, the new regulations permit a transaction covered by the fair market value exception to be renewed for an unlimited number of terms, so it operates similar to the "holdover" regulation.

Specifics:

1. The arrangement must otherwise satisfy all other requirements of the applicable exception, including fair market value and the "writing" requirements.
2. This is not a retroactive clarification.

Other Revisions and Clarifications

1. Defined "geographic area" for purposes of physician recruitment by Federally Qualified Health Centers and Rural Health Clinic.
2. Revised references in the exceptions for physician recruitment, medical staff incidental benefits, obstetrical malpractice insurance subsidies and professional courtesy discounts, so that the phrase "takes into account" the volume or value of referrals is used consistently. While term is not defined, comments on this topic have been solicited.

3. Corrected language in retention payment exception regarding how to calculate physician's current compensation prior to calculating the subsidy. The calculation of current compensation must assess the physician's compensation over the preceding 24 month period, in its entirety.
4. Clarified that an arrangement relying upon an exception which requires a term of at least one year need not state that it has a term of at least one year. Those relying upon such exceptions must be able to prove that the arrangement remained in place for at least a year or was terminated within the first year and was not renewed.
5. Clarifying that compensation paid to a physician organization cannot take into account the referrals of any physician in the physician organization, not just the physician who stands in the shoes of the physician organization.
6. DHS entities can give physicians/physician organizations items used solely for one or more of the purposes identified in the statute.
7. Clarified that a financial relationship does not exist when a physician provides services to hospital patients in the hospital if the hospital and the physician each bills independently for their services and there is no other remuneration passing between them. This is a clarification of existing policy – not a new policy. However, the OIG declined the opportunity to discuss how it will analyze exclusive agreements, with respect to this point.
8. Updated obsolete language in the exception for ownership of publicly-traded entities to allow over-the-counter transactions.
9. Removed unnecessary language from the definition of a locums tenens physician.

This summary is not intended as legal advice. Application of these new regulations to specific situations requires a case-by-case analysis. In addition, the information contained in this alert was accurate as of the day of publication. Regulations and their interpretation can change over time. Please consult one of our Firm's health law attorneys listed below or your own lawyers to understand how the revised regulations affect specific situations.

Visit our Healthcare Practice Area to learn more about the legal services we can provide in this area. If you have any questions or would like more information on the issues discussed in this communication, please contact any member of our Healthcare Practice Area.