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CMS and OIG Relax Requirements of Stark Law and Anti-Kickback Statute during COVID-19 Crisis

Scott Bennett and Marki Stewart, Coppersmith Brockelman PLC

April 9, 2020

In an effort to try to ensure that Medicare and Medicaid patients can receive needed health care during the COVID-19 crisis, the Centers for Medicare and Medicaid Services (CMS) has waived key provisions of the Stark Law. Similarly, the Office of Inspector General (OIG) within the U.S. Department of Health & Human Services announced in a policy statement that it will not enforce the Anti-Kickback Statute as to much of the conduct covered by the Stark waivers.

This briefing explains the key points of the Stark waivers and the OIG's policy statement.

What do the Stark Law waivers allow?

The Stark Law regulates financial relationships between physicians and entities that provide Designated Health Services (DHS). When there is a financial relationship between a physician (or immediate family member) and a DHS entity, the physician may not refer Medicare patients to that entity, and the entity may not bill Medicare for patients referred by the physician – unless the arrangement fits into one of the Stark Law's exceptions.

The COVID-19 waivers by CMS relax some of the requirements of various Stark Law exceptions. The critical limitation is that the waivers are limited to financial arrangements that are "solely related to COVID-19 Purposes."

CMS has articulated six specific "COVID-19 Purposes." Those are:

1. Diagnosing or treating any confirmed or suspected case of COVID-19;
2. Obtaining the services of physicians or other health care providers, including services not related to COVID-19;

3. Ensuring health care providers' ability to address patient and community needs;
4. Expanding health care providers' capacity to address patient and community needs;
5. Shifting patient care to alternative settings; and
6. Addressing the interruption of medical practices and businesses in order to maintain a sufficient supply of medical care and services.

What are the specific Stark waivers?

There are 18 specific waivers that can be grouped into six general categories. Here is a summary of the waivers, as well as concrete examples provided by CMS:

Category	**Examples**
Fair market value DHS entities may pay either more or less than fair market value (FMV) for services performed by a physician. DHS entities may pay physicians less than FMV (not more) for the lease of office space, equipment rental, or other items or services. Physicians may pay DHS entities less than FMV for the lease of office space, the use of the entity's premises, equipment rental, or other items or services. DHS entities and physicians may loan money to one another at an interest rate that is below FMV.	A hospital pays physicians more than FMV for providing professional services for COVID-19 patients in particularly hazardous or challenging circumstances. Independent physicians allow a hospital to use, for free, the physicians' medical office space, to treat patients who are not suspected of having COVID-19. An entity provides free equipment to physicians to facilitate telehealth visits for patients who are observing social distancing or in quarantine. A hospital covers a physician's normally-required 15% contribution for electronic health record items and services, to ensure the physician has uninterrupted access to patient records.
Incidental benefits & Nonmonetary compensation Hospitals may provide medical staff incidental benefits and nonmonetary compensation that exceed the normal annual limits.	A hospital provides meals, a change of clothing, or onsite child care with a value greater than $36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak.

Category	Examples
Location of in-office ancillary services Physicians may make referrals for DHS provided outside of the group practice's location, such as in the patient's home or in a nursing home.	A physician in a group practice whose principal medical practice is office-based orders radiology services that are furnished by the group practice to a Medicare beneficiary who is isolated or observing social distancing at home.
Physician-owned hospitals & Ambulatory surgery centers Physician-owners may make referrals to a hospital that has temporarily expanded its bed capacity, or to an ASC converted to a temporary hospital.	A physician-owned hospital temporarily converts observation beds to inpatient beds to accommodate patient surge.
Physician-owned home health agency Physicians may refer patients to a home health agency in which the physician (or an immediate family member) has an ownership or investment interest, regardless whether the agency qualifies as a rural provider.	A physician refers a Medicare beneficiary to a home health agency owned by an immediate family member of the physician because there are no other home health agencies with capacity to provide the necessary home health services.
Writing and signature requirements Allows compensation arrangements that meets all elements of a Stark exception except the writing and/or signature requirements.	A physician provides call coverage to a hospital before the arrangement is documented and signed. A physician's daughter begins working as a hospital's paid COVID-19 outbreak coordinator before the arrangement is documented and signed.

Do the waivers excuse arrangements from all Stark requirements?

No. The waivers modify or eliminate only the specified elements of various Stark exceptions. Arrangements must still meet all other elements of an exception. For example, the waivers modify the FMV requirement of the exception for personal service arrangements, by allowing DHS entities to pay either more or less than FMV for services provided by a physician (or immediate family member). But those arrangements must meet the other requirements of the personal-services exception, including that the compensation must be set in advance and commercially reasonable. In addition, the waivers apply to only those arrangements

that relate to one of the "COVID-19 Purposes," and do not apply to an arrangement that has no relationship to COVID-19 or access to care during the COVID-19 crisis.

Are there any other requirements for the Stark waivers?

- Documentation is important. Parties must make records relating to their use of the waivers available to CMS upon request. CMS is not requiring any specific form of documentation. It is a good idea, though, for parties who want to use the waivers to document both (1) the nature of the arrangement, and (2) how the arrangement is "solely related to COVID-19 Purposes."

- The waivers are not available if there is "fraud or abuse." CMS did not define or explain those terms. "Fraud" presumably means some kind of false statement or material omission. It is more difficult to say what "abuse" means in this context – perhaps parties attempting to use the Stark waivers as pretext for rewarding physicians who are significant referrals sources.

- The waivers are available only where the remuneration is directly between the DHS entity and (1) the physician, (2) the physician's group (if the physician "stands in the shoes of" the group for Stark purposes), or (3) an immediate family member of the physician. This means that the waivers would not apply when, for example, a hospital rents space from a physician's real-estate LLC, or obtains free items from a medical-supply company owned by a physician's spouse.

Are the Stark waivers available only the areas hit hardest by COVID-19?

The waivers are available nationwide.

What is the effective start date of the Stark waivers?

March 1, 2020

When will the Stark waivers end?

CMS can modify or terminate the waivers at any time, by posting the changes on the CMS website. Any change that narrows the scope of the waivers, or terminates them, will be effective only prospectively.

What is the OIG's policy statement regarding the Anti-Kickback Statute?

After CMS issued the Stark waivers, the OIG announced that it will not enforce the Anti-Kickback Statute for some of the arrangements covered by the waivers. The OIG explained its goal as allowing parties to avoid the need for a legal review under the Anti-Kickback Statute for conduct protected by the Stark waivers.

The OIG's policy statement does not extend to all of the conduct covered by the Stark waivers. Presumably that is because the OIG believes that some of the conduct covered by the Stark waivers does not implicate the Anti-Kickback Statute. The OIG's policy statement extends to all of the Stark waivers that involve the transfer of money, items, or services; but not the Stark waivers that relate to the location where services are provided.

The OIG emphasized that the policy statement provides no protection to arrangements that are outside the scope of the Stark waivers. For example, financial relationships between physicians and drug or device companies are still subject to enforcement under the Anti-Kickback Statute.

What is the effective start date of the OIG's policy statement?

The OIG's policy statement applies to conduct starting on April 3, 2020, which is 34 days after the effective date of the Stark waivers. The OIG did not explain why it chose a later start date. However, it seems unlikely that the OIG would seek penalties under the Anti-Kickback Statute for conduct protected by the Stark waivers, even if that conduct occurred from March 1 to April 2 of 2020.

When will the OIG's policy statement terminate?

On the same date that the Stark waivers terminate.

Where can I get more information about the Stark waivers or OIG policy statement?

You can read the full text of the CMS waivers here, and the OIG policy statement here. The OIG is also publishing FAQs relating to the COVID-19 pandemic.

About the Authors

Scott Bennett helps health care providers and businesses comply with the Stark Law, Anti-Kickback Statute, and other fraud and abuse laws. He also advises clients on the use of current and emerging technologies, and data privacy and security. Scott is the chair of the digital health affinity group of the American Health Law Association, and is a Certified Information Privacy Professional through the International Association of Privacy Professionals (CIPP/US).

Marki Stewart has a special focus and interest in telemedicine, including licensing, reimbursement, credentialing, and security issues. She has represented various health care providers before regulatory boards and bodies, including the Arizona Medical Board, health insurance disciplinary committees, and the Office for Civil Rights. She has also conducted hearings before government agencies.