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Health Care Practice Check-Up: Are You Violating Stark Without Knowing It?

By Christina M. Kuta

Anyone involved in the health care industry has heard of the Stark Law (Stark). Most people understand it to prohibit referrals of certain "designated health services" between persons or entities that have a compensation or investment/ownership relationship. While you have undoubtedly worked hard to ensure your practice complies with Stark, you may be overlooking a lesser-known Stark requirement, putting your practice in legal and financial jeopardy.

What Does Stark Require for Certain Imaging Services?

Physicians who:

- refer ***Medicare*** patients for ***MRI, PET or CT*** scans that are provided and billed by the provider's practice; and
- rely on the Stark "***In-Office Ancillary Services***" (IOAS) exception for those referrals to comply with Stark

must provide a written disclosure document to these patients at the time a referral is made for any of these diagnostic tests.

What is Required to be in the Disclosure Document?

- Must be in a writing given to the patient and written in a manner that can reasonably be understood;
- State the patient may receive the diagnostic test from a supplier other than the referring physician's practice;
- List the name, address and telephone number for at least five other suppliers (physicians, group practices, and freestanding imaging centers) that provide the diagnostic test for which the patient is being referred that are located within a 25-mile radius of the referring physician's office location (at the time of the referral);
- If there are fewer than five other suppliers located within a 25-mile radius, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location (a written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius).

How do you Prove the Disclosure was Provided?

CMS does not require a specific method to document providing the disclosure. It is recommended that, at a minimum, the patient's chart reflect the date and time the disclosure document was received by the patient. A better practice is to have the patient sign an acknowledgment of receipt and maintain such document in their chart.

What are the Consequences for Not Providing the Disclosure?

Failing to provide the disclosure document is considered a Stark violation (i.e., a failure to meet the IOAS exception). Failure to meet the IOAS exception (unless another exception applies) means the referral is prohibited by Stark, and therefore, any payment made for that service must be repaid to CMS. Additionally, the practice could be subject to additional civil monetary penalties and violations of the False Claims Act.

What are your Next Steps?

If your practice has failed to provide the necessary disclosure document routinely in the last six years, our health care attorneys can assist you in understanding any repayment obligations you may have and navigating the self-disclosure protocols. If you have been compliant with the disclosure requirements, now is the time to review the disclosure and make sure the alternate suppliers are still operating in the relevant area. If just one of the five listed alternate suppliers has changed its address or contact information, your disclosure is technically not Stark-compliant. Do not let a failure to meet this obligation financially impact your practice!

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