

PHYSICIAN PRACTICES DISPENSING UROLOGICAL SUPPLIES TO PATIENTS: STARK LAW ISSUES

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**PHYSICIAN PRACTICES DISPENSING UROLOGICAL SUPPLIES TO PATIENTS:
STARK LAW ISSUES**

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This White Paper addresses the applicability of 42 U.S.C. § 1395nn (“Stark Law”) to the practice of a physician (i) mailing urological supplies (e.g., catheters) to his/her patients and/or (ii) directing an employee to hand deliver urological supplies to patients in the physician’s office.

Stark Law

The Stark Law is a federal civil strict liability statute that, unless an exception applies, prohibits physicians (as broadly defined by the Stark Law) from referring patients for designated health services (“DHS”) to an entity with which the physician has a financial relationship.

Definition of DHS

DHS is defined to include prosthetics, such as urological supplies. 42 CFR § 411.351.

Definition of “Referral” and Explanation of “Personally Provided”

A “referral” is defined as ordering DHS for which payment may be made under Medicare Part B. However, a “referral” does *not* occur if the DHS is “personally provided” by the referring physician. 42 CFR § 411.351.

The Centers for Medicare and Medicaid Services’ (“CMS”) commentary in its 2007 Phase III Stark Final Rule provides clarification on the meaning of the phrase “personally provided.” According to the 2007 Final Rule, “there are few, if any, situations in which a referring physician would personally furnish DME and supplies ... because doing so would require that the physician ... *personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c).*” See 72 FR 51019, available at <https://www.federalregister.gov/d/07-4252/page-51019>.

According to the 2007 Final Rule, it is “highly unlikely” that a referring physician would meet the criteria for personally performed services when dispensing DME. “*The dispensing of DME by a physician almost always constitutes a “referral” for the physician self-referral statute*, as would the dispensing of DME by anyone else affiliated with the referring physician, such as a nurse or physician assistant.” *Id.* (emphasis added).

If the physician is ordering and furnishing urological supplies for which payments will be made under Medicare Part B, and if the physician is not personally providing the urological supplies, then the physician must comply with a Stark Law exception.

In-Office Ancillary Services (“IOAS”) Exception to the Stark Law

There are multiple Stark Law exceptions, including an exception for IOAS. *See* 42 CFR 411.355(b). To meet the IOAS exception, the referral for urological supplies must comply with a number of requirements, including (i) who must furnish the service, (ii) where the service is furnished, and (iii) compliance with applicable Medicare billing and coverage rules. *See* 42 CFR 411.355(b); CMS, Physician Self-Referral Law Frequently Asked Questions, available at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf>.

Under the IOAS exception, urological supplies must be furnished personally by the referring physician, a physician who is a member of the same group as the referring physician, or an individual who is supervised by the physician or by another physician in the group practice. 42 CFR 411.355(b)(1). The urological supplies must be furnished in the same or a centralized building used for the provision of some or all of the physician’s medical services. 42 CFR 411.355(b)(2). This location requirement is not satisfied if a patient receives urological supplies by mail outside the physician’s office, as the urological supplies would not be dispensed to the patient in the office.

“Put another way, items that are designated health services to which the exception is applicable, such as intermittent catheters (which are prosthetic devices), fall within the scope of the exception for in-office ancillary services only when a patient directly receives the item in the physician’s office and in a manner that is sufficient to meet applicable Medicare billing and coverage rules. The “location requirement” at 42 C.F.R. §411.355(b)(2) would not be satisfied if a patient receives an item by mail outside the physician’s office, as it would not be dispensed to the patient in the office. This is true regardless of whether Medicare coverage and payment rules would permit the supplier to mail the item to the patient and bill the Medicare program for the item.”

Physician Self-Referral Law Frequently Asked Questions (cms.gov) page 9
(published September 20, 2021)

Analysis

If a physician orders and furnishes urological supplies for which payment will be made under Medicare Part B, then a “referral” under the Stark Law occurs unless the urological supplies are personally provided by the physician.

The commentary to the Final Rule states that it is rare for a physician to personally provide urological supplies because physicians rarely perform all activities required by the DMEPOS Supplier Standard to satisfy the “personally provided” definition.

The physician’s referrals for urological supplies are for DHS because DHS is defined to include prosthetics, and urological supplies are considered prosthetics.

The IOAS exception may be satisfied if (i) the urological supplies are furnished personally by the referring physician or by an individual who is supervised by the referring physician or is supervised by another physician in the referring physician's group practice and (ii) the urological supplies are furnished in the same or a centralized building used for the provision of some or all of the physician's medical services.

To the extent that the urological supplies are mailed to a patient's home, the IOAS exception is not satisfied, and such delivery would likely violate the Stark Law.

THIS WHITE PAPER DOES NOT CONSTITUTE LEGAL ADVICE. THIS WHITE PAPER WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS WHITE PAPER WAS WRITTEN. BEFORE ACTING ON THE ISSUES DISCUSSED IN THIS WHITE PAPER, IT IS IMPORTANT THAT THE READER OBTAIN ADVICE FROM A HEALTH CARE ATTORNEY.