In June 2021, the Centers for Medicare and Medicaid Services (CMS) issued a notable interpretation of the Physician Self-Referral Law (aka the Stark Law) in Advisory Opinion No. CMS-AO-2021-01 (Advisory Opinion) regarding whether a physician practice can furnish designated health services (DHS) through a wholly-owned subsidiary and still qualify as a group practice (as defined under the Physician Self-Referral Law) for purposes of compliance with various Physician Self-Referral Law exceptions.

**Physician Self-Referral Law**

The Physician Self-Referral Law prohibits a physician from making a referral for certain DHS payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. One exception often relied upon by physician practices is the exception for referrals of in-office ancillary services, which exception is available to any physician practice...
consisting of two or more physicians if the physician practice qualifies as a “group practice” under the Physician Self-Referral Law. The Physician Self-Referral Law regulations in turn provide in part that a group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice, but also note that a group practice may itself own subsidiary entities.

Question Presented

In this Advisory Opinion, CMS was asked whether a physician practice would fail to qualify as a group practice under the Physician Self-Referral Law if the practice furnishes DHS through a wholly-owned subsidiary entity that is a physician practice but doesn’t qualify as a “group practice” as defined under the Physician Self-Referral Law. The request was submitted in connection with a transaction under which a physician practice proposes to acquire two subsidiaries, and provide DHS and other services to patients through those subsidiaries with revenues flowing up to the parent entity. The subsidiaries would be unable to qualify as group practices because they would be owned by another entity: the requestor.

Approval of the Arrangement

CMS concludes that this arrangement would not preclude the requestor practice from qualifying as a group practice, based on preamble commentary in its 1995 Final Rule and 2001 Phase I rulemaking, noting in part that the regulatory exception expressly contemplates a group practice owning subsidiaries that in turn provide services. CMS states that in its August 1995 final rule, CMS interpreted the physician self-referral statute to permit a single group practice to own other legal entities for the purpose of providing services to the group practice. For example, CMS observed that the exception for in-office ancillary services appears to anticipate that a group practice may wholly own separate legal entities for billing or providing ancillary services, and in both the 1995 and 2001 rules used the example of a wholly-owned laboratory facility that provides laboratory services to a group practice as potentially compliant with the in-office ancillary services exception. CMS thus determines that the proposed arrangement would not prevent the requestor from qualifying as a group practice, and thus being able to rely on certain exceptions under the Physician Self-Referral law if all requirements are otherwise satisfied.

CMS cautions that its Advisory Opinion analysis applies only to the extent the subsidiaries remain wholly-owned by the requestor, and CMS expresses no opinion on whether the proposed transaction otherwise satisfies the Physician Self-Referral Law, or whether any DHS furnished by physicians employed or contracted by the requestor would actually satisfy the in-office ancillary services exception.

The Advisory Opinion thus provides a limited assurance for physician practices seeking to meet the “group practice” requirements under the Physician Self-Referral Law and operate wholly-owned subsidiaries. The Advisory Opinion is the first CMS advisory opinion addressing the Physician Self-Referral Law in 2021, and comes as CMS considers additional changes to Physician Self-Referral Law regulations in the 2022 physician fee schedule.

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