

Why Update the Stark Law Regulations Now?

As many healthcare providers are aware, the difficulty of Stark Law compliance begins, and sometimes ends, in the mixed bag of regulatory exceptions and technical terminology. On July 8, 2015, the Centers for Medicare and Medicaid Services (CMS) released proposed regulations that, if finalized as proposed, will establish two new exceptions and clarify a number of technical hurdles and interpretative snags in the application of the Stark Law regulations. CMS used its experiences with stakeholder inquiries and self-disclosures made under its Voluntary Self-Disclosure Protocol to design the proposed regulations, which CMS contends will modernize and simplify the Stark Law regulations in light of evolving healthcare delivery models and payments systems.

Proposed New Exception for Assistance Subsidies to Employ Nonphysician Practitioners

Responding to changes in the healthcare delivery payment systems and primary care workforce shortage trends, CMS proposes to establish a new Stark Law exception to permit subsidy payments made by a donor hospital, federally qualified health center or rural health center to a physician to assist the physician in employing a nonphysician practitioner in the donor's geographic service area. The proposed exception tracks many of the requirements of the existing physician recruitment exception, such that the nonphysician practitioner is a bona fide employee of the physician or physician practice receiving the donor's payments. Accordingly, CMS proposes to limit qualifying nonphysician practitioners to include only physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives. The proposed exception is limited to situations in which the purpose of the employment is to provide primary care services to patients of the physician practice, and includes a two-year limit and a cap on the donor's payments. CMS is specifically interested in comments on the scope of qualifying services and applicable safeguards from program or patient abuse for that proposed exception.

Proposed New Exception for Timeshare Leases

Responding to a growing interest among physicians for licensing alternatives to the traditional office space lease arrangement, CMS proposes to establish a new exception for qualifying timeshare arrangements between physicians (as the licensee) and hospitals or physician organizations (as the licensor). To qualify under the proposed exception, timeshare arrangements must meet certain criteria, including that the licensee use the licensed premises, equipment and other subjects of the license predominantly to furnish evaluative and management services to patients, and that the arrangement does not cover advanced imaging equipment, radiation therapy equipment or some laboratory equipment.

Highlights of the Proposed Clarification of Requirements and Terminology

Writing Requirements

Several Stark Law exceptions, e.g., the rental of office space, require a writing or written agreement. In addition to a single formal contract, CMS clarified in the commentary to the proposed regulations that the writing requirement can be satisfied by a collection of contemporaneous documents, evidencing the course of the parties' conduct. As such to avoid future confusion, CMS proposes to substitute the term "arrangement" for the terms "agreement" and "contract" found in several exceptions.

Term Requirements

Stark Law exceptions for the rental of office space, the rental of equipment, and personal service arrangements are conditioned on a term of at least one year. CMS proposes to clarify that that requirement is met where the arrangement lasts as a matter of fact for at least one year. That is, an explicit "term" provision in a formal written contract is not necessarily required.

Missing Signature Requirements

The Stark Law differentiates between the timeframes to correct temporary noncompliance of the contemporaneous signature requirement based on "advertent" or "inadvertent" noncompliance. CMS proposes to do away with the distinction between an advertent and inadvertent late signature, and instead to allow the parties up to 90 days to obtain all required signatures for arrangements involving temporary noncompliance with signature requirements.

Holdover Arrangement Time Limitations

Stark Law regulations for certain exceptions currently permit a holdover arrangement for up to six months under certain circumstances. CMS proposes to eliminate those time limitations and to allow for indefinite holdovers or, in the alternative, to extend the holdover period to a definite period greater than the current six months.

Call for Comments on the Application of the Stark Law in the Evolving Healthcare Environment

CMS specifically asks for comments about perceived barriers from the Stark Law regulations to achieve clinical and financial integration. CMS recognizes that the Stark Law impacts the progress of healthcare delivery and payment reform and that those evolving models and systems are premised on the close integration of a variety of healthcare providers. CMS is specifically interested in comments regarding the effect of the Stark Law's "volume or value" and "other business generated" standards on integration planning and efforts.

What Can You Do?

The proposed regulations were published in the Federal Register on July 15, 2015. A full-text copy of the [published proposed regulations](#) is available online. CMS currently is soliciting comments for recommendations and changes or amendments from the public. Comments must be received by CMS no later than 5 p.m. on September 8, 2015, and may be submitted electronically, by postal mail or by hand delivery. If you would like additional information about the proposed regulations or are interested in submitting a comment, please contact one of the Squire Patton Boggs lawyers listed in this publication.

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