

2018 Changes to the Federal Physician Self-Referral Law (Stark Law)

On February 9, 2018, Congress passed and President Trump signed into law [H.R. 1892](#), the Bipartisan Budget Act of 2018 (the “Budget Act”), which included changes to the federal physician self-referral law (commonly known as the “Stark law”). Among these revisions are allowing indefinite holdovers in two notable exceptions to the Stark law: (1) personal services arrangements and (2) rental (i.e., leases) of equipment and office space. Such “holdover” allowances had previously been limited to six (6) months by regulation. The Budget Act also codified regulatory language and guidance regarding “in writing” and signature requirements.

“Stark law” refers to a set of federal laws enacted in the late-1980s and 1990s, as subsequently amended and revised, that generally prohibit a physician from referring Medicare and Medicaid beneficiaries to providers of “designated health services” (or “DHS”)^[1] if the physician (either directly or standing in the shoes of his/her physician organization), or one of the physician’s immediate family members, has a financial relationship with the health care provider that is receiving the referral (also known as the “DHS Entity”).

A DHS Entity is prohibited from billing for services furnished pursuant to a prohibited referral. A DHS Entity that bills for services furnished pursuant to a prohibited referral is subject to the denial of payment of claims, repayment of any money received for a prohibited referral, and potential liability under the federal [False Claims Act](#) if money received for a prohibited referral is not repaid. Physicians and DHS entities that violate the Stark law can also be subject to civil money penalties and exclusion from Medicare and Medicaid. Thus, Stark law and its amendments affect physicians as well as organizations and providers that have entered into financial relationships with physicians.

Notably, the Centers for Medicare and Medicaid Services (“CMS”) has crafted several exceptions to Stark law, many of which require that the particular compensation arrangement be “in writing.” See, e.g., 42 C.F.R. 411.357. Even though a compensation arrangement may comply with the substantive requirements of an applicable exception, there are still a number of “technical” grounds on which that compensation arrangement may fail.

The Budget Act amends Stark law to codify certain CMS guidance and existing regulations in an effort to ease the burden of some of those more “technical” requirements. Because the changes imposed on Stark law by the Budget Act are merely codifications of existing guidance and regulations, they may not open the door to substantial changes in practice, but they do “set in stone” the relaxation of a few key technical requirements.

Specifically, the Budget Act amends Stark law in the following areas, more fully explained below:

1. **Creates an indefinite “holdover” period for certain arrangements;**
2. **Codifies CMS guidance on the “written” or “writing” requirement; and**
3. **Codifies regulatory language on signature requirements.**

1. Creates an indefinite “holdover” period for certain arrangements

As summarized above, the Budget Act eases “holdover” limits on the following types of arrangements, which used to be limited to six months under Stark regulations for personal service and lease arrangements for equipment or space. The law does require that the other requirements of Stark continue to be met during the holdover period (e.g., fair market value) and the terms and conditions of the arrangement remain the same. Since “fair market value” can change from year to year, agreements should not be left in holdover indefinitely.

1. Codifies CMS guidance on the “written” or “writing” requirement

Next, the Budget Act codifies guidance that was previously offered by CMS in the [2016 Medicare Physician Fee Schedule Final Rule](#): namely, that in addition to a written contract, a collection of documents can be relied upon to

meet the writing requirement of various compensation exceptions. The text of the Budget Act specifically provides for an amendment to the Stark law to reflect that “[i]n the case of any requirement pursuant to this section for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.” This amendment serves to codify CMS’ prior guidance and officially allows healthcare providers to use a collection of documents evidencing the course of conduct between the parties – as opposed to a single formal contract – to satisfy the exceptions’ requirements.

Though the amendment itself does not provide any further specifics on the “collection of documents,” CMS has offered guidance in the Final Rule, providing examples of “contemporaneous documents” that can be relied upon to satisfy the writing requirement of an applicable exception: “Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of service to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent.” CMS guidance further provides that the available contemporaneous documents must permit “a reasonable person to verify compliance with the applicable exception at the time that a referral is made.” See [80 Fed. Reg. 70,886, 71,314-71,316 \(Nov. 16, 2015\)](#).

1. Codifies regulatory language on signature requirements

Finally, the Budget Act amends the Stark law to allow for a 90-day window for parties to an arrangement to obtain the necessary signatures. The amended language reads: “In the case of any requirement pursuant to this section for a compensation arrangement to be in writing and signed by the parties, such signature requirement shall be met if – (i) not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the parties obtain the required signatures; and (ii) the compensation arrangement otherwise complies with all criteria of the applicable exception.” This amendment aligns the statutory language with the regulatory language at [42 C.F.R. § 411.353\(g\)\(1\)\(ii\)](#).

The foregoing is not an exhaustive summary of the healthcare provisions included in the Budget Act (which additionally included updates to the Children’s Health Insurance Program, increased civil and criminal penalties for federal health care program fraud and abuse, and enhanced Medicare coverage for telehealth services, to name a few), but is merely a summary of the most recent Stark law updates.

[1] The term “designated health services” means any of the following items or services: (a) Clinical laboratory services; (b) Physical therapy services; (c) Occupational therapy services; (d) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; (e) Radiation therapy services and supplies; (f) Durable medical equipment and supplies; (g) Parenteral and enteral nutrients, equipment, and supplies; (h) Prosthetics, orthotics, and prosthetic devices and supplies; (i) Home health services; (j) Outpatient prescription drugs; (k) Inpatient and outpatient hospital services; and (l) Outpatient speech-language pathology services. See [42 C.F.R. 411.351](#). The List of CPT/HCPCS Codes that identifies the items and services included within each DHS category is found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.