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From Chapter 400: The Stark Law Exceptions

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CHAPTER 400

THE STARK LAW EXCEPTIONS

¶400 OVERVIEW OF THE STARK LAW EXCEPTIONS

The Stark law generally prohibits a physician from making referrals for Medicare-covered designated health services (DHS) to an entity with which the physician or an immediate family member has a “financial relationship.” 42 U.S.C. § 1395nn(a)(1)(A); § 411.353(a). “Financial relationship” is defined as “a direct or indirect ownership or investment interest” or “a direct or indirect compensation arrangement.” § 411.354(a)(1); see ¶226. In addition, an entity may not bill a patient, the Medicare program, or anyone else, including a third-party payer or another individual, for services rendered pursuant to a prohibited referral.
42 U.S.C. § 1395nn(a)(1)(B); § 411.353(b). This general prohibition applies, for example, to referrals for Medicare-covered DHS made by a physician to any hospital, freestanding imaging center, or independent clinical laboratory with which that physician has a compensation arrangement.

The Stark law’s broad ban on physician self-referrals is subject to numerous exceptions:

- The general exceptions to both the ownership/investment and compensation arrangement prohibitions apply to certain designated health services (DHS) provided under specific circumstances, regardless of the type of financial relationship between the referring physician and the entity furnishing the service. These general exceptions are discussed in ¶410.
- The ownership/investment interest exceptions discussed in ¶420 apply only to specific types of ownership/investment interests.
- The Phase II regulations implementing the Stark law provided 21 exceptions for compensation arrangements. Two more exceptions for electronic prescribing and health records technology were added in 2006. The 23 exceptions are discussed in ¶430.
- The law also provides two narrow circumstances when, if present, the DHS Entity’s lack of knowledge or intent will serve as an exception to the general prohibition on payment of prohibited DHS claims. These “innocent entity” exceptions are discussed in ¶440.

Stark also provides exceptions for certain clinical laboratory actions in the definition of “remuneration” in §411.351 (see ¶1354).

The text of the Stark law and regulations is reproduced in Tabs ¶¶3000 and 3100. The preambles, behind Tab ¶3300, are located on the CD accompanying each update. Please refer to these locations to find a citation.

1410  **GENERAL EXCEPTIONS TO THE OWNERSHIP AND COMPENSATION ARRANGEMENT PROHIBITIONS**

The Stark law and regulations provide nine general exceptions to the ownership and compensation prohibitions:

1. Physician services (see ¶411)
2. In-office ancillary services (see ¶412)
3. Prepaid plans (see ¶413)
4. Intra-family rural referrals (see ¶414)
5. Academic medical centers (¶415)
6. Implants furnished by an ASC (see ¶416.1);
7. EPO and other dialysis-related drugs furnished or ordered by an ESRD facility (see ¶416.2);
8. Preventive screening tests, immunizations and vaccines (see ¶416.3); and
9. Eyeglasses and contact lenses following cataract surgery (see ¶416.4).

The Phase II regulations added the exception for “intra-family rural referrals” and eliminated the exception for ambulatory surgical centers (ASC)/end-stage renal dialysis (ESRD)/hospice services that had been included in the Phase I regulations. The ASC/ESRD/hospice services exception was eliminated because CMS determined that it was duplicative, given that those services are reimbursed by Medicare on a composite rate basis and for this reason are excluded from the definition of “designated health services” (DHS) in §411.351.

1411  **THE PHYSICIAN SERVICES EXCEPTION**

According to the Stark law and regulations, the general prohibition on ownership/investment and compensation arrangements does not apply to services furnished on a referral basis, if those services are provided

- personally by another physician in the same group practice as the referring physician or
- under the personal supervision of another physician in the same group practice as the referring physician. §411.355(a).

Note that this exception is available only to physicians whose organization meets the definition of “group practice.” The requirement that the services be furnished “under the personal supervision of another physician” refers to those services provided by nonphysician practitioners and covered by Medicare as services “incident-to” the services of a physician in the group practice.⁴ There is no requirement that a group practice physician be physically present in the room when the services are provided, but as a general rule, the physician must be in the office suite. §411.351 and 42 C.F.R. §410.26.

Here’s an example of how the physician services exception would work:

A physician refers a hospital inpatient for an ultrasound, and a member of the referring physician’s group practice interprets the ultrasound. See Phase II, 69 Fed. Reg. 16100.

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⁴ “Incident-to” services are those services that are furnished incident to physician professional services in the physician’s office, regardless where the office is located, or in the patient’s home. Specific supervisory and presence requirements must be met to qualify as “incident-to services.” For a summary of Medicare requirements for “incident-to” services, see MLN Matters SE 0441, www.cms.hhs.gov/MLNMattersArticles/downloads/SE0441.pdf.
Section 411.355(a)(2) defines “incident-to” services for purposes of the exception as those services that are “physician services” as defined in 42 C.F.R. §410.20(a)\(^2\) (e.g., professional interpretations of Medicare-covered x-rays). Phase III, 72 Fed. Reg. 51032. Because of this restriction, the exception does not extend to the majority of “incident-to services,” such as therapy treatments and other types of nonphysician services. §411.355(a)(2).

The exception does not cover professional services provided by nonphysician practitioners even if the service would be a “physician service” if performed by a physician. See Phase I, 66 Fed. Reg. 880. However, it is available to independent contractors who meet the definition of “physician in the group practice.” See ¶1211.11. One of the requirements of the definition is that the services are performed in the group practice facilities; independent contractors performing services off-site for the group practice in facilities that are not group facilities are not covered by the exception.

¶412 THE IN-OFFICE ANCILLARY SERVICES EXCEPTION

The in-office ancillary services exception applies to those physicians ordering DHS in the context of their own practices. The Phase I regulations, effective January 4, 2002, established the exception largely as it is in effect today with the exception of the “same building” requirement and a new disclosure and notice requirement. Phase I, 66 Fed. Reg. 880. It is designed to protect the in-office provision of a DHS that is truly ancillary to the medical services being provided by the physician practice. This is the principal exception relied upon by physicians who are owners and employees of, and contractors to, medical groups in order to make DHS referrals to their own group or to other physicians in their group. Unlike many of the Stark exceptions, use of the in-office ancillary services exception does not hinge on setting compensation in advance, fair market value, or the volume and value of referrals prohibitions. To qualify under this exception, the group must meet supervision, location, and billing tests, as well as satisfy the “group practice” requirements (discussed in ¶1200). Effective January 1, 2011, groups that provide certain imaging services also will have to comply with a disclosure and notice requirement.

Since the Phase I rule was issued in 2001, CMS has received comments about the potential for abuse inherent in the exception. (See e.g., 71 Fed. Reg. 49055 (Aug. 22, 2006), regarding “pod” or “condominium” labs.) These abusive arrangements appear to capitalize on the meaning of terms in the “location test.” The Phase II regulations modified the “location test” for this exception in an effort to curb some of these abusive arrangements (Phase II, 69 Fed. Reg. 16070), and in the final 2009 Medicare Physician Fee Schedule rule, again addressed the issue, but through revisions to the anti-markup provision in §414.50, not the in-office ancillary services exception (73 Fed. Reg. 69799 (Nov. 19, 2008)).

¶412.1 Services Included Within the In-Office Ancillary Exception

The in-office ancillary services exception pertains to three types of services:

- DHS;
- certain durable medical equipment (DME) provided for the convenience of the patient under specific conditions; and
- infusion pumps that are DME (including external ambulatory infusion pumps).

\(^2\) 42 CFR §410.20(a) reads as follows: *Included services.* Medicare Part B pays for physicians’ services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

\(^3\) [Reserved]
412.1.1 **Durable Medical Equipment**

The Phase I regulation designated a small group of DME furnished for the convenience of the patient as eligible for the in-office ancillary services exception. Specifically, the item must be:

- one that a patient requires for the purpose of ambulating and uses in order to depart from the physician’s office—canes, walkers, crutches, and manual folding wheel chairs; or
- a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 each) also falls into the exception. A blood glucose monitor may be furnished only by a physician or an employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

In addition, to be covered by the exception, the following criteria must be met (§411.355(b)(4); Phase I, 66 Fed. Reg. 883):

- The equipment must be furnished in a building that meets the “same building” requirement (see ¶412.2.2) where the physician-patient encounter occurred and the patient was treated
- A physician or group practice meets all DME supplier standards located in 42 C.F.R. §424.57(c). The Phase II regulations clarify that the physician group must be approved by CMS as a DME provider of services in order to furnish the permitted DME services. Phase II, 69 Fed. Reg. 16071.
- The arrangement does not violate the anti-kickback statute, §1128B(b) of the Social Security Act (exclusion from federal health programs), or any law or regulation governing billing or claims submission.
- All other requirements of the in-office ancillary services exception must be met.

412.1.2 **Outpatient Prescription Drugs**

While outpatient prescription drugs are DHS, referrals for administration of these drugs may be protected by the in-office ancillary services exception. Chemotherapy and other outpatient drugs, as well as chemotherapy infusions, dispensed and/or administered in the physician’s office are considered “furnished” in the office for purposes of this exception, even if they are self-administered at home by the patient. §411.355(b)(5). See ¶412.2.1.

412.1.3 **Imaging Services**

Section 6003(a) of the Patient Protection and Affordable Care Act (PPACA), also known as the health care reform bill, has imposed a new requirement on physicians who are referring patients to their group practice for certain imaging services and are relying on the in-office ancillary services exception. They must inform a patient in writing at the time of the referral that the patient may obtain these services from other suppliers and to provide a list of suppliers within 25 miles of the office. The requirement applies to magnetic resonance imaging (MRIs), CT and PET scans, but HHS has the authority to expand the list to include other DHS.

In the 2011 Physician Fee Schedule rule, CMS finalized its regulations to implement section 6003 of the PPACA. The notice requirement takes effect on January 1, 2011. See ¶3307 (on the CD) (75 Fed. Reg. 73443 and 73616 (Nov. 29, 2010)) for the preamble explanation and ¶3101 for the amendment to §411.355(b)(7) of the regulations. See ¶1383 for details on the requirements.
¶412.2 The Requirements

Currently, The in-office ancillary services exception has three tests that must be met to claim the exception:

1. The practitioner test (who may furnish the services)
2. The location test
3. The billing test

¶412.2.1 Who May Furnish the In-Office Ancillary Services

In order to meet the requirements of the in-office ancillary services exception, the services must be “furnished” personally by one of the following individuals:

- The referring physician
- A physician who is a “member of the same group practice” as the referring physician; that is, a direct or indirect physician owner, a physician employee, a locum tenens physician, or an on-call physician while the physician is providing patient care services for the group practice
- An individual who is supervised by the referring physician, or if the referring physician is in a group practice, by another “physician in the group practice,” provided that the supervision complies with all applicable Medicare payment and coverage rules for the services (i.e., the “incident-to” rules)

Independent contractor physicians and leased employees are not considered members of the group practice. However, in the Phase I rule, CMS interpreted “physicians in the group practice” to include independent contractor physicians who, while not “members of the group,” contract to provide services to the group’s patients in the group’s facilities pursuant to an arrangement that complies with the reassignment rules in §424.80(b)(3). Phase I, 66 Fed. Reg. 899. As December 4, 2007, these independent contractors must contract directly with the group, which precludes any leased employees from being “physicians in the group practice.”

THE MEANING OF ‘FURNISHED’

The meaning of the term “furnished” is critical to identifying what services or items may be protected by the exception. In Phase I, CMS redefined the term to make clear that an item or service is “furnished” in the location where the service is rendered or the item is dispensed. §411.355(b)(5). By so defining the term, many outpatient drugs that are dispensed in a physician’s office but used by the patient at home may be protected by the exception, as long as all other requirements are met. CMS explicitly noted that chemotherapy infusion drugs are likely covered if administered in the physician or group practice office under the requisite supervision requirements. Likewise, the provision of antigens (which is a physician service) and allergen treatments may be protected by the exception. Phase I, 66 Fed. Reg. 882; Phase II, 69 Fed. Reg. 16070.

¶412.2.2 The Location Requirement

In order to comply with the regulations, the delivery of the in-office ancillary services must meet one of two location requirements. §411.355(b)(2). The services must be performed either in the “same building” where the referring physicians provide their regular medical services or in a “centralized building” (with respect to a group practice).

‘SAME BUILDING’

The same building must be one in which the referring physician (or a member of his group practice) furnishes services unrelated to the furnishing of DHS. In the Phase I regulations, which were in effect
between January 4, 2002, and July 25, 2004, CMS interpreted this standard as requiring the referring physician (or a member of his group practice) to furnish in the same building “substantial” physician services unrelated to the furnishing of DHS. CMS also construed the standard to require that the primary purpose of the patient seeing the physician in that building was to receive physician services that were unrelated to DHS. Phase II, 69 Fed. Reg. 16072. Under the Phase I regulations, the term “physician services” was defined by means of a three-part test.4

Many commentators raised concerns about the Phase I three-part test, and CMS itself became concerned that the test might be susceptible to abuse.5 As a result, CMS developed three new alternative tests in Phase II. §411.355(b)(2)(i).

Effective July 26, 2004, DHS are furnished in the same building if the circumstances meet one of the three tests below:

1. The building is a principal place of practice for the physician or group, as evidenced by all of the following:
   - An office of the physician or group that is normally open to the physician’s or group’s patients for medical services at least 35 hours per week.
   - The referring physician or one or more members of the physician’s group practice regularly furnishes physician services to patients at the office at least 30 hours per week.
   - At least some of the physician services are unrelated to DHS payable by any payer.

2. The referring physician practices at least one day per week at the office, and the office is the principal place at which the physician’s patients usually receive services from the physician or members of his group, as evidenced by the following:
   - The patient receiving the DHS usually receives physician services from the referring physician or members of his group at the building.
   - The office is owned or leased by the referring physician or his group and is normally open to the physician’s or the group’s patients for medical services at least eight hours per week.
   - The referring physician regularly practices medicine and furnishes services at the office at least six hours per week.
   - At least some of the services furnished during those six hours are unrelated to DHS payable by any payer.

3. The referring physician or his group provides physician services at the office at least one day per week, and either DHS are ordered during a patient visit, or the physician or a member of the group is present during the furnishing of DHS, as evidenced by the following:
   - The referring physician or his group owns or rents an office that is normally open to the physician’s or group’s patients for medical services at least eight hours per week.
   - The physician (or members of his group) regularly practices and furnishes physician services at the office at least six hours per week.
   - At least some of the services furnished during those six hours are unrelated to DHS payable by any payer.

4 The Phase I three-part test required the following: (1) Physician services that are neither federal nor private-pay DHS, even if the physician services lead to the ordering of a designated health service; (2) the physician services unrelated to the furnishing of DHS that are furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides; (3) the DHS furnished in the building must be furnished to patients whose primary reason for coming in contact with the referring physician (or his or her group practice) is the receipt of physician services unrelated to the furnishing of DHS.” Phase II, 69 Fed. Reg. 16072.

5 The issue was raised to address the problem of independent contractor pathologists who perform services for group practices off-site in “pod labs.” CMS acknowledged the problem and said it continues to study the issue. It also noted that off-site services performed by group practices raise significant anti-kickback concerns. Phase III, 72 Fed. Reg. 51032.
— The referring physician is present and orders DHS during a visit on the premises, or the referring physician or a member of his group is present while DHS are being furnished during occupancy of the premises. §411.355(b)(2)(i).

In sum, DHS must be furnished in an office that meets one of the Phase II “same building” tests, but it does not necessarily need to be performed in the same space or part of the building as other services provided by the physician. CMS points out that the requirement that the office “normally” be open, or that the physician or group “regularly” practice at the site is not breached if the office is occasionally open fewer hours due to “unfilled appointment slots, cancellations, or other occasional gaps in the furnishing of services.” Phase II, 69 Fed. Reg. 16073.

Also, the requirement that “some” unrelated services be performed at the office has its common sense meaning and does not require that any particular minimum amount of unrelated services be performed. “Unrelated services” are construed by CMS to include physical examinations and other services that can be reasonably anticipated to lead to the ordering of DHS (e.g., laboratory or x-ray services). Phase II, 69 Fed. Reg. 16073.

With the elimination of the “primary purpose” and “substantial unrelated service” standards, DHS referrals by radiologists and oncologists now should be able to meet the location test of the in-office ancillary services exception.

However, groups or combinations of groups and independent DHS suppliers (e.g., imaging suppliers) that share a DHS facility in reliance on the same building approach need to ensure that their arrangements comply with current standards and be aware that CMS may make additional changes.

CMS continues to express concern about shared arrangements that purport to meet the “same building” test. In the 2008 final rule, it stated the following with regard to shared facilities:

A physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. To satisfy the in-office ancillary services exception, an arrangement must meet all of the requirements of §411.355(b), not merely on paper, but in operation. As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health service. Shared facility arrangements must be carefully structured and operated (for example, with respect to billing and supervision of the staff members who provide DHS in the facility). We note that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute. Phase III, 72 Fed. Reg. 51033.

‘Centralized Building’

The definition of a “centralized building” for purposes of the location test remains essentially unchanged from the Phase I regulations. It means

- all or part of a building, mobile vehicle, van, or trailer
- owned or leased by the group practice
- on a full-time basis (24 hours per day, 7 days per week) for a term of not less than six months and
- is used exclusively by the group practice (e.g., it is not shared with any other provider or supplier). The exclusive use requirement, in essence, precludes, for example, part-time MRI or CAT scan rentals, from qualifying for the exception.
¶410 • General Exceptions to the Ownership and Compensation Prohibitions

If the mobile vehicle is shared, it does not qualify as a centralized building. Mobile equipment may qualify if it is placed in the “same building” but will not qualify if it is used in the loading dock, parking lot, or garage. Phase II, 69 Fed. Reg. 16074.

For purposes of the location test, DHS in the form of services are deemed to be “furnished” at the location where services are performed upon the patient. §411.355(b)(5).

A group practice may have more than one centralized building (Phase I, 66 Fed. Reg. 892), and the group practice is not precluded from providing services to other providers or suppliers in the group practice’s centralized building. §411.351.

CMS has expressed concern over “misuse” of the centralized building test. For example, a group practice makes a referral for DHS to a specialist who is an independent contractor to the group. The independent contractor performs the test in a “centralized building,” reassigns his or her right to Medicare payment, and the group bills Medicare at a profit.6 In addition, because of the proliferation of in-office imaging equipment and labs, physicians are able to order and then subsequently perform ancillary services without referring the patient to a specialist. 72 Fed. Reg. 38181 (July 21, 2007).

While it has not changes the exception, CMS clearly is watching what it considers abusive arrangements.

Private Homes. CMS also recognizes that physicians whose practices consist of treating patients in the patients’ “private homes” generally be will unable to meet the location test. Phase I, 66 Fed. Reg. 884-885. However, CMS will deem ancillary services furnished in the patient’s private home to meet the location test, as long as

- the referring physician’s principal medical practice consists of treating patients in their private homes; and
- the DHS is provided contemporaneously with a non-DHS physician service furnished by the referring physician in the patient’s private home. §411.355(b)(6).

¶412.2.3 The Billing Requirement

To qualify for the in-office ancillary services exception, DHS must be billed by one of the following:

- The physician performing or supervising the service
- The group practice of which the performing or supervising physician is a member, under the group practice’s billing number
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician’s group practice
- A third-party billing agent acting as an agent of the physician, group practice, or the wholly owned entity referred to above, under a billing number assigned to the physician, group practice, or such entity §411.355(b)(3).

As an example, CMS responded to questions regarding billing by a physical therapist who is employed by a physician practice. If the physical therapist bills under her own billing number, the billing requirement of the in-office ancillary services exception is not met. However, if the physical

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6  As of Jan. 1, 2008, CMS imposed an anti-markup provision on anatomic pathology diagnostic testing services that were performed in the “centralized building” but did not meet the “same building” definition in the Stark law. Originally the anti-markup provision would have had an impact on many more testing arrangements, but CMS delayed the effective date for one year to Jan. 1, 2009. 73 Fed. Reg. 404 (Jan. 3, 2008). As of Jan. 1, 2009, a revised anti-markup provision, which focuses on “substantially all services” or office of the billing physician, is in effect for diagnostic tests.
therapist reassigned her right to payment to the group and the group bills under its billing number, the billing requirement is met.

**IMPORTANT**

CMS considers this Stark billing requirement a threshold rule. Only if the item or service fits into the in-office ancillary services exception may it be billed to Medicare. If it may be submitted, the claim must comply with all Medicare billing, payment, and coverage rules. Phase II, 69 Fed. Reg. 16076.

¶413 THE PREPAID PLAN EXCEPTION

Prepaid plans constitute another exception to the ownership and compensation prohibitions of the Stark law.” 42 U.S.C. §1395nn(b)(3). Specifically, the law provides an exception for DHS furnished by an organization

- that has a contract under §1876 of the Social Security Act (Payments to health maintenance organizations and competitive medical plans to an individual enrolled with the organizations);
- that is described in §1833(a)(1)(A) of the Social Security Act (Payment of benefits) to an individual enrolled with the organization;
- that receives payments on a prepaid basis, under a demonstration project pursuant to §402(a) of the Social Security amendments of 1967 or §222(a) of the Social Security amendments of 1972, to an individual enrolled with the organization; or
- that is a qualified health maintenance organization (HMO) (within the meaning of §1310(d) of the Public Health Service Act) to an individual enrolled with the organization.

Under the Phase I regulations, this exception covered only federally qualified HMOs, HMOs with Medicare risk or cost contracts, or HMOs with demonstration project status. The Phase I regulations did not include an exception for Medicaid prepaid plans. Under the Phase II regulations, effective July 26, 2004, the prepaid plan exception has been extended to Medicaid prepaid plans. §411.355(c).

¶414 THE INTRA-FAMILY RURAL REFERRAL EXCEPTION

The Stark regulations in §411.355(j) include an exception to allows a referral to a family member under narrow and specific circumstances. Essentially, a physician may refer patients to a member of his immediate family or to an entity furnishing DHS with which his immediate family has a financial relationship, if the following requirements are met:

- The patient who is referred resides in a rural area.
- No other person or entity is available to furnish the services in a timely manner in light of the patient’s condition within 25 miles of the patient’s residence or within 45 minutes transportation time from the patient’s home at the time the referral is made.
- The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles or more than 45 minutes from the patient’s residence.
Phase II, which added the exception, only included the 25-mile test. Phase III added the 45-minute test as an alternative to the 25-mile test.

In expanding the exception, CMS notes that the tests now take into consideration distance, speed limits, and weather conditions. As such, a decision in the winter may be different than in the summer. Physicians using the 45-minute test must maintain documentation of the information used to determine the transportation time, including Web sites, such as MapQuest, and weather reports. Phase III, 72 Fed. Reg. 51040.

\section*{¶415 The Academic Medical Center Exception}

The academic medical center (AMC) exception, set out in §411.355(e) of the Stark regulations, exempts from the Stark prohibition referrals by physicians to AMC components when all elements of the exception are met. This exception, therefore, protects both ownership and compensation arrangements held by faculty physicians that could potentially implicate Stark.

To qualify for this exception, the following standards must be met:

- The AMC must meet defined structural requirements
- The referring physician must be a \textit{bona fide} employee of a component of the AMC on a full-time or substantial part-time basis and must meet other credentialing and teaching requirements.
- The referring physician’s compensation must meet the “set in advance,” “fair market value,” and “volume/value” standards for referrals and other business generated, common to the compensation exceptions (see ¶432).
- The referring physician’s compensation arrangement, as distinguished from all arrangements within the academic medical center, must not violate the federal anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

Each of these standards has its own requirements. These are discussed in detail in ¶1320.

\section*{¶416 Other General Exceptions}

The statute gives the secretary of the Department of Health and Human Services the authority to create additional exceptions for financial relationships as long as there is no risk of program or patient abuse. The secretary has used this authority to create, among others, four other general exceptions, added in the Phase I rule:

1. Implants furnished by an ASC
2. EPO and other dialysis-related drugs furnished in or by an ESRD facility
3. Preventive screening tests, immunizations, and vaccines
4. Eyeglasses and contact lenses following cataract surgery

\subsection*{¶416.1 Exception for Implants Furnished by an ASC}

If certain requirements are met, implants furnished by an ASC are excepted from the general Stark law prohibitions with respect to ownership and compensation. These implants include, but are not limited to, cochlear implants, intraocular lenses, and other implanted prosthetic devices, and implanted DME. §411.355(f).
In order for this exception to apply, the following requirements must be met:

- The implant is placed by the referring physician or a member of the referring physician’s group practice in a Medicare-certified ASC with which the referring physician has a financial relationship.
- The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure.
- The arrangement does not violate the anti-kickback statute.
- The billing and claims submissions for the implant comply with all federal and state laws. §411.355(f).

**IMPORTANT**

The Phase II regulations clarify that this exception applies only to implants billed by an ASC as an ASC service. The exception does not include those implants billed by a physician or medical group, even if furnished in an ASC setting. Phase II, 69 Fed. Reg. 16111.

In the Phase II rule, CMS stated that the implantation of radioactive seeds in the course of brachytherapy is not covered under this exception. Phase II, 69 Fed. Reg. 16111. However, in its Stark Frequently Asked Questions, it states that “we are interpreting 42 C.F.R. §411.355(f) to include implanted brachytherapy sources.” Stark FAQ, 2305.

¶416.2 Exception for EPO and Other Dialysis-Related Drugs

Phase I of the Stark regulations provides an exception for erythropoietin (EPO) and other dialysis-related drugs furnished in or by an ESRD facility. This exception includes “outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on CMS’s List of CPT and HCPCS Codes.” §411.355(g)(1). For this exception to be applicable, the drugs must be furnished in or by an ESRD facility, or in the case of EPO or Aranesp, dispensed by the ESRD facility for use at home. §411.355(g)(1).

However, as of January 1, 2011, this exception has become almost irrelevant. As of that date, these drugs are paid under the ESRD prospective payment system (ESRD PPS). Because §411.351 excludes services reimbursed by Medicare as part of a composite rate, such as a PPS, EPO and other dialysis-related outpatient prescription drugs were no longer DHS unless they had no injectable equivalents or other forms of administration. These remained DHS and subject to the Stark law until January 1, 2014. They now are paid under the ESRD PPS. Since 2011, there have been no dialysis-related drugs on the exceptions list.

¶416.3 Exception for Preventive Screening Tests, Immunizations, and Vaccines

The Stark regulations provide for an exception with respect to preventive screening tests, immunizations, and vaccines. §411.355(h). In order for these services to be included in this exception, the following conditions must be met:

- The services must be covered under Medicare and must be listed on the List of CPT/HCPCS Codes (see ¶301).
The physician self-referral prohibition does not apply to the following screening, immunization, and vaccine codes if they satisfy the conditions in §411.355(h).

### Preventive Screening Tests (§411.355(h))

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77052</td>
<td>Comp screen mammogram add-on</td>
</tr>
<tr>
<td>77057</td>
<td>Mammogram, screening</td>
</tr>
<tr>
<td>80061</td>
<td>Lipid panel [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V81.2]</td>
</tr>
<tr>
<td>82270</td>
<td>Occult blood, feces</td>
</tr>
<tr>
<td>82465</td>
<td>Assay, bld/serum cholesterol [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V81.2]</td>
</tr>
<tr>
<td>82947</td>
<td>Assay, glucose, blood quant [only when billed with ICD-9-CM code V77.1]</td>
</tr>
<tr>
<td>82950</td>
<td>Glucose test [only when billed with ICD-9-CM code V77.1]</td>
</tr>
<tr>
<td>82951</td>
<td>Glucose tolerance test (GTT) [only when billed with ICD-9-CM code V77.1]</td>
</tr>
<tr>
<td>83718</td>
<td>Assay of lipoprotein [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V81.2]</td>
</tr>
<tr>
<td>84478</td>
<td>Assay of triglycerides [only when billed with one of the following ICD-9-CM codes: V81.0, V81.1, or V81.2]</td>
</tr>
<tr>
<td>G0103</td>
<td>PSA screening</td>
</tr>
<tr>
<td>G0106</td>
<td>Colon CA screen; barium enema</td>
</tr>
<tr>
<td>G0118</td>
<td>Glaucoma scrn HGH risk direc</td>
</tr>
<tr>
<td>G0120</td>
<td>Colon ca scrn; barium enema</td>
</tr>
<tr>
<td>G0123</td>
<td>Screen cerv/vag thin layer</td>
</tr>
<tr>
<td>G0124</td>
<td>Screen c/v thin layer by MD</td>
</tr>
<tr>
<td>G0141</td>
<td>Scr c/v cyto,autosys and md</td>
</tr>
<tr>
<td>G0143</td>
<td>Scr c/v cyto,thinlayer,rescr</td>
</tr>
<tr>
<td>G0144</td>
<td>Scr c/v cyto,thinlayer,rescr</td>
</tr>
<tr>
<td>G0145</td>
<td>Scr c/v cyto,thinlayer,rescr</td>
</tr>
<tr>
<td>G0147</td>
<td>Scr c/v cyto, automated sys</td>
</tr>
<tr>
<td>G0148</td>
<td>Scr c/v cyto, autosys, rescr</td>
</tr>
<tr>
<td>G0202</td>
<td>Screeningmammographydigital</td>
</tr>
<tr>
<td>G0328</td>
<td>Fecal blood scrn immunoassay</td>
</tr>
<tr>
<td>G0389</td>
<td>Ultrasound exam AAA screen</td>
</tr>
<tr>
<td>G0464</td>
<td>Colorec CA scr, sto bas DNA</td>
</tr>
<tr>
<td>P3000</td>
<td>Screen pap by tech w md supv</td>
</tr>
<tr>
<td>P3001</td>
<td>Screening pap smear by phys</td>
</tr>
</tbody>
</table>

### Immunization and Vaccine Codes (§411.355(h))

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90630</td>
<td>Flu vacc iv4 no preserv id</td>
</tr>
<tr>
<td>90654</td>
<td>Flu vaccine no preserv, ID</td>
</tr>
<tr>
<td>90655</td>
<td>Flu vaccine no preserv 6-35m</td>
</tr>
<tr>
<td>90656</td>
<td>Flu vaccine no preserv 3 &amp; &gt;</td>
</tr>
<tr>
<td>90657</td>
<td>Flu vaccine, 3 yrs, im</td>
</tr>
<tr>
<td>90660</td>
<td>Flu vaccine, nasal</td>
</tr>
</tbody>
</table>

continued
The services remain subject to the CMS-mandated frequency limits.

The arrangement for the provision of these services does not violate the anti-kickback statute.

Billing and claims submission for these services complies with all federal and state laws.

The codes in Figure 416.3-1 are those that are protected by the exception. This list is updated annually, usually in November, in the physician payment policy rulemaking and posted on the Stark Web page, www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

The Phase II regulations removed all bone densitometry services from this exception because CMS views them as diagnostic services as opposed to preventive screening tests. Screening mammographies are covered preventive tests; diagnostic mammographies and PAP smears are not (but see “Tip” in ¶1382 regarding diagnostic mammograms performed pursuant to a consultation). Phase II, 69 Fed. Reg. 16143. Also eliminated under the Phase II regulations is the requirement that the eligible services be reimbursed by Medicare on a fee schedule basis because some of the covered items and services were found to be paid under other methodologies.
¶416.4 Exception for Eyeglasses and Contact Lenses Following Cataract Surgery

Another exception under the Stark regulations includes eyeglasses and contact lenses that are covered by Medicare when furnished to patients following surgery §411.355(i). For purposes of Medicare, these items are considered prosthetic devices, and as such, they fall into that category of DHS. For this exception to apply, all of the following conditions must be met:

■ The eyeglasses or contact lenses are provided in accordance with Medicare coverage and payment policies.
■ The arrangement for providing the items does not violate the anti-kickback statute.
■ The billing and claim submissions for eyeglasses or contact lenses must comply with all federal and state laws. §§411.355(i)(1)–(3).
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