## Stark Law Exceptions and Anti-Kickback Safe Harbors

### Services Furnished by an Organization to Enrollees

<table>
<thead>
<tr>
<th>Stark</th>
<th>Anti-Kickback</th>
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<tbody>
<tr>
<td>Stark exception related to both ownership/investment and compensation</td>
<td>[No comparable safe harbor]</td>
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The services are furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization): a) an HMO or a CMP in accordance with a contract with CMS, which set forth qualifying conditions for Medicare contracts; enrollment, entitlement, and disenrollment under Medicare contracts; Medicare contract requirements; and change of ownership and leasing of facilities: effect on Medicare contracts; b) a health care prepayment plan in accordance with an agreement with CMS; c) an organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project; d) a qualified HMO; e) a coordinated care plan offered by an organization in accordance with a contract with CMS; f) a managed care organization (MCO) contracting with a State; g) a prepaid inpatient health plan or prepaid ambulance health plan contracting with a State; h) a health insuring organization (HIO) contracting with a State; and i) an entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

### In-Office Ancillaries

<table>
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<th>Stark</th>
<th>Anti-Kickback</th>
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<tr>
<td>Stark exception related to both ownership/investment and compensation for in-house ancillary services</td>
<td>[No comparable safe harbor]</td>
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NOTE: This exception has been modified by the Patient Protection and Affordable Care Act. [Review the changes.]

Services are all designated health services and can include certain items of durable medical equipment (DME), and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)

The services are furnished personally by one of the following individuals: a) the referring physician; b) a physician who is a member of the same group practice as the referring physician; or c) an individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services

They are furnished in one of the following locations:

- The same building, but not necessarily in the same space or part of the building, in which one of the following conditions are satisfied:
  a. The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week.

(The 30 hours must include some
| a. | physician services that are unrelated to the furnishing of designated health services payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of designated health services; or |
| b. | the patient receiving the designated health services usually receives physician services from the referring physician or members of the referring physician's group practice (if any) and the referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and the referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. (The 6 hours must include some physician services that are unrelated to the furnishing of designated health services payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of designated health services; or |
| c. | the referring physician is present and orders the designated health services during a patient visit |
on the premises or the referring physician or a member of the referring physician's group practice (if any) is present while the designated health service is furnished during occupancy of the premises; and the referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of designated health services payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of designated health services.

- A centralized building that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services; or

- A centralized building that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).
The services must be billed by one of the following: a) the physician performing or supervising the service; b) the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice; c) the group practice if the supervising physician is a “physician in the group” under a billing number assigned to the group practice; d) an entity that is wholly owned by the performing or supervising physician or by that physician’s group practice under the entity’s own billing number or under a billing number assigned to the physician or group practice; e) an independent third party billing company acting as an agent of the physician, group practice, or entity under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of Sec. 424.80(b)(6) of this chapter. A group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

- The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.
- The item is furnished in a building that meets the “same building” requirements in the in-office
ancillary services exception as part of the
treatment for the specific condition for which the
patient-physician encounter occurred.

• The item is furnished personally by the
  physician who ordered the DME, by another
  physician in the group practice, or by an
  employee of the physician or the group practice.
• A physician or group practice that furnishes
  the DME meets all DME supplier standards
  located in Sec. 424.57(c) of this chapter.
• The arrangement does not violate the anti-
  kickback statute or any federal or state law or
  regulation governing billing or claims
  submission.
• All other requirements of the in-office
  ancillary services exception are met.

In the case of a referring physician whose principal medical
practice consists of treating patients in their private homes,
the "same building" requirements are met if the referring
physician (or a qualified person accompanying the physician,
such as a nurse or technician) provides the designated
health services contemporaneously with a physician service
that is not a designated health service provided by the
referring physician to the patient in the patient's private
home. A private home does not include a nursing, long-term
care, or other facility or institution, except that a patient may
have a private home in an assisted living or independent
living facility.