Summary of the Federal Physician Self-Referral Law (the “Stark Law”)

The requisite elements of the Stark Law are as follows: a physician is prohibited from (1) making a “referral” of a Medicare patient to an entity;1 (2) for the furnishing of “designated health services;” (3) if there is a “financial relationship” between the referring physician (or an immediate family member of the referring physician) and the entity; (4) unless an exception applies.2

The Stark Law defines a “referral” to mean a request by a physician for, or the ordering of, or the certifying of the need for, or the establishment of a plan of care including, any designated health service (“DHS”) for which payment may be made under the Medicare program.3 In general, the definition of referral includes referrals between a physician and the physician’s employed staff, such as nurses or mid-level providers. In responding to comments regarding the definition of referral, CMS explicitly stated its interpretation “that ‘incident to’ services performed by others, as well as services performed by a physician’s employees, are referrals within the meaning of . . . the Act.”4

The Stark Law defines a “financial relationship” to mean either: (1) an ownership or investment interest in the entity; or (2) a compensation arrangement between the physician and the entity.5 Under the Stark II regulations,6 a financial relationship is also defined to include indirect ownership interests and indirect compensation arrangements.7 As discussed below, the Stark II regulations set forth extensive provisions defining these indirect relationships.

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1 Federal Medicaid statutes also prohibit the federal government from making Medicaid matching payments (also known as “federal financial participation” or FFP payments) to states for DHS services provided to Medicaid beneficiaries pursuant to a referral that would have violated the Stark Law if it had been provided to a Medicare beneficiary. See 42 U.S.C. § 1396b(s).
3 The following categories of items and services are considered “DHS” when covered by Medicare: clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology services, including magnetic resonance imaging (“MRI”), computerized axial tomography (“CAT”) scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.
6 CMS has issued a series of regulations to implement the Stark Law, including the “Stark I” regulations on January 4, 2001, the “Stark II” regulations on March 26, 2004, and the “Stark III” regulations on September 5, 2007.
7 See 42 C.F.R. § 411.354(b)(5)(i).
An “indirect compensation” relationship exists where (1) an unbroken chain of ownership or compensation arrangements exists between a physician and a DHS entity, (2) the referring physician receives aggregate compensation from the person or entity with which he has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the DHS entity, and (3) the DHS entity has actual knowledge, or acts in reckless disregard of, the fact that a referring physician receives aggregate compensation that varies with or reflects the volume or value of referrals from the physician to the entity. These requirements are conjunctive; all are required to create an indirect compensation relationship. Determining whether a physician receives compensation that varies with the volume of referrals requires an examination of the non-ownership/non-investment interest closest to the referring physician. Thus, an indirect compensation arrangement exists (and the Stark Law is implicated) only where the closest compensation arrangement to the physician provides for payments that vary with the volume or value of referrals to the DHS entity.

One relatively recent change that has affected the analysis of indirect compensation arrangements involved an expansion of the “stand in the shoes” concept. Under this expansion, a referring physician is deemed to “stand in the shoes” of any physician organization in which the physician has an ownership or investment interest. Physician organization is defined as including a physician, physician’s practice, or group practice, but not including a hospital or a medical school that does not operate a faculty practice plan but employs physicians to provide clinical and academic services. As a result of the expanded stand in the shoes requirements, some arrangements between a DHS entity and a group practice, for example, must comply with a direct compensation exception, rather than relying on the definition of an indirect compensation relationship to avoid Stark Law requirements. According to CMS, this change was intended to close an unintended loophole, whereby parties were structuring arrangements between a DHS entity and a physician organization in order to avoid meeting the more difficult requirements involved with meeting a direct compensation exception.

The Stark Law is not intent-based. If a financial relationship exists, the physician cannot make a referral for DHS and the service provider cannot bill the government for the service, even if there is no intent to induce referrals, unless an exception applies. Significant civil monetary and administrative penalties may be assessed for violations of the Stark Law, and a person violating the law may be excluded from participation in Medicare and Medicaid. The potential penalties for a Stark Law violation include: denial of payment for the service; civil fines of $15,000 per service; civil fines of

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8 See 42 C.F.R. § 411.354(c)(2)
9 42 C.F.R. § 411.354(c)(1)(ii).
10 42 C.F.R. § 411.351. The elements of the “group practice” definition are articulated in 42 C.F.R. § 411.352. A specific list of entities that are not considered “physician organizations” was included in FAQ2331 on the CMS website, available at https://questions.cms.gov/.
11 See discussion regarding indirect compensation analysis below.
$100,000 per arrangement for circumvention schemes; potential exclusion from Medicare or Medicaid; and potential False Claims Act liability.\(^{12}\)

\(^{12}\) 42 U.S.C. § 1395nn.