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TO IMPROVE PATIENT ACCESS TO HIGH-QUALITY HEALTHCARE OUTCOMES AT LOWER COSTS, THE FEDERAL HEALTH FRAUD LAWS NEED TO BE CHANGED AND SIMPLIFIED

Part 2 of a 3-part Special Series

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STARK LAW

Stark was passed to prevent self-dealing in referrals that benefit the healthcare provider and his/her family.[1] Under Stark, 42 U.S.C. Section 1395nn:

> (a) Prohibition of certain referrals
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> (1) In general
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> Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—
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> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
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> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).[2]

Stark, like the AKS, imposes a strict liability standard in assessing whether or not the financial arrangement involved is in violation of the law.[3] Moreover, Stark also applies to the acquisition of healthcare services practices by other providers or entities.[4] Much like the AKS safe harbors and the OIG, Stark gives authority to the HHS Center for Medicare & Medicaid Services ("hereafter, CMS") to issue Advisory Opinions (hereafter, "AOs") to clarify and identify exceptions to Stark that are permissible under the law.[5]

Stark applies generally to "a financial relationship of a physician (or an immediate family member of such physician)[6] There are, however, different sets of exceptions to Stark within the law, the first being categorized as "general exceptions to both ownership and compensation arrangement prohibitions."[7] The exceptions include the following: (1) healthcare services for "another physician in the same group practice;"[8] (2) in office services "other than durable medical

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[1] Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. Health Care Compliance 5-6 (2016).
[2] *Stark Law*, 42 U.S.C.A. § 1395nn (West 2010).
[3] Corbin Santo, *Walking A Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 Case W. Res. L. Rev. 1377, 1390 (2014).
[4] Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, Health Law., April 2014, at 24, 24 (2014).
[5] Corbin Santo, *Walking A Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 Case W. Res. L. Rev. 1377, 1390 (2014).
[6] *Stark Law*, 42 U.S.C.A. § 1395nn(a)(2) (West 2010).
[7] *Stark Law*, 42 U.S.C.A. § 1395nn(b) (West 2010).
[8] *Stark Law*, 42 U.S.C.A. § 1395nn(b)(1) (West 2010).

equipment;"[9] (3) prepaid plans under five different provisions in other laws;[10] (4) "other permissible exceptions;"[11] and (5) electronic medication prescribing.[12]

Another set of exceptions to Stark fall under "general exception related *only* to ownership or investment prohibition for ownership in publicly traded securities and mutual funds" (emphasis added).[13] These exceptions allow for investment in publicly-traded entities either available for sale to the public or traded on stock exchanges.[14]

The third set of exception to Stark fall under the heading "additional exceptions related *only* to ownership or investment prohibition" (emphasis added).[15] These exceptions include Puerto Rican hospitals, rural healthcare providers, and hospital ownership in specific circumstances.[16]

The fourth set of exceptions to Stark relate to "other compensation arrangements.[17] These arrangements include equipment and office space rent,[18] employment relationships,[19] personal services,[20] "remuneration unrelated to the provision of designated health services,"[21] "physician recruitment,"[22] "isolated transactions,"[23] "certain group practice arrangements with a hospital,"[24] and "payments by a physician for items and services," all under certain circumstances as specified under Stark.[25]

The statute then goes on to discuss certain reporting requirements,[26] and then the sanctions for violating the Stark law.[27] Sanction may include the following: (1) reimbursement denial,[28] (2) mandatory refunds,[29] (3) civil monetary penalties (up to $15,000 for improper claims and up to $100,000 for circumvention schemes),[30] (4) exclusion from participating in government payor systems,[31] and (5) daily penalties up to $10,000 for failure to meet reporting requirements under the law.[32]

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[9] *Stark Law,* 42 U.S.C.A. § 1395nn(b)(2) (West 2010).
[10] *Stark Law,* 42 U.S.C.A. § 1395nn(b)(3) (West 2010).
[11] *Stark Law,* 42 U.S.C.A. § 1395nn(b)(4) (West 2010).
[12] *Stark Law,* 42 U.S.C.A. § 1395nn(b)(5) (West 2010).
[13] *Stark Law,* 42 U.S.C.A. § 1395nn(c) (West 2010).
[14] *Stark Law,* 42 U.S.C.A. § 1395nn(c)(1) (West 2010).
[15] *Stark Law,* 42 U.S.C.A. § 1395nn(d) (West 2010).
[16] *Stark Law,* 42 U.S.C.A. § 1395nn(d)(3) (West 2010).
[17] *Stark Law,* 42 U.S.C.A. § 1395nn(e) (West 2010).
[18] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(1) (West 2010).
[19] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(2) (West 2010).
[20] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(3) (West 2010).
[21] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(4) (West 2010).
[22] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(5) (West 2010).
[23] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(6) (West 2010).
[24] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(7) (West 2010).
[25] *Stark Law,* 42 U.S.C.A. § 1395nn(e)(8) (West 2010).
[26] *Stark Law,* 42 U.S.C.A. § 1395nn(f) (West 2010).
[27] *Stark Law,* 42 U.S.C.A. § 1395nn(g) (West 2010).
[28] *Stark Law,* 42 U.S.C.A. § 1395nn(g)(1) (West 2010).
[29] *Stark Law,* 42 U.S.C.A. § 1395nn(g)(2) (West 2010).
[30] *Stark Law,* 42 U.S.C.A. § 1395nn(g)(3-4) (West 2010).
[31] *Stark Law,* 42 U.S.C.A. § 1395nn(g)(3-4) (West 2010).
[32] *Stark Law,* 42 U.S.C.A. § 1395nn(g)(5) (West 2010).

General Provisions Against Self-Dealing

Stories of doctors engaging in self-dealing were prevalent in the U.S. during the 1980s.[33] The OIG issued reports regarding the self-dealing issues it was uncovering about clinical laboratory referrals specifically, showing that self-dealing was prevalent in 45% of referrals.[34] Since the passage of the AKS and Stark, these stories became less and less common over time, as doctors were de-incentivized from making referrals for their patients after which the doctors could then receive an investor payout for the referral.[35] Specifically, a doctor and his family members are prohibited under Stark from any self-dealing with regard to patients under Medicare and/or Medicaid reimbursement programs.[36] "Intent" is not an element that must be proven under Stark. [37] What this means is that although the American Medical Association lobbied heavily for the passage of Stark, and the Federal Trade Commission lobbied against the passage of Stark, that there needed to be a Congressional act passed, at the time, in order to curb the eroding trust of patients for doctors in the healthcare system overall.[38] Stark's controversial passage is still palpable today as practitioners continue to aim to strike a balance under this law.[39]

Stark Advisory Opinions

Like the AKS, there are AOs issued to requesters who ask for them; "Section 1877(g)(6) of the Social Security Act (the Act) requires that the Centers from Medicare & Medicaid Services (hereafter, "CMS") issue certain written advisory opinions."[40] However, it is not the Office of Inspector General that issues the AOs under Stark as the OIG does for the AKS; Stark AOs are issued by CMS directly.[41] Like the AOs issued under the AKS, AOs issued under Stark are redacted and published online.[42] Also like the AOs issued under AKS, the AOs issued under Stark are specific to the individual request made by the requestor for an AO and cannot be relied upon, legally, by any other entity.[43]

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[33] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 2 (2003).
[34] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 5 (2003).
[35] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 2 (2003).
[36] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 8 (2003).
[37] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 9 (2003).
[38] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 13-18 (2003).
[39] Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 13-21 (2003).
[40] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
[41] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
[42] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
[43] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.

Sampling of Recent Stark Advisory Opinions

Stark Advisory Opinion CMS-AO-2016-01

This AO titled, "Concerning whether a physician-owned hospital's addition of certain observation beds, which are not licensed by the state where the hospital is located, would violate the limitation on expansion of facility capacity set forth in section 1877(i)(1)(B) of the Social Security Act,"[44] begins with an introduction that in reply to a requestor of a "Proposed Arrangement," that would expand a hospital facility to added "outside observation beds" to a hospital facility that is owned by physicians, and whether such a expansion would run afoul of a facility expansion prohibition in the law, specifically "1877(i)(1)(B) of the Social Security Act"[45] that states in relevant part, "the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date the law was passed is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date."

The information submitted by the requestor is acknowledged in the AO by CMS as certified and the AO indicates that it can only be relied upon, legally, if all information was properly submitted to CMS by the requestor or the AO "is without force and effect."[46] The requestor is an "acute-care hospital," and the proposed new hospital beds "are not intended for use for patients admitted to the hospital as inpatients."[47]

CMS starts its legal analysis in the AO of this proposal by reaffirming the intent of Stark to prevent the self-dealing through referrals of Medicare patients in a manner that results in a benefit for the referring physician.[48] CMS also discussed the exceptions to Stark written into the law, specifically the "'whole hospital' exception" that allows physician ownership of hospitals if the following conditions are met: (1) physician ownership of a hospital if the "referring physician is authorized to perform services at the hospital," (2) "the ownership or investment interest is in the hospital itself," and (3) "additional restrictions under the ACA are satisfied."[49] The exception can be

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[44] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
[45] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 1, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[46] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 1, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[47] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), pp. 1-2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[48] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[49] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.

granted only if the state in which the hospital operates is licensed by that state in accordance with the state's rule on hospital licensure, something this AO points out is not defined in the ACA.[50]

Finding the hospital to indeed be licensed, CMS then evaluates whether or not the state licensing entity makes a distinction between "licensed" hospital beds and other "categories of beds that are not."[51] Finding that such distinction is not made, the AO concludes, "beds that are used exclusively for observation services are not "setup and staffed inpatient beds" and, therefore, are not subject to licensure in the State."[52] Based upon this legal analysis and the certifications and assurances made by the requestor, the AO ultimately concludes that the requestor's proposal does not run afoul of Stark and therefore would be permitted under the law.[53] The AO ends by stating the same type of limitations of the AO include the use thereof by the requestor should information that was submitted for the AO be incomplete, or by use of other entities.[54]

Stark Advisory Opinion CMS-AO-2014-01

This AO titled, concerning whether the value of any ownership or investment interests attributable to assets that were committed for contribution but not transferred to a physician-owned hospital (or an entity whose assets would include the hospital) should be included when determining the hospital's aggregate physician ownership or investment interests as of March 23, 2010 under section 1877(i)(1)(D)(i) of the Social Security Act,[55] concerns a proposal from a requestor on the issue of how to "calculate the aggregate percentage of physician-held ownership or investment interests in a hospital."[56] The AO acknowledged the usual certifications made by the requestor and the limitations of reliance thereupon.[57] The hospital in this case "is an acute care hospital" that the requestor started developing 2009.[58] The requestor was developing its land for use by the

[50] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[51] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), pp. 4-5, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[52] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 5, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[53] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), p. 5, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[54] CMS Advisory Opinion No. CMS-AO-2016-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Mar. 2016), pp. 6-7, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf.
[55] *Advisory Opinions (AOs)*, Centers for Medicare & Medicaid Services (May 22, 2017), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.
[56] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 1, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[57] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 1, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[58] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 1, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.

hospital and was attempting to secure investment funds from "owners of two ambulatory surgery centers (ASCs) regarding their potential investment in the hospital."[59] One "ASC was physician-owned" and the other ASC was publicly-traded.[60] The AO states that "80 percent of the ownership was by physicians and that it was to be "owned and operated by a newly formed business entity."[61]

The AO then reveals that the "requestor certified that on March 23, 2010, prior to the transfer of assets to the newly formed business entity, the physicians held, in the aggregate, 88 percent of the total value of ownership and investment interests in the requestor."[62] The closing of the deal "occurred April 30, 2010" and thereafter on "September 29, 2010, the public ASC withdrew from it, "resulting in the "physician owners having a 78.04 percent ownership interest in the newly-formed business entity."[63] The newly-formed business entity subsequently merged with the requestor, and actually merged in to it.[64] In its AO request, the "requestor certified that, upon the merger and until May 17, 2011, the physician owners had a 78.04 percent ownership interest in the requestor, and non-physician investor had a 21.96 percent ownership interest in the requestor.[65] On "May 17, 2011," a "1.96 percent interest in requestor" was sold bringing "the aggregate percentage of physician ownership to 80 percent."[66] The requestor subsequently enrolled in Medicare.[67] The requestor's physician owners refer patients to "the hospital for services reimbursed by the Medicare program."[68]

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[59] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[60] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[61] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[62] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[63] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[64] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[65] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[66] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 2, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[67] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[68] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.

CMS begins its legal analysis by invoking the intent of Stark to avoid physician self-dealing at the expense of taxpayers through the federal healthcare payment programs.[69] The ACA specifically amended the law to create "additional restrictions on existing physician-owned hospitals."[70] The intent was to de-incentivize physicians from the self-referral of patients to hospitals they own.[71] Under the ACA, hospitals are restricted in the amount of physician ownership that they can have, but there is an exception to this rule that allows for grandfathering of existing hospital ownership so long as the hospital ownership arrangement was formed prior to "December 31, 2010."[72] Arrangements that are outside of the scope of this exception cannot take federal healthcare payment funds or they risk implicating Stark.[73] CMS found that the changes brought by the ACA were not "intended to disrupt physician investment in entities developing hospitals that were close to completion at the time of the enactment of the ACA."[74] CMS did not find that in this case, the physician ownership allocation was not in aggregate of the new law.[75] The AO concluded with the same types of limitations as discussed above in other AOs, including who could rely on the AO, that the AO could not be used to obligate any U.S. government body, and that the AO could not be used in defense of charge under other health fraud laws, among other limitations.

Key Differences Between Stark and the Anti-Kickback Statute

It is important to note the key differences between Stark and the AKS: (1) AKS prohibits receiving anything of value to increase billing of government payors, whereas Stark prohibits referrals to other entities that physicians/providers have a family or financial relationship with; (2) intent need only be established in the AKS, not Stark; and (3) the AKS has both criminal and civil provisions, whereas Stark has only civil provisions.

[69] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[70] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[71] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[72] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf (42 U.S.C. § 1395nn(i)(1)(A)(ii)).
[73] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[74] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 3, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.
[75] CMS Advisory Opinion No. CMS-AO-2014-01, Department of Health and Human Services: Centers for Medicare & Medicaid Services (Dec. 2014), p. 4, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2014-01-REDACTED.pdf.

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