§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) Physician services. (1) Physician services as defined in § 410.20(a) of this chapter that are furnished --

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, "physician services" include only those "incident to" services (as defined at § 411.351) that are physician services under § 410.20(a) of this chapter.

(b) In-office ancillary services. Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, 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)), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) 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 other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), or (b)(2)(i)(C) of this section are satisfied:

(A)(1) 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

(B)(1) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);
(2) 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

(3) 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 DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(1) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(2) of this section;

(2) 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

(3) 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 DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at § 411.351) 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).

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group practice" (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) 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.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of § 424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, 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:

(i) The item is one that a patient requires for the purpose of ambulating, a patient 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.

(ii) 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.

(iii) 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.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in § 424.57(c) of this chapter.
(v) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "furnished" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) Special rule for home care physicians. In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS 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. For purposes of paragraph (b)(5) of this section only, 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.

(7) Disclosure requirement for certain imaging services.

(i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined in § 400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) Services furnished by an organization (or its contractors or subcontractors) to enrollees. Services 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):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.
(d) [Reserved]

(e) Academic medical centers. (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician --

(A) Is a bona fide employee of a component of the academic medical center on a full-time or substantial part-time basis. (A "component" of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at § 411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The "academic medical center" for purposes of this section consists of --

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at § 411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) Implants furnished by an ASC. Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under § 416.65 of this chapter.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) EPO and other dialysis-related drugs. EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "EPO and other dialysis-related drugs" means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and "furnished" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) Preventive screening tests, immunizations, and vaccines. Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission.
The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) Eyeglasses and contact lenses following cataract surgery. Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.

(j) Intra-family rural referrals. (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) 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 of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.


AUTHORITY: AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

NOTES: [EFFECTIVE DATE NOTE: 75 FR 73170, 73616, Nov. 29, 2010, added paragraph (b)(7), effective Jan. 1, 2011.]

NOTES APPLICABLE TO ENTIRE CHAPTER:

NOTES APPLICABLE TO ENTIRE PART:
PUBLISHER'S NOTE: For Federal Register citations concerning Part 411 Interpretations, see: 70 FR 13397, Mar. 21, 2005.]
LexisNexis (R) Notes:

CASE NOTES

CASE NOTES Applicable to entire Part: Part Note


Overview: Hospital and various medical personnel were allowed to show they satisfied Academic Medical Center exception to the Stark law, 42 C.F.R. § 411.355(e), by showing that referring physicians were bona fide employees of medical school, faculty practice plan, or hospital, on full-time basis, and that they were licensed to practice medicine in Kentucky.

. The safe harbor provisions are known as the Academic Medical Center exception to the Stark law. 42 C.F.R. § 411.355(e) (2006). Go To Headnote

. The regulations, 42 C.F.R. § 411.355(e) (2006), defining the scope of the Academic Medical Center exception to the Stark law constitute a reasonable and permissible construction of the statute, 42 U.S.C.S. § 1395nn. Go To Headnote


Overview: Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

. With regard to reimbursement under Medicaid, the first category of the academic medical center (AMC) exception criteria imposes four requirements on the referring physicians themselves. Specifically, the regulations require that the referring physicians be bona fide employees of a component of the academic medical center on a full-time or substantial part-time basis, that they be licensed to practice medicine in the state(s) in which they practice medicine, and that they have a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital. 42 C.F.R. § 411.355(e)(1)(i)(A) -- (C). Go To Headnote

. With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, a referring physician faculty member must provide either substantial academic services or substantial clinical services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or eight hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or eight hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical services) is not precluded from qualifying under this paragraph. 42 C.F.R. §
A physician who fails to meet this safe harbor is not precluded from qualifying under this requirement. Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, the second category of requirements under the AMC exception concerns the total compensation paid to referring physicians, and mandates that the compensation of the referring physician meet all three of the following requirements: (A) the total compensation paid by each academic medical center component to the referring physician is set in advance; (B) in the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided; (C) the total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center. 42 C.F.R. § 411.355(e)(1)(ii). The purpose of this requirement is to make sure that physicians are paid based on the value of their work rather than the value of their referral business to the hospitals. Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, a purported AMC must consist of: (i) an accredited medical school or an accredited academic hospital; (ii) one or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and (iii) one or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. 42 C.F.R. § 411.355(e)(2). Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, an accredited academic hospital is defined by the rule as being a hospital or a health system that sponsors four or more approved medical education programs. 42 C.F.R. § 411.355(e)(3). Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, the AMC exception imposes three requirements upon the organization and financial transfers among the entities of which the purported AMC is comprised: (A) all transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service; (B) the relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component; and (C) all money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant. 42 C.F.R. § 411.355(e)(1)(iii). Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, the AMC exception includes a requirement that the referring physician's compensation arrangement not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission. 42 C.F.R. § 411.355(e)(1)(iv). Defendants must avoid the inference that any of them "knowingly and willfully" paid or received money to induce patient referrals. 42 U.S.C.S. § 1320a-7b(b)(2). Go To Headnote


Overview: Hospital and various medical personnel were allowed to show they satisfied Academic Medical Center exception to the Stark law, 42 C.F.R. § 411.355(e), by showing that referring physicians were bona fide employees of medical school, faculty practice plan, or hospital, on full-time basis, and that they were licensed to practice medicine in Kentucky.

One of the requirements for the Academic Medical Center exception is that the financial arrangement does not violate the Anti-kickback statute. 42 C.F.R. § 411.355(e)(1)(iv) (2006). The Anti-kickback statute provides in relevant part: Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $ 25,000 or imprisoned for not more than five years, or both. 42 U.S.C.S. § 1320a-7b(b)(2). Go To Headnote
Although as a matter of law the Academic Medical Center (AMC) exception to the Stark rule, 42 U.S.C.S. § 1395m, does not apply to the Anti-kickback statute, as a practical matter satisfaction of the former will indicate there has been no violation of the latter. Payments made between the components of an AMC necessarily support the missions of teaching, indigent care, research, or community service and may not exceed the fair market value of the academic and clinical teaching services provided. 42 C.F.R. § 411.355(e) (2006). As such, they are not made to induce referrals and thus cannot be characterized as kickbacks that would violate 42 U.S.C.S. § 1320a-7b.

Overview: Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

With regard to reimbursement under Medicaid, a "component" of an academic medical center (AMC) is defined as an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center. 42 C.F.R. § 411.355(e)(1)(i)(A).

Overview: Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

With regard to reimbursement under Medicaid, the first category of the academic medical center (AMC) exception criteria imposes four requirements on the referring physicians themselves. Specifically, the regulations require that the referring physicians be bona fide employees of a component of the academic medical center on a full-time or substantial part-time basis, that they be licensed to practice medicine in the state(s) in which they practice medicine, and that they have a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital. 42 C.F.R. § 411.355(e)(1)(i)(A) -- (C).

With regard to reimbursement under Medicaid, a "component" of an academic medical center (AMC) is defined as an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center. 42 C.F.R. § 411.355(e)(1)(i)(A).

Overview: Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, a referring physician faculty member must provide either substantial academic services or substantial clinical services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or eight hours per week providing academic
services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or eight hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical services) is not precluded from qualifying under this paragraph. 42 C.F.R. § 411.355(e)(1)(i)(D). A physician who fails to meet this safe harbor is not precluded from qualifying under this requirement. Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, an accredited academic hospital is defined by the rule as being a hospital or a health system that sponsors four or more approved medical education programs. 42 C.F.R. § 411.355(e)(3). Go To Headnote


**Overview:** Defendants' motion for summary judgment was granted because defendants met the legal requirements of the academic medical center (AMC) exception with regard to Medicaid reimbursement claims, as such, there remained no underlying Stark law, 42 U.S.C.S. § 1395nn violation upon which plaintiffs' FCA claim could proceed.

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, a referring physician faculty member must provide either substantial academic services or substantial clinical services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or eight hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or eight hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical services) is not precluded from qualifying under this paragraph. 42 C.F.R. § 411.355(e)(1)(i)(D). A physician who fails to meet this safe harbor is not precluded from qualifying under this requirement. Go To Headnote

With regard to reimbursement under Medicaid and the academic medical center (AMC) exception, the AMC exception includes a requirement that the referring physician's compensation arrangement not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission. 42 C.F.R. § 411.355(e)(1)(iv). Defendants must avoid the inference that any of them "knowingly and willfully" paid or received money to induce patient referrals. 42 U.S.C.S. § 1320a-7b(b)(2). Go To Headnote