

§ 411.362

42 CFR Ch. IV (10–1–24 Edition)

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

[72 FR 51098, Sept. 5, 2007, as amended at 80 FR 71378, Nov. 16, 2015; 81 FR 61561, Sept. 6, 2016]

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) *Definitions.* For purposes of this section—

Ownership or investment interest means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which

catheterizations, angiographies, angiograms, and endoscopies are performed).

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) *General requirements.* (1) *Physician ownership and provider agreement.* The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is approved under § 411.363.

(3) *Disclosure of conflicts of interest.* (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) Not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

(4) *Ensuring bona fide investment.* The hospital satisfies the following criteria:

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under

the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(5) *Patient safety.* The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) *Prohibition on conversion from an ambulatory surgery center.* The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014; 80 FR 71378, Nov. 16, 2015; 85 FR 86299, Dec. 29, 2020; 88 FR 59328, Aug. 28, 2023]

§411.363 Process for requesting an exception from the prohibition on facility expansion.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure