

§ 411.353

compensation, must be made available to the Secretary upon request.

[66 FR 956, Jan. 4, 2001]

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff; however, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who

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made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal laws, rules, and regulations.

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§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities (not including an agent of the physician, the immediate family member, or the entity furnishing DHS).

(3) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

- (i) An interest in a retirement plan;
- (ii) Stock options and convertible securities until the stock options are exercised or the convertible securities are converted to equity (before this time they are compensation arrangements as defined in paragraph (c) of this section);
- (iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section); or
- (iv) An “under arrangements” contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS “under arrangements” to the hospital.

(4) An ownership or investment interest that meets an exception set forth in §§411.355 or 411.356 need not also meet an exception for compensation arrangements set forth in §411.357 with respect to profit distributions, dividends, interest payments on secured obligations, or the like.

(5) *Indirect ownership or investment interest.* (i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests between them; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) The entity furnishing DHS need not know, or act 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.

(c) *Compensation arrangement.* A compensation arrangement can be any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician’s imme-

mediate family) and an entity. An “under arrangements” contract between a hospital and an entity providing DHS “under arrangements” to the hospital creates a compensation arrangement for purposes of these regulations.

(1) A compensation arrangement does not include any of the following:

(i) The portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term “remuneration” in §411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(ii) Payments made by a consultant to a referring physician under §414.65(e) of this chapter.

(2) *Indirect compensation arrangement.* An indirect compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a *direct* financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or

noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and these regulations in subpart J of this part.

(1) Compensation will be considered “set in advance” if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement between the parties in sufficient detail so that it can be objectively verified. The payment amount must be fair market value compensation for services or items actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician at the time of the initial agreement or during the term of the agreement. Percentage compensation arrangements do not constitute compensation that is “set in advance” in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

(2) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account “the volume or value of referrals” if the compensation is fair

market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

(3) Compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account “other business generated between the parties” so long as the compensation is fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.

(4) A physician’s compensation may be conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is fixed in advance for the term of the agreement;

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals);

(iii) Complies with an applicable exception under §§411.355 or 411.357; and

(iv) Complies with the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient’s insurer determines the provider, practitioner, or supplier; or the referral is not in the patient’s best medical interests in the physician’s judgment.

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EFFECTIVE DATE NOTE: At 66 FR 958, Jan. 4, 2001, §411.354 was added, effective Jan. 4, 2002. At 66 FR 60154, Dec. 3, 2001, the effective date of the last sentence in §411.354(d)(1) was delayed from Jan. 4, 2002, until Jan. 6, 2003.