

§411.356

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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.

[72 FR 51088, Sept. 5, 2007; 72 FR 68076, Dec. 4, 2007, as amended at 75 FR 73616, Nov. 29, 2010]

§411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly-traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers.

(2) They are in a corporation that had stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. "Stockholder equity" is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this subpart) by the provider. A "rural provider" is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such

other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

[72 FR 51091, Sept. 5, 2007, as amended at 75 FR 72260, Nov. 24, 2010]

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined—

(i) In a manner that takes into account the volume or value of any refer-

als or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of paragraphs (a)(1) through (a)(6) of this section satisfies the requirements of paragraph (a) of this section, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

(3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined—

(i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or

(ii) Using a formula based on—