

to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPSC Codes) only, are dispensed by the ESRD facility for use at home.

(2) [Reserved]

(3) [Reserved]

(4) The exception set forth in this paragraph (g) 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 and vaccines.* (1) Preventive screening tests and vaccines that meet the following conditions:

(i) The preventive screening test or vaccine is listed on the List of CPT/HCPSC Codes as a code to which the exception in this paragraph is applicable.

(ii) The preventive screening test or vaccine is covered by Medicare.

(iii) The preventive screening test or vaccine is subject to a CMS-mandated frequency limit.

(2) During such period as the vaccine is not subject to a CMS-mandated frequency limit, paragraph (h)(1)(iii) of this section does not apply to a COVID-19 vaccine identified on the List of CPT/HCPSC Codes as a code to which the exception in this paragraph is applicable.

(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) [Reserved]

(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

(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.

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§ 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 (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;

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

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(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 part) 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.

[85 FR 77656, Dec. 2, 2020]

§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 the arrangement meets the following requirements:

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

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

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement 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. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

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