spect to the findings and conclusions made as a result of such study.

STUDY EVALUATING THE EXTENT OF, AND REASONS FOR, TERMINATION BY MEDICARE BENEFICIARIES OF MEMBERSHIP IN ORGANIZATIONS WITH CONTRACTS UNDER THIS SECTION

Pub. L. 97–248, title I, § 114(e), Sept. 3, 1982, 96 Stat. 352, directed Secretary of Health and Human Services to conduct a study evaluating the extent of, and reasons for, the termination by medicare beneficiaries of their memberships in organizations with contracts under section 1876 of the Social Security Act (this section), with Secretary to submit an interim report to Congress, within two years after the initial effective date (as defined in subsec. (c)(4) of section 114 of Pub. L. 97–248), and a final report within five years after such date containing the respective interim and final findings and conclusions made as a result of such study.

REIMBURSEMENT FOR SERVICES

Pub. L. 92–603, title II, § 226(b), Oct. 30, 1972, 86 Stat. 1403, provided that:

''(1) Notwithstanding the provisions of section 1814 and section 1833 of the Social Security Act [42 U.S.C. 1395f, 1395*l*], any health maintenance organization which has entered into a contract with the Secretary pursuant to section 1876 of such Act [42 U.S.C. 1395mm] shall, for the duration of such contract, (except as provided in paragraph (2)) be entitled to reimbursement only as provided in section 1876 of such Act [42 U.S.C. 1395mm] for individuals who are members of such organizations.

''(2) With respect to individuals who are members of organizations which have entered into a risk-sharing contract with the Secretary pursuant to subsection (i)(2)(A) [of this section] prior to July 1, 1973, and who, although eligible to have payment made pursuant to section 1876 of such Act [42 U.S.C. 1395mm] for services rendered to them, chose (in accordance with regulations) not to have such payment made pursuant to such section, the Secretary shall, for a period not to exceed three years commencing on July 1, 1973, pay to such organization on the basis of an interim per capita rate, determined in accordance with the provisions of section 1876(a)(2) of such Act [42 U.S.C. 1395mm(a)(2)], with appropriate actuarial adjustments to reflect the difference in utilization of out-of-plan services, which would have been considered sufficiently reasonable and necessary under the rules of the health maintenance organization to be provided by that organization, between such individuals and individuals who are enrolled with such organization pursuant to section 1876 of such Act [42 U.S.C. 1395mm]. Payments under this paragraph shall be subject to retroactive adjustment at the end of each contract year as provided in paragraph (3).

''(3) If the Secretary determines that the per capita cost of any such organization in any contract year for providing services to individuals described in paragraph (2), when combined with the cost of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such year for providing out-of-plan services to such individuals, is less than or greater than the adjusted average per capita cost (as defined in section 1876(a)(3) of such Act [42 U.S.C. 1395mm(a)(3)]) of providing such services, the resulting savings shall be apportioned between such organization and such Trust Funds, or the resulting losses shall be absorbed by such organization, in the manner prescribed in section 1876(a)(3) of such Act [42 U.S.C. 1395mm(a)(3)].''

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b), if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d), an ownership or investment interest in the entity, or

(B) except as provided in subsection (e), a compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) 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 providing the designated health service.

(b) General exceptions to both ownership and compensation arrangement prohibitions

Subsection (a)(1) shall not apply in the following cases:

(1) Physicians' services

In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4)) as the referring physician.

(2) In-office ancillary services

In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)—

(A) that are furnished—

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice—

(aa) for the provision of some or all of the group's clinical laboratory services, or

(bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),

unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,

if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse. Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1395x(d) of this title) who furnish such services in the area in which such individual resides.

(3) Prepaid plans

In the case of services furnished by an organization—

(A) with a contract under section 1395mm of this title to an individual enrolled with the organization,

(B) described in section 1395*l*(a)(1)(A) of this title to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 1395b–1(a) of this title or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization,

(D) that is a qualified health maintenance organization (within the meaning of section 300e–9(d)[1] of this title) to an individual enrolled with the organization, or

(E) that is a Medicare+Choice organization under part C that is offering a coordinated care plan described in section 1395w–21(a)(2)(A) of this title to an individual enrolled with the organization.

(4) Other permissible exceptions

In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(5) Electronic prescribing

An exception established by regulation under section 1395w–104(e)(6) of this title.[1]

[1] See References in Text note below.

(c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds

Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are—

(A)(i) securities listed 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 interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $75,000,000.

(2) Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75,000,000.

(d) Additional exceptions related only to ownership or investment prohibition

The following, if not otherwise excepted under subsection (b), shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) Hospitals in Puerto Rico

In the case of designated health services provided by a hospital located in Puerto Rico.

(2) Rural providers

In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if—

(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area;

(B) effective for the 18-month period beginning on December 8, 2003, the entity is not a specialty hospital (as defined in subsection (h)(7)); and

(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).

(3) Hospital ownership

In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if—

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

(B) effective for the 18-month period beginning on December 8, 2003, the hospital is not a specialty hospital (as defined in subsection (h)(7));

(C) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital); and

(D) the hospital meets the requirements described in subsection (i)(1) not later than 18 months after March 23, 2010.

(e) Exceptions relating to other compensation arrangements

The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B):

(1) Rental of office space; rental of equipment

(A) Office space

Payments made by a lessee to a lessor for the use of premises if—

(i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,

(ii) 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, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such 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 such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Equipment

Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if—

(i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

(ii) 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,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(C) Holdover lease arrangements

In the case of a holdover lease arrangement for the lease of office space or equipment, which immediately follows a lease arrangement described in subparagraph (A) for the use of such office space or subparagraph (B) for the use of such equipment and that expired after a term of at least 1 year, payments made by the lessee to the lessor pursuant to such holdover lease arrangement, if—

(i) the lease arrangement met the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment when the arrangement expired;

(ii) the holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment.

(2) Bona fide employment relationships

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(3) Personal service arrangements

(A) In general

Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if—

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,

(iv) the term of the arrangement is for at least 1 year,

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Physician incentive plan exception

(i) In general

In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.

(II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1395mm(i)(8)(A)(ii) of this title, the plan complies with any requirements the Secretary may impose pursuant to such section.

(III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

(ii) "Physician incentive plan" defined

For purposes of this subparagraph, the term ''physician incentive plan'' means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

(C) Holdover personal service arrangement

In the case of a holdover personal service arrangement, which immediately follows an arrangement described in subparagraph (A) that expired after a term of at least 1 year, remuneration from an entity pursuant to such holdover personal service arrangement, if—

(i) the personal service arrangement met the conditions of subparagraph (A) when the arrangement expired;

(ii) the holdover personal service arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A).

(4) Remuneration unrelated to the provision of designated health services

In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

(5) Physician recruitment

In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if—

(A) the physician is not required to refer patients to the hospital,

(B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and

(C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(6) Isolated transactions

In the case of an isolated financial transaction, such as a one-time sale of property or practice, if—

(A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and

(B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(7) Certain group practice arrangements with a hospital

(A)[2] In general

An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if—

(i) with respect to services provided to an inpatient of the hospital, the arrange-

[2] So in original. No subpar. (B) has been enacted.

ment is pursuant to the provision of inpatient hospital services under section 1395x(b)(3) of this title,

(ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,

(iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,

(iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,

(v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and

(vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(8) Payments by a physician for items and services

Payments made by a physician—

(A) to a laboratory in exchange for the provision of clinical laboratory services, or

(B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

(9) Physician wellness programs

A bona fide mental health or behavioral health improvement or maintenance program offered to a physician by an entity, if—

(A) such program—

(i) consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

(ii) is made available to a physician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician;

(iii) is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial changes to the operation of such program), that includes—

(I) a description of the content and duration of the program;

(II) a description of the evidence-based support for the design of the program;

(III) the estimated cost of the program;

(IV) the personnel (including the qualifications of such personnel) conducting the program; and

(V) the method by which such entity will evaluate the use and success of the program;

(iv) is offered by an entity described in subparagraph (B) with a formal medical staff to all physicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

(v) is offered to all such physicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician for such entity;

(vi) is evidence-based and conducted by a qualified health professional; and

(vii) meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

(B) such entity is—

(i) a hospital;

(ii) an ambulatory surgical center;

(iii) a community health center;

(iv) a rural emergency hospital;

(v) a rural health clinic;

(vi) a skilled nursing facility; or

(vii) a similar entity, as determined by the Secretary; and

(C) neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician to such entity or the amount or value of other business generated by such physician for the entity.

(f) Reporting requirements

Each entity providing covered items or services for which payment may be made under this subchapter shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including—

(1) the covered items and services provided by the entity, and

(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides[3] services for which payment may be made under this subchapter very infrequently.

[3] So in original. Probably should be ''provide''.

(g) Sanctions

(1) Denial of payment

No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1).

(2) Requiring refunds for certain claims

If a person collects any amounts that were billed in violation of subsection (a)(1), the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.

(3) Civil money penalty and exclusion for improper claims

Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than $15,000 for each such service. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(5) Failure to report information

Any person who is required, but fails, to meet a reporting requirement of subsection (f) is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(6) Advisory opinions

(A) In general

The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) Application of certain rules

The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) and take into account the regulations promulgated under subsection (b)(5) of section 1320a–7d of this title in the issuance of advisory opinions under this paragraph.

(C) Regulations

In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(D) Applicability

This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after August 5, 1997, and before the close of the period described in section 1320a–7d(b)(6) of this title.

(h) Definitions and special rules

For purposes of this section:

(1) Compensation arrangement; remuneration

(A) The term ''compensation arrangement'' means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

(B) The term ''remuneration'' includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(ii) The provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or

(II) order or communicate the results of tests or procedures for such entity.

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market

value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(D) WRITTEN REQUIREMENT CLARIFIED.—In the case of any requirement pursuant to this section for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.

(E) SPECIAL RULE FOR SIGNATURE REQUIREMENTS.—In the case of any requirement pursuant to this section for a compensation arrangement to be in writing and signed by the parties, such signature requirement shall be met if—

(i) not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the parties obtain the required signatures; and

(ii) the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) Employee

An individual is considered to be ''employed by'' or an ''employee'' of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

(3) Fair market value

The term ''fair market value'' means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(4) Group practice

(A) Definition of group practice

The term ''group practice'' means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

(ii) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

(iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

(iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

(v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and

(vi) which meets such other standards as the Secretary may impose by regulation.

(B) Special rules

(i) Profits and productivity bonuses

A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

(ii) Faculty practice plans

In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.

(5) Referral; referring physician

(A) Physicians' services

Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a ''referral'' by a ''referring physician''.

(B) Other items

Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a ''referral'' by a ''referring physician''.

(C) Clarification respecting certain services integral to a consultation by certain specialists

A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a ''referral'' by a ''referring physician''.

(6) Designated health services

The term ''designated health services'' means any of the following items or services:

(A) Clinical laboratory services.

(B) Physical therapy services.

(C) Occupational therapy services.

(D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.

(E) Radiation therapy services and supplies.

(F) Durable medical equipment and supplies.

(G) Parenteral and enteral nutrients, equipment, and supplies.

(H) Prosthetics, orthotics, and prosthetic devices and supplies.

(I) Home health services.

(J) Outpatient prescription drugs.

(K) Inpatient and outpatient hospital services.

(L) Outpatient speech-language pathology services.

(7) Specialty hospital

(A) In general

For purposes of this section, except as provided in subparagraph (B), the term ''specialty hospital'' means a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that is primarily or exclusively engaged in the care and treatment of one of the following categories:

(i) Patients with a cardiac condition.

(ii) Patients with an orthopedic condition.

(iii) Patients receiving a surgical procedure.

(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section.

(B) Exception

For purposes of this section, the term ''specialty hospital'' does not include any hospital—

(i) determined by the Secretary—

(I) to be in operation before November 18, 2003; or

(II) under development as of such date;

(ii) for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) for which the type of categories described in subparagraph (A) at any time on or after such date is no different than the type of such categories as of such date;

(iv) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) that meets such other requirements as the Secretary may specify.

(i) Requirements for hospitals to qualify for rural provider and hospital exception to ownership or investment prohibition

(1) Requirements described

For purposes of subsection (d)(3)(D), the requirements described in this paragraph for a hospital are as follows:

(A) Provider agreement

The hospital had—

(i) physician ownership or investment on December 31, 2010; and

(ii) a provider agreement under section 1395cc of this title in effect on such date.

(B) Limitation on expansion of facility capacity

Except as provided in paragraph (3), the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010, is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.

(C) Preventing conflicts of interest

(i) The hospital submits to the Secretary an annual report containing a detailed description of—

(I) the identity of each physician owner or investor and any other owners or investors of the hospital; and

(II) the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital has procedures in place to require that any referring physician owner or investor discloses to the patient being referred, by a time that permits the patient to make a meaningful decision regarding the receipt of care, as determined by the Secretary—

(I) the ownership or investment interest, as applicable, of such referring physician in the hospital; and

(II) if applicable, any such ownership or investment interest of the treating physician.

(iii) The hospital does 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.

(iv) The hospital discloses the fact that the hospital is partially owned or invested in by physicians—

(I) on any public website for the hospital; and

(II) in any public advertising for the hospital.

(D) Ensuring bona fide investment

(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.

(E) Patient safety

(i) Insofar as the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to such patient, before admitting the patient—

(I) the hospital discloses such fact to a patient; and

(II) following such disclosure, the hospital receives from the patient a signed acknowledgment that the patient understands such fact.

(ii) The hospital has the capacity to—

(I) provide assessment and initial treatment for patients; and

(II) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.

(F) Limitation on application to certain converted facilities

The hospital was not converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

(2) Publication of information reported

The Secretary shall publish, and update on an annual basis, the information submitted by hospitals under paragraph (1)(C)(i) on the public Internet website of the Centers for Medicare & Medicaid Services.

(3) Exception to prohibition on expansion of facility capacity

(A) Process

(i) Establishment

The Secretary shall establish and implement a process under which a hospital that is an applicable hospital (as defined in subparagraph (E)) or is a high Medicaid facility described in subparagraph (F) may apply for an exception from the requirement under paragraph (1)(B).

(ii) Opportunity for community input

The process under clause (i) shall provide individuals and entities in the community in which the applicable hospital applying for an exception is located with the opportunity to provide input with respect to the application.

(iii) Timing for implementation

The Secretary shall implement the process under clause (i) on February 1, 2012.

(iv) Regulations

Not later than January 1, 2012, the Secretary shall promulgate regulations to carry out the process under clause (i).

(B) Frequency

The process described in subparagraph (A) shall permit an applicable hospital to apply for an exception up to once every 2 years.

(C) Permitted increase

(i) In general

Subject to clause (ii) and subparagraph (D), an applicable hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed above the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital (or, if the applicable hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after the application of the most recent increase under such an exception).

(ii) 100 percent increase limitation

The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, proce-

dure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital.

(iii) Baseline number of operating rooms, procedure rooms, and beds

In this paragraph, the term ''baseline number of operating rooms, procedure rooms, and beds'' means the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement).

(D) Increase limited to facilities on the main campus of the hospital

Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

(E) Applicable hospital

In this paragraph, the term ''applicable hospital'' means a hospital—

(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application under subparagraph (A)) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;

(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under subchapter XIX is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

(iv) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and

(v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

(F) High Medicaid facility described

A high Medicaid facility described in this subparagraph is a hospital that—

(i) is not the sole hospital in a county;

(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under subchapter XIX that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and

(iii) meets the conditions described in subparagraph (E)(iii).

(G) Procedure rooms

In this subsection, the term ''procedure rooms'' includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

(H) Publication of final decisions

Not later than 60 days after receiving a complete application under this paragraph, the Secretary shall publish in the Federal Register the final decision with respect to such application.

(I) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the process under this paragraph (including the establishment of such process).

(4) Collection of ownership and investment information

For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (1), the Secretary shall collect physician ownership and investment information for each hospital.

(5) Physician owner or investor defined

For purposes of this subsection, the term ''physician owner or investor'' means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

(6) Clarification

Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital's provider agreement if not in compliance with regulations implementing section 1395cc of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1877, as added Pub. L. 101–239, title VI, §6204(a), Dec. 19, 1989, 103 Stat. 2236; amended Pub. L. 101–508, title IV, §4207(e)(1)–(3), (k)(2), formerly §4027(e)(1)–(3), (k)(2), Nov. 5, 1990, 104 Stat. 1388–121, 1388–122, 1388–124, renumbered Pub. L. 103–432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 103–66, title XIII, §13562(a), Aug. 10, 1993, 107 Stat. 596; Pub. L. 103–432, title I, §152(a), (b), Oct. 31, 1994, 108 Stat. 4436; Pub. L. 105–33, title IV, §4314, Aug. 5, 1997, 111 Stat. 389; Pub. L. 106–113, div. B, §1000(a)(6) [title V, §524(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–387; Pub. L. 108–173, title I, §101(e)(8)(B), title V, §507(a), Dec. 8, 2003, 117 Stat. 2152, 2295; Pub. L. 110–275, title I, §143(b)(9), July 15, 2008, 122 Stat. 2543; Pub. L. 111–148, title VI, §§6001(a), 6003(a), title X, §10601(a), Mar. 23, 2010, 124 Stat. 684, 697, 1005; Pub. L. 111–152, title I, §1106, Mar. 30, 2010, 124 Stat. 1049; Pub. L. 115–123, div. E, title IV, §50404, Feb. 9, 2018, 132 Stat. 218; Pub. L. 117–328, div. FF, title IV, §4126(a), Dec. 29, 2022, 136 Stat. 5913.)

Editorial Notes

REFERENCES IN TEXT

Section 222(a) of the Social Security Amendments of 1972, referred to in subsec. (b)(3)(C), is section 222(a) of Pub. L. 92–603, Oct. 30, 1972, 86 Stat. 1329, which is set out as a note under section 1395b–1 of this title.

Section 300e–9(d) of this title, referred to in subsec. (b)(3)(D), was redesignated section 300e–9(c) of this title by Pub. L. 100–517, § 7(b), Oct. 24, 1988, 102 Stat. 2580.

Section 1395w–104(e)(6) of this title, referred to in subsec. (b)(5), was in the original ''section 1860D–3(e)(6)'', and was translated as reading ''section 1860D–4(e)(6)'', meaning section 1860D–4(e)(6) of the Social Security Act, to reflect the probable intent of Congress, because section 1860D–3, which is classified to section 1395w–103 of this title, does not contain a subsec. (e), and section 1860D–4(e)(6) relates to electronic prescription program regulations.

The Internal Revenue Code, referred to in subsecs. (c)(2) and (h)(2), is classified generally to Title 26, Internal Revenue Code.

PRIOR PROVISIONS

A prior section 1395nn, act Aug. 14, 1935, ch. 531, title XVIII, § 1877, as added and amended Oct. 30, 1972, Pub. L. 92–603, title II, §§ 242(b), 278(b)(8), 86 Stat. 1419, 1454; Oct. 25, 1977, Pub. L. 95–142, § 4(a), 91 Stat. 1179; Dec. 5, 1980, Pub. L. 96–499, title IX, § 917, 94 Stat. 2625; July 18, 1984, Pub. L. 98–369, div. B, title III, § 2306(f)(2), 98 Stat. 1073; Oct. 21, 1986, Pub. L. 99–509, title IX, § 9321(a)(1), 100 Stat. 2016; Aug. 18, 1987, Pub. L. 100–93, § 4(c), 101 Stat. 689, enumerated offenses relating to the Medicare program and penalties for such offenses, prior to repeal by Pub. L. 100–93, §§ 4(e), 15(a), Aug. 18, 1987, 101 Stat. 689, 698, effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period.

AMENDMENTS

2022—Subsec. (e)(9). Pub. L. 117–328 added par. (9).

2018—Subsec. (e)(1)(C). Pub. L. 115–123, § 50404(b)(1), added subpar. (C).

Subsec. (e)(3)(C). Pub. L. 115–123, § 50404(b)(2), added subpar. (C).

Subsec. (h)(1)(D). Pub. L. 115–123, § 50404(a)(1), added subpar. (D).

Subsec. (h)(1)(E). Pub. L. 115–123, § 50404(a)(2), added subpar. (E).

2010—Subsec. (b)(2). Pub. L. 111–148, § 6003(a), inserted at end of concluding provisions ''Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1395x(d) of this title) who furnish such services in the area in which such individual resides.''

Subsec. (d)(2)(C). Pub. L. 111–148, § 6001(a)(1), added subpar. (C).

Subsec. (d)(3)(D). Pub. L. 111–148, § 6001(a)(2), added subpar. (D).

Subsec. (i). Pub. L. 111–148, § 6001(a)(3), added subsec. (i).

Subsec. (i)(1)(A)(i). Pub. L. 111–152, § 1106(1), substituted ''December 31, 2010'' for ''August 1, 2010''.

Pub. L. 111–148, § 10601(a)(1), substituted ''August 1, 2010'' for ''February 1, 2010''.

Subsec. (i)(3)(A)(i). Pub. L. 111–152, § 1106(2)(A), substituted ''a hospital that is an applicable hospital (as defined in subparagraph (E)) or is a high Medicaid facility described in subparagraph (F)'' for ''an applicable hospital (as defined in subparagraph (E))''.

Subsec. (i)(3)(A)(iii). Pub. L. 111–148, § 10601(a)(2)(A), substituted ''February 1, 2012'' for ''August 1, 2011''.

Subsec. (i)(3)(A)(iv). Pub. L. 111–148, § 10601(a)(2)(B), substituted ''January 1, 2012'' for ''July 1, 2011''.

Subsec. (i)(3)(C)(iii). Pub. L. 111–152, § 1106(2)(B), inserted ''(or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement)'' after ''March 23, 2010''.

Subsec. (i)(3)(F) to (I). Pub. L. 111–152, § 1106(2)(C), (D), added subpar. (F) and redesignated former subpars. (F) to (H) as (G) to (I), respectively.

2008—Subsec. (h)(6)(L). Pub. L. 110–275 added subpar. (L).

2003—Subsec. (b)(5). Pub. L. 108–173, § 101(e)(8)(B), added par. (5).

Subsec. (d)(2). Pub. L. 108–173, § 507(a)(2), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: ''In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area.''

Subsec. (d)(3)(B), (C). Pub. L. 108–173, § 507(a)(1)(A), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (h)(7). Pub. L. 108–173, § 507(a)(1)(B), added par. (7).

1999—Subsec. (b)(3)(C). Pub. L. 106–113, § 1000(a)(6) [title V, § 524(a)(1)], struck out ''or'' at the end.

Subsec. (b)(3)(D). Pub. L. 106–113, § 1000(a)(6) [title V, § 524(a)(2)], substituted '', or'' for period at end.

Subsec. (b)(3)(E). Pub. L. 106–113, § 1000(a)(6) [title V, § 524(a)(3)], which directed addition of provisions at end of par. (3) but which separated directory language from language to be added because of the apparent placement out of sequence of pars. (2) and (3) of § 524(a), was executed by adding subpar. (E) at end of par. (3) to reflect the probable intent of Congress.

1997—Subsec. (g)(6). Pub. L. 105–33 added par. (6).

1994—Subsec. (f). Pub. L. 103–432, § 152(a)(1), (4), (5), in introductory provisions, substituted ''ownership, investment, and compensation arrangements'' for ''ownership arrangements'', and in closing provisions, substituted ''designated health services'' for ''covered items and services'' and struck out ''Such information shall first be provided not later than October 1, 1991.'' after ''shall specify.'' and ''The Secretary may waive the requirements of this subsection (and the requirements of chapter 35 of title 44 with respect to information provided under this subsection) with respect to reporting by entities in a State (except for entities providing designated health services) so long as such reporting occurs in at least 10 States, and the Secretary may waive such requirements with respect to the providers in a State required to report so long as such requirements are not waived with respect to parenteral and enteral suppliers, end stage renal disease facilities, suppliers of ambulance services, hospitals, entities providing physical therapy services, and entities providing diagnostic imaging services of any type.'' at end.

Subsec. (f)(2). Pub. L. 103–432, § 152(a)(2), (3), inserted '', or with a compensation arrangement (as described in subsection (a)(2)(B)),'' after ''investment interest (as described in subsection (a)(2)(A))'' and ''interest or who have such a compensation relationship with the entity'' before period at end.

Subsec. (h)(6). Pub. L. 103–432, § 152(b), in subpar. (D), substituted ''services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services'' for ''or other diagnostic services'', and in subpars. (E), (F), and (H), inserted ''and supplies'' before period at end.

1993—Subsecs. (a) to (e). Pub. L. 103–66, § 13562(a)(1), amended headings and text of subsecs. (a) to (e) generally, substituting present provisions for provisions which related to: prohibition of certain referrals in subsec. (a), general exceptions to both ownership and com-

pensation arrangement prohibitions in subsec. (b), general exception related only to ownership or investment prohibition for ownership in publicly-traded securities in subsec. (c), additional exceptions related only to ownership or investment prohibition in subsec. (d), and exceptions relating to other compensation arrangements in subsec. (e).

Subsec. (f). Pub. L. 103–66, §13562(a)(3), substituted ''designated health services'' for ''clinical laboratory services'' in concluding provisions.

Subsec. (g)(1). Pub. L. 103–66, §13562(a)(4), substituted ''designated health service'' for ''clinical laboratory service''.

Subsec. (h). Pub. L. 103–66, §13562(a)(2), amended heading and text of subsec. (h) generally, substituting pars. (1) to (6) for former pars. (1) to (7) which defined ''compensation arrangement'', ''remuneration'', ''employee'', ''fair market value'', ''group practice'', ''investor'', ''interested investor'', ''disinterested investor'', ''referral'', and ''referring physician''.

1990—Subsec. (b)(4), (5). Pub. L. 101–508, §4207(e)(2), formerly §4027(e)(2), as renumbered by Pub. L. 103–432, §160(d)(4), added par. (4) and redesignated former par. (4) as (5).

Subsec. (f). Pub. L. 101–508, §4207(e)(3)(B), (C), formerly §4027(e)(3)(B), (C), as renumbered by Pub. L. 103–432, §160(d)(4), substituted ''October 1, 1991'' for ''1 year after December 19, 1989'' in third sentence and inserted at end ''The requirement of this subsection shall not apply to covered items and services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this subchapter very infrequently. The Secretary may waive the requirements of this subsection (and the requirements of chapter 35 of title 44 with respect to information provided under this subsection) with respect to reporting by entities in a State (except for entities providing clinical laboratory services) so long as such reporting occurs in at least 10 States, and the Secretary may waive such requirements with respect to the providers in a State required to report so long as such requirements are not waived with respect to parenteral and enteral suppliers, end stage renal disease facilities, suppliers of ambulance services, hospitals, entities providing physical therapy services, and entities providing diagnostic imaging services of any type.''

Subsec. (f)(2). Pub. L. 101–508, §4207(e)(3)(A), formerly §4027(e)(3)(A), as renumbered by Pub. L. 103–432, §160(d)(4), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''the names and all of the medicare provider numbers of the physicians who are interested investors or who are immediate relatives of interested investors.''

Subsec. (g)(5). Pub. L. 101–508, §4207(k)(2), formerly §4027(k)(2), as renumbered by Pub. L. 103–432, §160(d)(4), inserted at end ''The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.''

Subsec. (h)(6). Pub. L. 101–508, §4207(e)(1)(C), formerly §4027(e)(1)(C), as renumbered by Pub. L. 103–432, §160(d)(4), added par. (6). Former par. (6) redesignated (7).

Pub. L. 101–508, §4207(e)(1)(A), (B), formerly §4027(e)(1)(A), (B), as renumbered by Pub. L. 103–432, §160(d)(4), substituted ''in the case of an item or service for which payment may be made under part B of this subchapter, the request by a physician for the item or service,'' for ''in the case of a clinical laboratory service which under law is required to be provided by (or under the supervision of) a physician, the request by a physician for the service,'' in subpar. (A) and struck out ''in the case of another clinical laboratory service,'' after ''subparagraph (C),'' in subpar. (B).

Subsec. (h)(7). Pub. L. 101–508, §4207(e)(1)(C), formerly §4027(e)(1)(C), as renumbered by Pub. L. 103–432, §160(d)(4), redesignated par. (6) as (7).

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title VI, §6003(b), Mar. 23, 2010, 124 Stat. 697, provided that: ''The amendment made by this section [amending this section] shall apply to services furnished on or after January 1, 2010.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §524(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–388, provided that: ''The amendment made by this section [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [Nov. 29, 1999].''

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, §152(d)(1), Oct. 31, 1994, 108 Stat. 4437, provided that: ''The amendments made by subsections (a) and (b) [amending this section] shall apply to referrals made on or after January 1, 1995.''

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, §13562(b), Aug. 10, 1993, 107 Stat. 604, as amended by Pub. L. 103–432, title I, §152(c), Oct. 31, 1994, 108 Stat. 4437, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [amending this section] shall apply to referrals—

''(A) made on or after January 1, 1992, in the case of clinical laboratory services, and

''(B) made after December 31, 1994, in the case of other designated health services.

''(2) EXCEPTIONS.—With respect to referrals made for clinical laboratory services on or before December 31, 1994—

''(A) the second sentence of subsection (a)(2), and subsections (b)(2)(B) and (d)(2), of section 1877 of the Social Security Act [42 U.S.C. 1395nn(a)(2), (b)(2)(B), (d)(2)] (as in effect on the day before the date of the enactment of this Act [Aug. 10, 1993]) shall apply instead of the corresponding provisions in section 1877 (as amended by this Act);

''(B) section 1877(b)(4) of the Social Security Act [42 U.S.C. 1395nn(b)(4)] (as in effect on the day before the date of the enactment of this Act) shall apply;

''(C) the requirements of section 1877(c)(2) of the Social Security Act [42 U.S.C. 1395nn(c)(2)] (as amended by this Act) shall not apply to any securities of a corporation that meets the requirements of section 1877(c)(2) of the Social Security Act (as in effect on the day before the date of the enactment of this Act);

''(D) section 1877(e)(3) of the Social Security Act [42 U.S.C. 1395nn(e)(3)] (as amended by this Act) shall apply, except that it shall not apply to any arrangement that meets the requirements of subsection (e)(2) or subsection (e)(3) of section 1877 of the Social Security Act (as in effect on the day before the date of the enactment of this Act);

''(E) the requirements of clauses (iv) and (v) of section 1877(h)(4)(A), and of clause (i) of section 1877(h)(4)(B), of the Social Security Act [42 U.S.C. 1395nn(h)(4)(A)(iv), (v), (B)(i)] (as amended by this Act) shall not apply; and

''(F) section 1877(h)(4)(B) of the Social Security Act [42 U.S.C. 1395nn(h)(4)(B)] (as in effect on the day be-

fore the date of the enactment of this Act) shall apply instead of section 1877(h)(4)(A)(ii) of such Act (as amended by this Act).''

[Pub. L. 103–432, title I, § 152(d)(2), Oct. 31, 1994, 108 Stat. 4437, provided that: ''The amendment made by subsection (c) [amending section 13562(b) of Pub. L. 103–66, set out above] shall apply as if included in the enactment of OBRA–1993 [Pub. L. 103–66].'']

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, § 4207(e)(5), formerly § 4027(e)(5), Nov. 5, 1990, 104 Stat. 1388–123, as renumbered by Pub. L. 103–432, title I, § 160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that: ''The amendments made by this subsection [amending this section and provisions set out below] shall be effective as if included in the enactment of section 6204 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].''

EFFECTIVE DATE

Pub. L. 101–239, title VI, § 6204(c), Dec. 19, 1989, 103 Stat. 2242, provided that:

''(1) Except as provided in paragraph (2), the amendments made by this section [enacting this section and amending section 1395*l* of this title] shall become effective with respect to referrals made on or after January 1, 1992.

''(2) The reporting requirement of section 1877(f) of the Social Security Act [42 U.S.C. 1395nn(f)] shall take effect on October 1, 1990.''

DEADLINE FOR CERTAIN REGULATIONS

Pub. L. 101–239, title VI, § 6204(d), Dec. 19, 1989, 103 Stat. 2242, as amended by Pub. L. 101–508, title IV, § 4207(e)(4)(B), formerly § 4027(e)(4)(B), Nov. 5, 1990, 104 Stat. 1388–122, renumbered Pub. L. 103–432, title I, § 160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that: ''The Secretary of Health and Human Services shall publish final regulations to carry out section 1877 of the Social Security Act [42 U.S.C. 1395nn] by not later than October 1, 1991.''

ENFORCEMENT

Pub. L. 111–148, title VI, § 6001(b), Mar. 23, 2010, 124 Stat. 689, as amended by Pub. L. 111–148, title X, § 10601(b), Mar. 23, 2010, 124 Stat. 1005, provided that:

''(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act [42 U.S.C. 1395nn(i)(1)], as added by subsection (a)(3), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

''(2) AUDITS.—Beginning not later than May 1, 2012, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1).''

MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL

Pub. L. 111–148, title VI, § 6409, Mar. 23, 2010, 124 Stat. 772, provided that:

''(a) DEVELOPMENT OF SELF-REFERRAL DISCLOSURE PROTOCOL.—

''(1) IN GENERAL.—The Secretary of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, shall establish, not later than 6 months after the date of the enactment of this Act [Mar. 23, 2010], a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) pursuant to a self-referral disclosure protocol (in this section referred to as an 'SRDP'). The SRDP shall include direction to health care providers of services and suppliers on—

''(A) a specific person, official, or office to whom such disclosures shall be made; and

''(B) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.

''(2) PUBLICATION ON INTERNET WEBSITE OF SRDP INFORMATION.—The Secretary of Health and Human Services shall post information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose actual or potential violations pursuant to an SRDP.

''(3) RELATION TO ADVISORY OPINIONS.—The SRDP shall be separate from the advisory opinion process set forth in regulations implementing section 1877(g) of the Social Security Act [42 U.S.C. 1395nn(g)].

''(b) REDUCTION IN AMOUNTS OWED.—The Secretary of Health and Human Services is authorized to reduce the amount due and owing for all violations under section 1877 of the Social Security Act [42 U.S.C. 1395nn] to an amount less than that specified in subsection (g) of such section. In establishing such amount for a violation, the Secretary may consider the following factors:

''(1) The nature and extent of the improper or illegal practice.

''(2) The timeliness of such self-disclosure.

''(3) The cooperation in providing additional information related to the disclosure.

''(4) Such other factors as the Secretary considers appropriate.

''(c) REPORT.—Not later than 18 months after the date on which the SRDP protocol is established under subsection (a)(1), the Secretary shall submit to Congress a report on the implementation of this section. Such report shall include—

''(1) the number of health care providers of services and suppliers making disclosures pursuant to the SRDP;

''(2) the amounts collected pursuant to the SRDP;

''(3) the types of violations reported under the SRDP; and

''(4) such other information as may be necessary to evaluate the impact of this section.''

APPLICATION OF EXCEPTION FOR HOSPITALS UNDER DEVELOPMENT

Pub. L. 108–173, title V, § 507(b), Dec. 8, 2003, 117 Stat. 2296, provided that: ''For purposes of section 1877(h)(7)(B)(i)(II) of the Social Security Act [42 U.S.C. 1395nn(h)(7)(B)(i)(II)], as added by subsection (a)(1)(B), in determining whether a hospital is under development as of November 18, 2003, the Secretary [of Health and Human Services] shall consider—

''(1) whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received; and

''(2) any other evidence the Secretary determines would indicate whether a hospital is under development as of such date.''

STUDIES

Pub. L. 108–173, title V, § 507(c), Dec. 8, 2003, 117 Stat. 2296, provided that:

''(1) MEDPAC STUDY.—The Medicare Payment Advisory Commission, in consultation with the Comptroller General of the United States, shall conduct a study to determine—

''(A) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within specific diagnosis-related groups;

''(B) the extent to which specialty hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection;

''(C) the financial impact of physician-owned specialty hospitals on local full-service community hospitals;

''(D) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and

''(E) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

''(2) HHS STUDY.—The Secretary [of Health and Human Services] shall conduct a study of a representative sample of specialty hospitals—

''(A) to determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest;

''(B) to determine the referral patterns of physician owners, including the percentage of patients they referred to physician-owned specialty hospitals and the percentage of patients they referred to local full-service community hospitals for the same condition;

''(C) to compare the quality of care furnished in physician-owned specialty hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and

''(D) to assess the differences in uncompensated care, as defined by the Secretary, between the specialty hospital and local full-service community hospitals, and the relative value of any tax exemption available to such hospitals.

''(3) REPORTS.—Not later than 15 months after the date of the enactment of this Act [Dec. 8, 2003], the Commission and the Secretary, respectively, shall each submit to Congress a report on the studies conducted under paragraphs (1) and (2), respectively, and shall include any recommendations for legislation or administrative changes.''

GAO STUDY OF OWNERSHIP BY REFERRING PHYSICIANS

Pub. L. 101–239, title VI, §6204(e), Dec. 19, 1989, 103 Stat. 2242, directed Comptroller General to conduct a study of ownership of hospitals and other providers of medicare services by referring physicians and, by not later than Feb. 1, 1991, report to Congress on results of such study, prior to repeal by Pub. L. 104–316, title I, §122(h)(1), Oct. 19, 1996, 110 Stat. 3837.

STATISTICAL SUMMARY OF COMPARATIVE UTILIZATION

Pub. L. 101–239, title VI, §6204(f), Dec. 19, 1989, 103 Stat. 2243, as amended by Pub. L. 101–508, title IV, §4207(e)(4)(A), formerly §4027(e)(4)(A), Nov. 5, 1990, 104 Stat. 1388–122, renumbered Pub. L. 103–432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 104–316, title I, §122(h)(2), Oct. 19, 1996, 110 Stat. 3837, directed Secretary of Health and Human Services, not later than June 30, 1992, to submit to Congress a statistical profile comparing utilization of items and services by medicare beneficiaries served by entities in which the referring physician has a direct or indirect financial interest and by medicare beneficiaries served by other entities, for the States and entities specified in subsec. (f) of this section (other than entities providing clinical laboratory services).

§ 1395*oo*. Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the ''Board'') which shall be established by the Secretary in accordance with subsection (h) and (except as provided in subsection (g)(2)) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if—

(1) such provider—

(A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1395ww of this title,

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1) (B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(b) Appeals by groups

The provisions of subsection (a) shall apply to any group of providers of services if each provider of services in such group would, upon the filing of an appeal (but without regard to the $10,000 limitation), be entitled to such a hearing, but only if the matters in controversy involve a common question of fact or interpretation of law or regulations and the amount in controversy is, in the aggregate, $50,000 or more.

(c) Right to counsel; rules of evidence

At such hearing, the provider of services shall have the right to be represented by counsel, to introduce evidence, and to examine and cross-examine witnesses. Evidence may be received at any such hearing even though inadmissible under rules of evidence applicable to court procedure.

(d) Decisions of Board

A decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole. The Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination.