§ 1395nm. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b) of this section, 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) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) 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 the entity.

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

Subsection (a)(1) of this section 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) of this section) 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

...
(1) (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—
(a) for the provision of some or all of the group’s clinical laboratory services, or
(b) 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 1395f(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 330e–9(d)1 of this title) to an individual enrolled with the organization, or
(E) that is a Medicare+Choice organization under part C of this subchapter 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.

(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) of this section:
(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) traded 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
(B) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and
(C) 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) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:
(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) of this section); and

1See References in Text note below.
(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) of this section);

(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) of this section:

(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, 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.

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).

(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.

(3) Personal service arrangements

(A) In general

Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a non-profit 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 lease provides for a term of rental or lease of at least 1 year, and

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

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

(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 arrangement 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

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

(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 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 $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.

(5) Failure to report information

Any person who is required, but fails, to meet a reporting requirement of subsection (f) of this section 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) of this section 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.

So in original. Probably should be “provide”.
(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, or

(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.

(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 section 3121(d)(2) of the Internal Revenue Code of 1986).

(3) Fair market value

The term “fair market value” means the value in arm’s 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.
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(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 of this subchapter, 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 (F)) 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 sub-
paragraph (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, procedure 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 for any other hospital located in the county in which the hospital is located; and

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

**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 1395oo 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 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.

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, as added by act aug. 14, 1935, ch. 531, title xviii, § 1877, as added and amended oct. 30, 1972, pub. l. 92–603, title ii, § 342(b), 78 Stat. 1419, 1544; oct. 25, 1977, pub. l. 95–144, 91 stat. 1179; dec. 5, 1980, pub. l. 96–499, title ix, § 917, 94 stat. 2625; july 18, 1984, pub. l. 98–266, div. b, title iii, § 2306(c)(2), 98 stat. 1073; oct. 21, 1986, pub. l. 99–509, title ix, § 9522(a)(1), 100 stat. 1689, 1073; aug. 18, 1987, pub. l. 100–30, 91 stat. 689, 1006; effective at end of fourteen-day period beginning aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period.

amendments

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 (b)(3)(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)(ii) and provide such individual with a written list of suppliers (as defined in section 1395w–2 of this title) who furnish such services in the area in which such individual resides.”


subsec. (i)(3)(a)(i). pub. l. 111–152, § 1106c(2)(a), substituted “$1395nm” for “$1395nn”. 
and in subparts. (E), (F), and (H), inserted “and supplies” before period at end.

1985—Subsec. (a) to (e). Pub. L. 99–66, § 13562(a)(1), amended headings and text of subsec. (a) to (e) generally, substituting new provisions for provisions which related to: prohibition of certain referrals in subsec. (a), general exceptions to both ownership and compensation 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. (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.”


Subsec. (f). Pub. L. 101–508, § 4207(e)(3)(B), formerly § 4027(e)(3)(B), 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). Pub. L. 101–508, § 4207(k)(2), formerly § 4027(e)(3)(A), 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 (h)) 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. (l). 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” for “in the case of a clinical laboratory 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).”


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


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 1389k 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. 1586, 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


"(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(b)(2), (b)(2)(B), and (d)(2)] (as in effect on the day before the date of the enactment of this Act [Aug. 10, 1990]) shall apply in lieu 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 date of the enactment of this Act) shall apply in lieu of the corresponding provisions in section 1877 (as amended by this Act);

"(C) the requirements of section 1877(c)(2) of the Social Security Act [42 U.S.C. 1395nn(c)(2)] (as in effect on the date of the enactment of this Act) shall apply; and

"(D) section 1877(c)(3) of the Social Security Act [42 U.S.C. 1395nn(c)(3)] (as amended by this Act) shall apply, except that it shall not apply to any arrangement that meets the requirements of section 1877(c)(2) of the Social Security Act (as in effect on the date of the enactment of this Act) (as amended by this Act).”
“(E) the requirements of clauses (iv) and (v) of section 1877(b)(4)(A), and of clause (i) of section 1877(b)(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(b)(4)(B) of the Social Security Act (42 U.S.C. 1395nn(h)(4)(B)) (as in effect on the day before the date of the enactment of this Act) shall apply instead of section 1877(b)(4)(A)(ii) of such Act (as amended by this Act).”


**Effective Date of 1990 Amendment**


**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 1382 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**


**Enforcement**

Pub. L. 111–148, title VI, §6001(b), Mar. 23, 2010, 124 Stat. 689, as amended by Pub. L. 111–148, title X, §1053(a), Mar. 23, 2010, 124 Stat. 1065, provided that: “(1) ENSSURING 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(h)(1)], as added by subsection (a)(1)(A), 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.”

**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 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**


“(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**


“(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; and

“(B) the extent to which specialty hospitals, relative to local full-service community hospitals, treat patients covered under Medicare.”
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 for similar conditions and patient satisfaction with such care; and

"(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


Statistical Summary of Comparative Utilization


§ 1395oo. 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) of this section and (except as provided in subsection (g)(2) of this section) 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) of this section 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 and 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