Please Provide Responses to the Fields Below Electronically to be Accepted

Medicare Red Tape Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: 8/25/17
Name of Submitting Organization: UnityPoint Health
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Statutory ☑ **Regulatory** ☐

Please describe the submitting organization's interaction with the Medicare program:

UnityPoint Health is an integrated health system (more than 280 physician clinics, 33 hospitals, and home care services) in Iowa, western Illinois and southern Wisconsin. UnityPoint Accountable Care, our affiliated ACO, is the largest Next Generation ACO. In addition, we participate in the Bundled Payment for Care Improvement Model 2 and the Medicare Care Choices Model.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as "Appendix [insert label]"

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description: Stark Law and Anti-Kickback revisions

Summary:

By intent and design, Stark physician self-referral law ("Stark") separates entities that are furnishing designated health services from physicians who are providing care to Medicare beneficiaries. Health care professionals face the challenge of trying to achieve system-wide clinical and financial integration to lower costs and improve health access and outcomes, while simultaneously complying with current Stark, Anti-Kickback, and other laws and regulations that create care silos.

Related Statute/Regulation:

Sec. 1877. [42 U.S.C. 1395]; Section 1128B(b)(3) of the Social Security Act; Sec. 1115A. [42 U.S.C. 1315a]; Section 1833(z) of the Social Security Act

Proposed Solution:

Creation of an exemption in Stark and associated laws for value-based payments. Suggested language is provided in Attachment A.

Sec. 1877. [42 U.S.C. 1395] (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 title, and

(B) the entity may not present or cause to be presented a claim under this title 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.
Any ownership or investment interest in an entity or compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and an entity is presumed to meet each of the elements of the applicable exception(s) to subsection (c), (d), or (e) absent clear and convincing [a preponderance of] evidence to the contrary.

(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 1861(q)) 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 significant 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 significant risk of 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 1861(d)) 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 1876 to an individual enrolled with the organization,

(B) described in section 1833(a)(1)(A) to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 402(a) of the Social Security Amendments of 1967 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 1310(d) of the Public Health Service Act) 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 1851(a)(2)(A) 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 significant risk of program or patient abuse, such relationships shall not trigger the self-referral prohibition under § 1877(a)(1).

(5) Electronic prescribing.—An exception established by regulation under section 1860D-3(e)(6).

(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 1886(d)(2)(D)) 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 the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 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 the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 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 the date of the enactment of this subparagraph.

(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 is commercially reasonable, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against significant risk of 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 is commercially reasonable, and

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

(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 is commercially reasonable, and

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

Services provided to an entity under subsection (ii) means any service that furthers the purposes of the entity, including any charitable purpose.

(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 1876(i)(8)(A)(ii), 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 significant risk of 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 significant risk of program or patient abuse.

(7) Certain group practice arrangements with a hospital.—

(A) 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 1861(b)(3),

(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 that is commercially reasonable, and

(vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against significant risk of 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 any other items or services, including, but not limited to, space, equipment or other services , if the items or services are furnished at a price that is consistent with fair market value.

(9) Fair market value remuneration.

In the case of remuneration resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians for the provision of items or services by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The compensation must be consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on -

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or

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

(2) The arrangement is commercially reasonable

(10) Coordinated network arrangements. In the case of any arrangement within a Network as defined in this section, whereby remuneration is paid directly or indirectly between, among, or on behalf of one or more entities, and –

(A) the arrangement shall meet the following conditions–

(i) the terms of each authorized arrangement is in writing, including any items and services to be provided;

(ii) the compensation to be paid or recouped under each authorized arrangement is set in advance; and

(iii) the compensation must be determined by either the governing board of the Network or any entity within the Network to meet Network goals

(C) Definitions – For purposes of this exception, the following terms are defined as follows:

(i) “Network” is defined as either an arrangement or an entity that is established between or organized and operated by two or more entities, including providers, suppliers, or individuals to achieve one or more network goals through network risk-sharing arrangements.

(ii) “Network goals” are defined as any of the following:

(I) promoting accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services reimbursed for by different payors;

(II) managing and coordinating care for patients through arrangements approved by the network and administered, furnished, or arranged for through providers in the network; or

(III) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including but not limited to Medicare beneficiaries, where efficient service delivery includes, among other things, appropriate reduction of costs or growth in expenditures for health care items and services provided to patients, consistent with quality of care, physician medical judgment, and patient freedom of choice.

(iii) "Network risk-sharing arrangement" shall refer to one or more of the following mechanisms, which may be used in combination by a Network to advance Network goals –

(I) an agreement to accept capitation payment for each patient.

(II) an agreement to accept as payment a predetermined percentage of the network's revenue under the network risk-sharing arrangement.

(III) a network's use of significant financial incentives for entities in the network, to achieve Network goals.

(vi) "Significant financial incentives" include the following:

(I) arrangements where downstream providers and suppliers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(a) To cover losses of the network.
(b) To cover losses of other downstream providers and suppliers in the network.
(c) To be returned to other downstream providers and suppliers in the network if the network meets its utilization management or cost containment goals for the specified time period.
(d) To be distributed among downstream providers and suppliers if the network meets its utilization management or cost-containment goals for the specified time period.

(II) arrangements where downstream providers and suppliers agree to preestablished cost or utilization targets for the network and to subsequent significant financial rewards and penalties (which may include a reduction in payments to downstream providers or suppliers in the network) based on the

network's performance in meeting the targets.

(III) Other mechanisms that demonstrate significant shared financial risk or significantly assist network entities to meet risk sharing targets

(f) Reporting Requirements.—

Each entity providing covered items or services for which payment may be made under this title 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 services for which payment may be made under this title very infrequently.

(g) Sanctions.—

[(1) Civil Monetary Penalty – Any entity that submits a claim for a designated health service which is provided in violation of subsection (a)(1) shall be subject to a civil monetary penalty of $1000 for each such service not to exceed $25,000 for each financial relationship such entity has with a physician (or an immediate family member of such physician) who has made referrals to such entity in violation of subsection (a)(1).]

(1) Denial of payment.—No payment may be made under this title for a designated health service which is provided in violation of subsection (a)(1) except as provided in paragraph (4) of this section.

(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 1128A (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 1128A(a).

(4) Civil money penalty for documentation noncompliance.—In the case of a compensation arrangement between a physician (or an immediate family member of such physician) and an entity that is in violation of subsection (a)(1) solely due to documentation noncompliance, instead of the sanctions described in subsections (1), (2), and (3) of this paragraph, for any such violation, the entity with respect to such arrangement shall be subject to a single civil monetary penalty of not more than $5,000 for each year that an arrangement is in documentation noncompliance.

(5) 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 1128A (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 1128A(a).

(6) 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 1128A (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 1128A(a).

(7) 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. Requests for advisory opinions may involve an existing, proposed, or hypothetical arrangement or a general question of interpretation. 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 1128D in the issuance of advisory opinions under this paragraph, except that the Secretary may not decline a request because a similar arrangement between other parties is under investigation or is the subject of a proceeding involving another government agency.

(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 the date of the enactment of this paragraph

and before the close of the period described in section 1128D(b)(6).

(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 to a physician (or an immediate family member of such physician) and from an entity other than an arrangement involving only remuneration described in subparagraph (C). A compensation arrangement commences when the physician (or immediate family member) receives remuneration from the entity and ends the day after the physician (or immediate family member) last receives remuneration from the entity under that arrangement.

(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 significant risk of program or patient abuse.

(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. An annual or hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using an annual or hourly rate determined at or below the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation, recognized by the Secretary. This provision shall not be construed as establishing a presumption that hourly payment above the 75th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in any national survey of physician compensation, recognized by the Secretary is above fair market value. A compensation arrangement for a physician's personal services shall be presumed to be fair market value absent clear and convincing evidence to the contrary.

(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 by the physician or another physician in the group practice, 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" only if such request results in an additional or increase in payment for a DHS.

(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" only if such request results in an additional or increase in payment for DHS.

(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, 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 1886(d)(1)(B)) 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.

(8) Signed by the parties shall mean (i) a writing with signature(s) made manually or by means of a device or machine, and by the use of any name, including a trade or assumed name, or by a word, mark, or symbol executed or adopted by a person with present intention to authenticate a writing; or (ii) an agreement between the parties to the terms of price and services as reflected in a group of contemporaneous writings, including, but not limited to, the acceptance of payment in an amount that conforms with the payment terms specified in a contemporaneous writing(s).

(9) A compensation arrangement shall be deemed not to vary with or otherwise take into account the volume or value of referrals if the amount of compensation is fair market value at the inception of the arrangement and does not increase or decrease with the value or volume of past or anticipated referrals during its term. A compensation arrangement with a physician based on productivity shall be deemed not to vary with or otherwise take into account the volume or value of referrals solely because the physician's professional service is related to or correlates with the physician's DHS referrals, as in the case of surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic.

(10) Commercial reasonableness shall mean that the services or items purchased or contracted for are of use in the business of the purchasing or contracting party and are of the kind and type of items or services purchased or contracted for by similarly situated entities.

(11) Documentation noncompliance.—

(A) Documentation noncompliance defined.—The term "documentation noncompliance" means an arrangement that is in violation of subsection (a)(1) solely because—

(i) one or more terms of the arrangement is not set forth in writing;

(ii) the arrangement is not signed by one or more parties to the arrangement; or

(iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.

Parallel Anti-Kickback Remuneration Exception Amendment for Network Arrangements

Section 1128B(b)(3) of the Social Security Act is amended by adding a new subparagraph (K) as follows:

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

[…]

(K) remuneration paid directly or indirectly between, among, or on behalf of one or more downstream providers or suppliers in a network as defined in this section, and –

(i) the network's governing body members, who must have a fiduciary duty to the network, including the duty of loyalty, act consistent with that fiduciary duty:

(I) to make a bona fide determination that an arrangement or group of related arrangements is reasonably related to one or more of the network goals;

(II) to duly authorize an arrangement using the processes generally employed by the network's governing body; and

(III) agree to promptly supply documentation demonstrating the network's compliance with (I) and (II) to the Secretary upon request;

(ii) the network governing body's bona fide determination with respect to an arrangement shall –

(I) set the terms of each authorized arrangement in writing, including the items and services to be provided;

(II) set in advance the compensation to be paid or recouped under each authorized arrangement; and

(III) agree to require any downstream provider or supplier to comply with the requirements and conditions of the network's arrangements with the Centers for Medicare & Medicaid Services or with any other payor of items and services.

(iii) Definitions – For purposes of this exception, the following terms are defined as follows:

(I) "Downstream provider or supplier" shall refer to a provider or supplier in a network risk-sharing arrangement with a network or with another downstream provider.

(II) "Items and services" means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies, or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance.

(III) "Network" is defined as a public or private entity that is established or organized, and operated by, , a downstream provider or supplier or group of downstream providers or suppliers to achieve one or more network goals through network risk-sharing arrangements.

(IV) "Network goals" are defined as any of the following:

(aa) promoting accountability for quality, cost, coordination, and overall care of patient populations, including patient populations that receive services reimbursed for by different payors;

(bb) managing and coordinating care for patients through arrangements approved by the network and administered, furnished, or arranged for through providers in the network; or

(cc) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including but not limited to Medicare beneficiaries, where efficient service delivery includes, among other things, appropriate reduction of costs or growth in expenditures for health care items and services provided to patients, consistent with quality of care, physician medical judgment, and patient freedom of choice.

(V) "Network risk-sharing arrangement" shall refer to one or more of the following mechanisms, which may be used in combination by a network to advance network goals –

(aa) an agreement to accept capitation payment for each patient.

(bb) an agreement to accept as payment a predetermined percentage of the network's revenue under the network risk-sharing arrangement.

(cc) a network's use of significant financial incentives for downstream providers and suppliers in the network, with the aim of achieving utilization management and cost containment goals.

(VI) "Significant financial incentives" include the following:

(aa) arrangements where downstream providers and suppliers in the network agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(1) To cover losses of the network.
(2) To cover losses of other downstream providers and suppliers in the network.
(3) To be returned to other downstream providers and suppliers if the network meets its utilization management or cost containment goals for the specified time period.
(4) To be distributed among downstream providers and suppliers if the network meets its utilization management or cost-containment goals for the specified time period.

(bb) arrangements where downstream providers and suppliers agree to preestablished cost or utilization targets for the network and to subsequent significant financial rewards and penalties (which may include a reduction in payments to downstream providers and suppliers in the network) based on the network's performance in meeting the targets.

(cc) Other mechanisms that demonstrate significant shared financial risk.

Amendments to Facilitate Permanent Fraud and Abuse Waivers for Innovation Center Models and APMs

Sec. 1115A. [42 U.S.C. 1315a] (a) Center for Medicare and Medicaid Innovation Established.—

(1) In general.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the "CMI") to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).

[…]

(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

(d) Implementation.—

(1) Waiver authority.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) solely for purposes of carrying out this section):

Section 1833(z) of the Social Security Act

(z) Incentive payments for participation in eligible alternative payment models

(1) Payment incentive

(A) In general

In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model-

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) Form of payment
Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) Treatment of payment incentive
Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) Coordination
The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) Qualifying APM participant
For purposes of this subsection, the term "qualifying APM participant" means the following:

[…]

(4) Limitation
There shall be no administrative or judicial review under section 1395ff of this title, 1395oo 17 of this title, or otherwise, of the following:

> (A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).
>
> (B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(5) Waiver authority.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) solely for purposes of carrying out this subsection.

Safeharbor for Cybersecurity Protection

ESTABLISHMENT OF SAFE HARBOR.—The Secretary shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and services) used predominantly for information security purposes, including data protection, threat identification, and risk mitigation for electronic health records, medical devices, and other information technology that uses, captures, or maintains individually identifiable health information, as defined in section 1177.