

STARK ADMINISTRATIVE SIMPLIFICATION ACT OF 2017

DECEMBER 21, 2017.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BRADY of Texas, from the Committee on Ways and Means,
submitted the following

R E P O R T

[To accompany H.R. 3726]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 3726) to amend title XVIII of the Social Security Act to create alternative sanctions for technical noncompliance with the Stark rule under Medicare, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Stark Administrative Simplification Act of 2017”.

SEC. 2. ALTERNATIVE SANCTIONS FOR TECHNICAL NONCOMPLIANCE WITH STARK RULE UNDER MEDICARE.

Section 1877 of the Social Security Act (42 U.S.C. 1395nn) is amended by adding at the end the following new subsection:

“(j) SELF-DISCLOSURE PROTOCOLS.—

“(1) IN GENERAL.—Beginning one year after the date of the enactment of this subsection—

“(A) an entity or individual may voluntarily disclose a compensation arrangement with actual or potential inadvertent technical noncompliance with subsection (a)(1) (as defined in paragraph (3)(H)) pursuant to either the self-referral disclosure protocol (defined in paragraph (2)) or the alternative protocol for technical noncompliance under paragraph (3);

“(B) disclosures voluntarily withdrawn from the alternative protocol for technical noncompliance may be submitted to the self-referral disclosure protocol; and

“(C) an entity that, prior to the establishment of the alternative protocol for technical noncompliance, disclosed to the self-referral disclosure protocol a compensation arrangement that was in inadvertent technical noncompliance with subsection (a)(1), may elect, not later than one year after such alternative protocol is established, to withdraw such disclosure from the self-referral disclosure protocol and instead submit the disclosure to such alternative protocol.

“(2) SELF-REFERRAL DISCLOSURE PROTOCOL.—The term ‘self-referral disclosure protocol’ or ‘SRDP’ means the protocol specified in section 6409 of Public Law 111–148.

“(3) ALTERNATIVE PROTOCOL FOR INADVERTANT TECHNICAL NONCOMPLIANCE.—

“(A) IN GENERAL.—The Secretary shall establish, not later than one year after the date of the enactment of this subsection, an alternative protocol for technical noncompliance (in this subsection referred to as the ‘APTN’) to enable entities to disclose arrangements that were previously in inadvertent technical noncompliance with subsection (a)(1) and, upon the Secretary’s acceptance of the disclosure, make payment of a civil monetary penalty. Payment of such civil monetary penalty for an arrangement shall resolve only overpayments due and owing as a result of such arrangement’s inadvertent technical noncompliance with subsection (a)(1). The provisions of section 6409 of Public Law 111–148 shall not apply to this subsection.

“(B) DISCLOSURE REQUIREMENTS.—Arrangements disclosed to the APTN must—

“(i) involve only inadvertent technical noncompliance with subsection (a)(1) that was ended by termination or expiration of the arrangement, or by action of the parties to the arrangement to resolve the technical noncompliance, prior to the date of submission of the disclosure to the APTN;

“(ii) be made in the form and manner specified by the Secretary on the public Internet website of the Centers for Medicare & Medicaid Services and include descriptions of—

“(I) the compensation arrangement that was in technical noncompliance with subsection (a)(1);

“(II) how and when the technical noncompliance with subsection (a)(1) was ended or the arrangement was otherwise terminated; and

“(III) how the remuneration paid under the compensation arrangement being disclosed was—

“(aa) consistent with the fair market value of the items and services that were provided under the compensation arrangement; and

“(bb) not determined in a manner that directly or indirectly takes into account the volume or value of referrals or other business generated between the parties;

“(iii) include a form settlement agreement provided by the Secretary signed by the entity; and

“(iv) include a certification from the entity that, to the best of the entity’s knowledge, the information provided is truthful information and is based on a good faith effort to bring the matter to the Secretary’s attention.

“(C) ACCEPTANCE OR REJECTION OF DISCLOSURE BY THE SECRETARY.—The following rules shall apply to the acceptance or rejection of a disclosure under the APTN:

“(i) The Secretary shall accept or reject a complete, accurate, and timely disclosure.

“(ii) Upon receipt of a disclosure, the Secretary shall notify the disclosing party of such receipt.

“(iii) The Secretary may request additional information from the disclosing party.

“(iv) Upon acceptance by the Secretary, the Secretary shall notify the disclosing party in writing of such acceptance.

“(v) The disclosure shall be rejected if—

“(I) the disclosing party fails to furnish the additional information requested by the Secretary in such form and manner as the Secretary may specify; or

“(II) in the Secretary’s sole determination, the noncompliance disclosed did not meet the disclosure requirements specified in subparagraph (B).

“(vi) The disclosure shall be accepted if—

“(I) the Secretary has issued a written notice to the disclosing party that the disclosure is determined to satisfy the requirements for disclosures under this section; or

“(II) the disclosure is complete, accurate, and timely and satisfies each of the requirements for disclosures under this section, 180 calendar days have passed since notification of receipt by the Secretary of the disclosure, and the Secretary has not rejected the disclosure during that period.

“(vii) In determining whether to accept a disclosure, the Secretary may reasonably rely on the information and certifications included in the disclosure.

“(D) RULE FOR WITHDRAWAL OF DISCLOSURE.—Prior to acceptance or rejection of a disclosure by the Secretary, an entity may voluntarily withdraw such disclosure from the APTN.

“(E) CIVIL MONETARY PENALTIES PURSUANT TO THE ALTERNATIVE PROTOCOL FOR TECHNICAL NONCOMPLIANCE.—

“(i) IN GENERAL.—Subject to clause (ii), for each arrangement disclosed under this subsection and accepted under subparagraph (C), the Secretary shall impose a single civil monetary penalty of—

“(I) \$5,000, in the case in which disclosure of the inadvertent technical noncompliance with subsection (a)(1) was submitted to the Secretary not later than the date that is one year after the initial date of inadvertent technical noncompliance with subsection (a)(1); or

“(II) \$10,000, in the case in which the disclosure of the inadvertent technical noncompliance with subsection (a)(1) was submitted to the Secretary—

“(aa) after the date that is more than one year after the initial date of the entity’s inadvertent technical noncompliance with subsection (a)(1); and

“(bb) not after the date that is 3 years (or, in the case of a disclosure submitted after the 5th year for which this subsection applies, the date that is 2 years) from the initial date of the entity’s inadvertent technical noncompliance with subsection (a)(1).

“(ii) SPECIAL RULE FOR ENTITIES THAT DISCLOSED TO THE APTN AFTER WITHDRAWING A DISCLOSURE FROM THE SRDP.—In the case of an entity that elects under paragraph (1)(C) to withdraw a disclosure from the self-referral disclosure protocol (as defined in paragraph (2)) and instead submit the disclosure to the APTN under this subsection, in determining the applicable civil monetary penalty under clause (i), the date of disclosure to the self-referral disclosure protocol shall be substituted for the date of disclosure to the APTN.

“(F) RELATION TO ADVISORY OPINIONS.—The APTN shall be separate from the advisory opinion process set forth in regulations implementing subsection (g) of this section.

“(G) PUBLICATION ON INTERNET WEBSITE OF APTN INFORMATION.—Not later than one year after the date of the enactment of this subsection, the Secretary shall post information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose and make payment of a civil monetary penalty for inadvertent technical noncompliance with subsection (a)(1).

“(H) DEFINITIONS.—In this subsection:

“(i) TECHNICAL NONCOMPLIANCE.—The term ‘technical noncompliance with subsection (a)(1)’ means, with respect to a compensation arrangement, that—

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

“(II) following the expiration of the arrangement, the arrangement was a holdover arrangement for a period longer than permitted in regulations issued by the Secretary; or

“(III) the contemporaneous written documentation evidencing the terms of the arrangement identifies the parties to the arrangement and the items, services, space, or equipment, as applicable, but is not sufficient to satisfy the writing requirement of an applicable exception.

“(ii) INADVERTENT.—The term ‘inadvertent’ means, with respect to a compensation arrangement that is in technical noncompliance with subsection (a)(1), that an entity that is a party to the compensation arrangement did not know or should not have known of the noncompliance.

“(I) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to this subsection.

“(J) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the provisions of this paragraph by program instruction or otherwise.”.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 3726, the “Stark Administrative Simplification Act of 2017,” as ordered reported by the Committee on Ways and Means on September 13, 2017, would create an alternative pathway to resolve inadvertent technical violations of the “Stark Laws,” that prevent financial interests from interfering with clinical decisions.

B. BACKGROUND AND NEED FOR LEGISLATION

On September 11, 2017, Representative Marchant (R-TX) and Representative Kind (D-WI) introduced H.R. 3726, legislation to create alternative sanctions for technical noncompliance with the physician self-referral laws, commonly known as the “Stark Laws” under Medicare. The Committee on Ways and Means received an additional referral for the bill because it includes Medicare provisions that fall within the jurisdiction of the Committee, including changes to relevant provisions of the Social Security Act (“SSA”). Section 1877 of the SSA, commonly referred to as the “Stark Laws,” prohibits physicians from referring Medicare beneficiaries to facilities in which they (or a close family member) have a financial stake and prohibits that facility from billing for Medicare services performed as a result of such referral.

C. LEGISLATIVE HISTORY

Background

H.R. 3726 was introduced on September 11, 2017, and was referred to the Committee on Energy and Commerce and additionally to the Committee on Ways and Means.

Committee hearings

On June 8, 2017, the Committee held a hearing on The Department of Health and Human Services' Fiscal Year 2018 Budget Request, in which topics such as the Stark Laws were discussed.

On June 8, 2016, the Subcommittee on Health held a Member Day hearing on various proposals to make improvements to and strengthen the Medicare program for all beneficiaries.

Committee action

The Committee on Ways and Means marked up H.R. 3726, the Stark Administrative Simplification Act of 2017, on September 13, 2017, and ordered the bill, as amended, favorably reported (with a quorum being present).

Additionally, previously in the 115th Congress, the Committee on Ways and Means marked up H.R. 3178, the "Medicare Part B Improvement Act," on July 13, 2017, which included provisions to improve the application of Stark Law rules. That bill was ordered, as amended, favorably reported (with a quorum being present).

II. EXPLANATION OF THE BILL

A. STARK ADMINISTRATIVE SIMPLIFICATION ACT OF 2017

PRESENT LAW

Current law does not differentiate between unintentional, technical Stark violations like missing a signature, and intentional, substantial violations, such as hospital payments for physician services above fair-market value or an arrangement that induces referrals.

REASONS FOR CHANGE

Concerns remain that currently inadvertent, technical violations are fined in the same ways as substantial violations. In fact, penalties for technical violations can run into the millions of dollars regardless of knowing, substantive fraudulent behavior or not. The purpose of the legislation is to allow those with inadvertent, technical violations to self-report and pay a standard fine to resolve the violation.

EXPLANATION OF PROVISIONS

The legislation would create a pathway to resolve inadvertent, technical violations of the Stark Laws by allowing for the payment of civil monetary penalties ("CMPs"). Specifically, this section would establish a self-disclosure protocol whereby an entity or individual may voluntarily disclose inadvertent technical non-compliance under two pathways: (1) current law self-referral disclosure protocol; or (2) the new alternative protocol for technical noncompliance ("APTN").

Entities would be able to report under the new APTN only if the violations were technical in nature, if the arrangements otherwise met the fair-market standards, and if the arrangements were not based on inducing referrals. Technical violations include violations related to a missing signature requirements, insufficient written documentation requirements, and the continuation of lease arrangements that have expired more than one year. Through the newly established APTN, entities would be able to pay a CMP to resolve the violation in the amount of \$5,000 or \$10,000, depending on whether the entity self-reported within one or three years.

Participation in the APTN pathway would be available only for inadvertent actions that were ended prior to the date of submission of the disclosure to the APTN, and made public through CMS' website, among other requirements. The legislation lays out parameters for acceptance or rejection of disclosures by the Secretary of Health and Human Services, including a determination within 180 days of notice of receipt by the Secretary.

EFFECTIVE DATE

The legislation becomes effective one year after the date of enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 3726, the Stark Administrative Simplification Act of 2017, on September 13, 2017.

The Chairman's amendment in the nature of a substitute was adopted by a voice vote (with a quorum being present).

The bill, H.R. 3726, was ordered favorably reported as amended by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 3726, as reported. The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET
OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 22, 2017.

Hon. KEVIN BRADY,
*Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3726, the Stark Administrative Simplification Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 3726—Stark Administrative Simplification Act of 2017

H.R. 3726 would modify the process by which providers can disclose and resolve technical violations of the Medicare statute. In CBO's judgment, the process envisioned in H.R. 3726 would be very similar to current law and would result in similar outcomes. As a result, CBO estimates that enacting H.R. 3726 would have no effect on the federal budget.

Under current law, providers participating in Medicare may not refer beneficiaries to other providers in which they have a financial interest. Those statutory prohibitions are commonly called the Stark Law, after former Representative Pete Stark, who sponsored the original legislation, and certain exceptions are permitted.

The Affordable Care Act mandated the development of a new process, the Self-Referral Disclosure Protocol (SDRP), through which providers who had violated the Stark law could disclose that violation and pay penalties. According to data from the Centers for Medicare and Medicaid Services, as of the end of calendar year 2016, providers have settled 233 disclosures and paid \$23 million in fines.

H.R. 3726 would create an alternative to the SDRP for a small subset of violations and providers could choose between the SDRP and that new process. The alternative protocol would be limited to those technical violations involving paperwork issues or the extension of permitted arrangements for a longer period than permitted under current regulations.

CBO expects that the amount of fines collected under the alternative protocol would probably be similar to the fines that will be collected under the SDRP. Therefore, CBO estimates that enacting H.R. 3726 would have no effect on the federal budget.

Enacting H.R. 3726 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

CBO estimates that enacting H.R. 3726 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028. H.R. 3726 contains no private-sector or intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Lara Robillard. The estimate was approved by Theresa Gullo, Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill does not authorize funding, so no statement of general performance goals and objectives is required.

C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. DUPLICATION OF FEDERAL PROGRAMS

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

F. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (115th Congress), the following statement is made concerning directed rule makings:

The Committee advises that the bill requires no directed rulemakings within the meaning of such section.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * *

PART E—MISCELLANEOUS PROVISIONS

* * * * *

LIMITATION ON CERTAIN PHYSICIAN REFERRALS

SEC. 1877. (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.

(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 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, in-

clude 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 a risk of program or patient abuse.

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

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

(B) EQUIPMENT.—Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if—

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

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

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

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

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

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

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

(A) the employment is for identifiable services,

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

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

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

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

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

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

(3) PERSONAL SERVICE ARRANGEMENTS.—

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

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

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

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

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

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

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

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

(B) PHYSICIAN INCENTIVE PLAN EXCEPTION.—

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

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

(II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 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 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) 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 serv-

ices to be provided by the parties and the compensation for services provided under the agreement,

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

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

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

(8) PAYMENTS BY A PHYSICIAN FOR ITEMS AND SERVICES.—
Payments made by a physician—

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

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

(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) 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).

(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 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).

(5) FAILURE TO REPORT INFORMATION.—Any person who is required, but fails, to meet a reporting requirement of subsection (f) is subject to a civil money penalty of not more than \$10,000 for each day for which reporting is required to have been made. The provisions of section 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) ADVISORY OPINIONS.—

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

(B) APPLICATION OF CERTAIN RULES.—The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) and take into account the regulations promulgated under subsection (b)(5) of section 1128D 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 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 in-

volving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

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

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

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

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

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

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

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

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

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

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

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

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

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

(4) GROUP PRACTICE.—

(A) DEFINITION OF GROUP PRACTICE.—The term “group practice” means a group of 2 or more physicians legally organized as a partnership, professional corporation, founda-

tion, not-for-profit corporation, faculty practice plan, or similar association—

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

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

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

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

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

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

(B) SPECIAL RULES.—

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

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

(5) REFERRAL; REFERRING PHYSICIAN.—

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

(B) OTHER ITEMS.—Except as provided in subparagraph (C), the request or establishment of a plan of care by a

physician which includes the provision of the designated health service constitutes a “referral” by a “referring physician”.

(C) CLARIFICATION RESPECTING CERTAIN SERVICES INTEGRAL TO A CONSULTATION BY CERTAIN SPECIALISTS.—A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a “referral” by a “referring physician”.

(6) DESIGNATED HEALTH SERVICES.—The term “designated health services” means any of the following items or services:

(A) Clinical laboratory services.

(B) Physical therapy services.

(C) Occupational therapy services.

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

(E) Radiation therapy services and supplies.

(F) Durable medical equipment and supplies.

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

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

(I) Home health services.

(J) Outpatient prescription drugs.

(K) Inpatient and outpatient hospital services.

(L) Outpatient speech-language pathology services.

(7) SPECIALTY HOSPITAL.—

(A) IN GENERAL.—For purposes of this section, except as provided in subparagraph (B), the term “specialty hospital” means a subsection (d) hospital (as defined in section 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.

(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 1866 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 the date of the enactment of this subsection 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 the date of enactment of this subsection.

(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 the date of enactment of this subsection.

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

(3) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

(A) PROCESS.—

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

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

(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on February 1, 2012.

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

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

(C) PERMITTED INCREASE.—

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

(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, 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 the date of enactment of this subsection (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement).

(D) **INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.**—Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

(E) **APPLICABLE HOSPITAL.**—In this paragraph, the term “applicable hospital” means a hospital—

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

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

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

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

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

(F) **HIGH MEDICAID FACILITY DESCRIBED.**—A high Medicaid facility described in this subparagraph is a hospital that—

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

(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under title 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 1869, section 1878, or otherwise of the process under this paragraph (including the establishment of such process).

(4) COLLECTION OF OWNERSHIP AND INVESTMENT INFORMATION.—For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (1), the Secretary shall collect physician ownership and investment information for each hospital.

(5) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection, the term “physician owner or investor” means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

(6) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital’s provider agreement if not in compliance with regulations implementing section 1866.

(j) SELF-DISCLOSURE PROTOCOLS.—

(1) IN GENERAL.—Beginning one year after the date of the enactment of this subsection—

(A) an entity or individual may voluntarily disclose a compensation arrangement with actual or potential inadvertent technical noncompliance with subsection (a)(1) (as defined in paragraph (3)(H)) pursuant to either the self-referral disclosure protocol (defined in paragraph (2)) or the alternative protocol for technical noncompliance under paragraph (3);

(B) disclosures voluntarily withdrawn from the alternative protocol for technical noncompliance may be submitted to the self-referral disclosure protocol; and

(C) an entity that, prior to the establishment of the alternative protocol for technical noncompliance, disclosed to the self-referral disclosure protocol a compensation arrangement that was in inadvertent technical noncompliance with subsection (a)(1), may elect, not later than one year after such alternative protocol is established, to withdraw such disclosure from the self-referral disclosure protocol and instead submit the disclosure to such alternative protocol.

(2) SELF-REFERRAL DISCLOSURE PROTOCOL.—The term “self-referral disclosure protocol” or “SRDP” means the protocol specified in section 6409 of Public Law 111–148.

(3) *ALTERNATIVE PROTOCOL FOR INADVERTANT TECHNICAL NONCOMPLIANCE.*—

(A) *IN GENERAL.*—*The Secretary shall establish, not later than one year after the date of the enactment of this subsection, an alternative protocol for technical noncompliance (in this subsection referred to as the “APTN”) to enable entities to disclose arrangements that were previously in inadvertent technical noncompliance with subsection (a)(1) and, upon the Secretary’s acceptance of the disclosure, make payment of a civil monetary penalty. Payment of such civil monetary penalty for an arrangement shall resolve only overpayments due and owing as a result of such arrangement’s inadvertent technical noncompliance with subsection (a)(1). The provisions of section 6409 of Public Law 111–148 shall not apply to this subsection.*

(B) *DISCLOSURE REQUIREMENTS.*—*Arrangements disclosed to the APTN must—*

(i) involve only inadvertent technical noncompliance with subsection (a)(1) that was ended by termination or expiration of the arrangement, or by action of the parties to the arrangement to resolve the technical noncompliance, prior to the date of submission of the disclosure to the APTN;

(ii) be made in the form and manner specified by the Secretary on the public Internet website of the Centers for Medicare & Medicaid Services and include descriptions of—

(I) the compensation arrangement that was in technical noncompliance with subsection (a)(1);

(II) how and when the technical noncompliance with subsection (a)(1) was ended or the arrangement was otherwise terminated; and

(III) how the remuneration paid under the compensation arrangement being disclosed was—

(aa) consistent with the fair market value of the items and services that were provided under the compensation arrangement; and

(bb) not determined in a manner that directly or indirectly takes into account the volume or value of referrals or other business generated between the parties;

(iii) include a form settlement agreement provided by the Secretary signed by the entity; and

(iv) include a certification from the entity that, to the best of the entity’s knowledge, the information provided is truthful information and is based on a good faith effort to bring the matter to the Secretary’s attention.

(C) *ACCEPTANCE OR REJECTION OF DISCLOSURE BY THE SECRETARY.*—*The following rules shall apply to the acceptance or rejection of a disclosure under the APTN:*

(i) The Secretary shall accept or reject a complete, accurate, and timely disclosure.

(ii) Upon receipt of a disclosure, the Secretary shall notify the disclosing party of such receipt.

(iii) *The Secretary may request additional information from the disclosing party.*

(iv) *Upon acceptance by the Secretary, the Secretary shall notify the disclosing party in writing of such acceptance.*

(v) *The disclosure shall be rejected if—*

(I) *the disclosing party fails to furnish the additional information requested by the Secretary in such form and manner as the Secretary may specify; or*

(II) *in the Secretary's sole determination, the noncompliance disclosed did not meet the disclosure requirements specified in subparagraph (B).*

(vi) *The disclosure shall be accepted if—*

(I) *the Secretary has issued a written notice to the disclosing party that the disclosure is determined to satisfy the requirements for disclosures under this section; or*

(II) *the disclosure is complete, accurate, and timely and satisfies each of the requirements for disclosures under this section, 180 calendar days have passed since notification of receipt by the Secretary of the disclosure, and the Secretary has not rejected the disclosure during that period.*

(vii) *In determining whether to accept a disclosure, the Secretary may reasonably rely on the information and certifications included in the disclosure.*

(D) **RULE FOR WITHDRAWAL OF DISCLOSURE.**—*Prior to acceptance or rejection of a disclosure by the Secretary, an entity may voluntarily withdraw such disclosure from the APTN.*

(E) **CIVIL MONETARY PENALTIES PURSUANT TO THE ALTERNATIVE PROTOCOL FOR TECHNICAL NONCOMPLIANCE.**—

(i) **IN GENERAL.**—*Subject to clause (ii), for each arrangement disclosed under this subsection and accepted under subparagraph (C), the Secretary shall impose a single civil monetary penalty of—*

(I) *\$5,000, in the case in which disclosure of the inadvertent technical noncompliance with subsection (a)(1) was submitted to the Secretary not later than the date that is one year after the initial date of inadvertent technical noncompliance with subsection (a)(1); or*

(II) *\$10,000, in the case in which the disclosure of the inadvertent technical noncompliance with subsection (a)(1) was submitted to the Secretary—*

(aa) *after the date that is more than one year after the initial date of the entity's inadvertent technical noncompliance with subsection (a)(1); and*

(bb) *not after the date that is 3 years (or, in the case of a disclosure submitted after the 5th year for which this subsection applies, the date that is 2 years) from the initial date of the en-*

tity's inadvertent technical noncompliance with subsection (a)(1).

(ii) **SPECIAL RULE FOR ENTITIES THAT DISCLOSED TO THE APTN AFTER WITHDRAWING A DISCLOSURE FROM THE SRDP.**—*In the case of an entity that elects under paragraph (1)(C) to withdraw a disclosure from the self-referral disclosure protocol (as defined in paragraph (2)) and instead submit the disclosure to the APTN under this subsection, in determining the applicable civil monetary penalty under clause (i), the date of disclosure to the self-referral disclosure protocol shall be substituted for the date of disclosure to the APTN.*

(F) **RELATION TO ADVISORY OPINIONS.**—*The APTN shall be separate from the advisory opinion process set forth in regulations implementing subsection (g) of this section.*

(G) **PUBLICATION ON INTERNET WEBSITE OF APTN INFORMATION.**—*Not later than one year after the date of the enactment of this subsection, the Secretary shall post information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose and make payment of a civil monetary penalty for inadvertent technical noncompliance with subsection (a)(1).*

(H) **DEFINITIONS.**—*In this subsection:*

(i) **TECHNICAL NONCOMPLIANCE.**—*The term “technical noncompliance with subsection (a)(1)” means, with respect to a compensation arrangement, that—*

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

(II) following the expiration of the arrangement, the arrangement was a holdover arrangement for a period longer than permitted in regulations issued by the Secretary; or

(III) the contemporaneous written documentation evidencing the terms of the arrangement identifies the parties to the arrangement and the items, services, space, or equipment, as applicable, but is not sufficient to satisfy the writing requirement of an applicable exception.

(ii) **INADVERTENT.**—*The term “inadvertent” means, with respect to a compensation arrangement that is in technical noncompliance with subsection (a)(1), that an entity that is a party to the compensation arrangement did not know or should not have known of the noncompliance.*

(I) **ADMINISTRATION.**—*Chapter 35 of title 44, United States Code, shall not apply to this subsection.*

(J) **IMPLEMENTATION.**—*Notwithstanding any other provision of law, the Secretary may implement the provisions of this paragraph by program instruction or otherwise.*

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VII. EXCHANGES OF LETTERS WITH ADDITIONAL COMMITTEES OF REFERRAL

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DAVID STEWART, STAFF DIRECTOR

Congress of the United States U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS 1102 LONGWORTH HOUSE OFFICE BUILDING (202) 225-3625

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BRANDON CASEY, MINORITY CHIEF OF STAFF

December 5, 2017

The Honorable Greg Walden Chairman Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Walden,

Thank you for your letter concerning H.R. 3726, the "Stark Administrative Simplification Act of 2017," on which the Energy and Commerce Committee was granted the primary referral.

I am most appreciative of your decision to waive formal consideration of H.R. 3726. I acknowledge that although you waived formal consideration of the bill, the Energy and Commerce Committee is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bill that fall within your Rule X jurisdiction. I would support your effort to seek appointment of an appropriate number of conferees on any House-Senate conference involving this legislation.

I will include a copy of our letters in our committee report and in the Congressional Record should this legislation be considered on the House floor.

Sincerely,

Handwritten signature of Kevin Brady

Kevin Brady Chairman

cc: The Honorable Paul Ryan, Speaker; The Honorable Richard E. Neal; The Honorable Frank Pallone; Thomas J. Wickham, Jr., Parliamentarian

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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December 5, 2017

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Brady:

I write concerning H.R. 3726, Stark Administrative Simplification Act of 2017, which was referred to the Committee on Energy and Commerce.

I wanted to notify you that the Committee will forgo action on H.R. 3726 so that it may proceed expeditiously to the House floor for consideration. This is done with the understanding that the Committee's jurisdictional interests over this and similar legislation are in no way diminished or altered. In addition, the Committee reserves the right to seek conferees on H.R. 3726 and requests your support when such a request is made.

I would appreciate your response confirming this understanding with respect to H.R. 3726 and ask that a copy of our exchange of letters on this matter be included in the Congressional Record during consideration of the bill on the House floor.

Sincerely,


Greg Walden
Chairman

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