



AMERICAN **BAR** ASSOCIATION

Health Law Section

REDLINE

AKS & CMP 2020 FINAL RULE REGULATORY

REVISIONS^{v.1'}

- 1) Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements²
- 2) Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals And Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees³

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¹ Version 1 is based on pre-publication versions of the two final rules. Version 2 will be based on final versions, when published in the official Federal Register. Note that there are often typos and minor cleanup changes between pre-publication rules and the final publication rules.

Version 2 will replace Version 1 on the ABA's website.

The ABA Health Law Section will be separately publishing a redline showing the final corollary changes to Stark.

Stay tuned for ABA Health Law Section articles and webinars on the AKS/CMP and Stark Final Rules.

² Pre-publication version, and final version, will be available at www.federalregister.gov/d/2020-26072. Anticipated official publication date is 12/02/20. Version 2 of this redline will have official Federal Register citations.

³ Pre-publication version, and final version, will be available at www.federalregister.gov/d/2020-25841. Anticipated official publication date is 12/02/20. Version 2 of this redline will have official Federal Register citations.

⁴ Special thanks to Arturo Trafny, Lotan Helfman, and Olivia Dresevic who assisted in preparation of this publication.

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AKS & CMP FINAL 2020 REGULATION CHANGES

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AKS

42 C.F.R. § 1001.951 FRAUD AND KICKBACKS AND OTHER PROHIBITED ACTIVITIES.

(a) *Circumstance for exclusion.*

(1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.*

(1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare, Medicaid and all other Federal health care programs;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(iv) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(v) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question; or

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(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others.

(c) *Limitations.* The OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128B(b) of the Act occurred.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 67 FR 11933, Mar. 18, 2002; 82 FR 4114, Jan. 12, 2017]

AUTHORITY: 42 U.S.C. 1302; 1320a-7; 1320a-7b; 1395u(j); 1395u(k); 1395w-104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

**TITLE 42: PUBLIC HEALTH
PART 1001—PROGRAM INTEGRITY—
MEDICARE AND STATE HEALTH CARE
PROGRAMS**

SUBPART C—PERMISSIVE EXCLUSIONS

42 C.F.R. § 1001.952 EXCEPTIONS.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment interests.* As used in section 1128B of the Act, “remuneration” does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable

standards are met within one of the following three categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than \$50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of health care items and services, all of the following five standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781(b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms (including any direct or indirect transferability restrictions) and at a price equally available to the public when trading on a registered securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or in accordance with the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise

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generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(3)(i) If the entity possesses investment interests that are held by either active or passive investors and is located in an underserved area, all of the following eight standards must be met—

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(A) No more than 50 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. (For purposes of paragraph (a)(3)(i)(A) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(B) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(C) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(D) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(E) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors.

(F) At least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

(G) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(H) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(ii) If an entity that otherwise meets all of the above standards is located in an area that was an underserved area at the time of the initial investment, but subsequently ceases to be an underserved area, the entity will be deemed to comply with paragraph (a)(3)(i) of this section for a period equal to the lesser of:

(A) The current term of the investment remaining after the date upon which the area ceased to be an underserved area or

(B) Three years from the date the area ceased to be an underserved area.

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(4) For purposes of paragraph (a) of this section, the following terms apply.

Active investor means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity’s agents acting within the scope of their agency.

Investment interest means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units in a partnership or limited liability company, bonds, debentures, notes, or other debt instruments.

Investor means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest.

Passive investor means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security.

Underserved area means any defined geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department.

Medically underserved population means a Medically Underserved Population (MUP) in accordance with regulations issued by the Department.

(b) **Space rental.** As used in section 1128B of the Act, “remuneration” does not include any payment made by a lessee to a lessor for the use

of premises, as long as all of the following six standards are met —

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (b) of this section, the term **fair market value** means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for

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which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.

(c) **Equipment rental.** As used in section 1128B of the Act, “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note

that for purposes of paragraph (c) of this section, the term **fair market value** means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(d) **Personal services and management contracts and outcomes-based payment arrangements.**

(1) As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following ~~seven~~ standards are met:—

(~~i~~) The agency agreement is set out in writing and signed by the parties.

(~~ii~~) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

~~(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.~~

(~~iii~~)4) The term of the agreement is ~~for~~ not less than 1 year.

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(iv~~5~~) The ~~aggregate~~ methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(v~~6~~) The services performed under the agreement do not involve the ~~counselling~~ counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vi~~7~~) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

(2) As used in section 1128B of the Act, “remuneration” does not include any outcomes-based payment as long as all of the standards in paragraphs (d)(2)(i) through (viii) of this section are met:

(i) To receive an outcomes-based payment, the agent achieves one or more legitimate outcome measures that:

(A) Are selected based on clinical evidence or credible medical support; and

(B) Have benchmarks that are used to quantify:

(1) Improvements in, or the maintenance of improvements in, the quality of patient care;

(2) A material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients; or

(3) Both.

(ii) The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement is: set in advance; commercially reasonable; consistent with fair market value; and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.

(iii) The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states at a minimum: a general description of the services to be performed by the parties for the term of the agreement; the outcome measure(s) the agent must achieve to receive an outcomes-based payment; the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s); and the schedule for the parties to regularly monitor and assess the outcome measure(s).

(iv) The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.

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(v) The term of the agreement is not less than 1 year.

(vi) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(vii) For each outcome measure under the agreement, the parties:

(A) Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care; and

(B) Periodically assess, and as necessary revise, benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair market value in an arm's length transaction as required by paragraph (d)(2)(ii) of this section during the term of the agreement.

(viii) The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

(3) For purposes of this paragraph (d):

(i) An agent of a principal is any person other than a bona fide employee of the principal who has an agreement to perform services for or on behalf of the principal.

(ii) Outcomes-based payments are limited to payments between or among a principal and an agent that:

(A) Reward the agent for successfully achieving an outcome measure described in paragraph (d)(2)(i) of this section; or

(B) Recoup from or reduce payment to an agent for failure to achieve an outcome measure described in paragraph (d)(2)(i) of this section.

(iii) Outcomes-based payments exclude any payments:

(A) Made directly or indirectly by the following entities:

(1) A pharmaceutical manufacturer, distributor, or wholesaler;

(2) A pharmacy benefit manager;

(3) A laboratory company;

(4) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(5) A manufacturer of a device or medical supply as defined in paragraph (ee)(14)(iv) of this section;

(6) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply, as defined in paragraph (ee)(14)(iv) of this section; or

(7) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

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(B) Related solely to the achievement of internal cost savings for the principal; or

(C) Based solely on patient satisfaction or patient convenience measures.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a *bona fide* employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) **Sale of practice.** (1) As used in section 1128B of the Act, “remuneration” does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(i) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs after 1 year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, “remuneration” does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

(i) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made under Medicare, Medicaid or other Federal health care programs.

(iii) The practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner’s specialty area.

(iv) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that:

(A) May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and

(B) Will satisfy the conditions of the practitioner recruitment safe harbor in accordance with paragraph (n) of this section.

(f) **Referral services.** As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value between an individual or entity (“participant”) and another entity serving as a referral service (“referral service”), as long as all of the following four standards are met—

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(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants and is based only on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of ~~an item~~ one or more items and services (provided the warranty covers at least one item) to the buyer (such as a health care provider or beneficiary) of the ~~item~~ items and services, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and ~~(g)(2)~~ of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) ~~and (g)(4)~~ through (6) of this section:—

(1) The buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of ~~the~~ an item or service (including a free item or service), ~~which that~~ was obtained as part of the warranty; in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

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(3) The manufacturer or supplier must comply with either of the following ~~two~~ standards:—

(i) The manufacturer or supplier must fully and accurately report ~~the any~~ price reduction of ~~the an item or service~~ (including ~~a free items and services~~), ~~which was that the buyer~~ obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs ~~(a)(1) and (a)(2)~~ (g)(1) and (2) of this section.

(ii) ~~Where~~ When the amount of ~~the any~~ price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when ~~the any~~ price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the ~~item itself~~ items and services subject to the warranty.

(5) If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.

(6) The manufacturer or supplier must not condition a warranty on a buyer's exclusive

use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

(7) For purposes of this paragraph (g) of this section, the term *warranty* means:

(i) Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;

(ii) Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items; or

(iii) ~~either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a~~ A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items (which is covered by an agreement made in accordance with this ~~statutory provision~~ paragraph (g)), on terms equal to the agreement that it replaces.

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(h) **Discounts.** As used in section 1128B of the Act, “remuneration” does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within one of the three following categories—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year

in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care

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programs to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under

paragraph (h)(1) of this section; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs. The offeror must comply

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with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report

such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term **discount** means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;



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(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; ~~or~~

(vii) Other remuneration, in cash or in kind, not explicitly described in this paragraph (h)(5) ~~of this section;~~ or

(viii) A reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

(6) For purposes of this paragraph (h), the term manufacturer carries the meaning ascribed to it in Social Security Act section 1927(k)(5).

(7) For purposes of this paragraph (h), the terms wholesaler and distributor are used interchangeably and carry the same meaning as the term “wholesaler” defined in Social Security Act section 1927(k)(11).

(8) For purposes of this paragraph (h), the term pharmacy benefit manager or PBM means any entity that provides pharmacy benefit management on behalf of a health plan that manages prescription drug coverage.

(9) For purposes of this paragraph (h), a prescription pharmaceutical product means either a drug or biological product as those terms are described in Social Security Act section 1927(k)(2)(A), (B), and (C).

(i) **Employees.** As used in section 1128B of the Act, “remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) **Group purchasing organizations.** As used in section 1128B of the Act, “remuneration” does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known,

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the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term **group purchasing organization (GPO)** means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) **Waiver of beneficiary copayment, coinsurance and deductible amounts.** As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Federal health care program beneficiary’s obligation to pay copayment, coinsurance or deductible (for purposes of this subparagraph (k) “cost-sharing”) amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.

(1) If the cost-sharing amounts are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, the hospital must comply with all of the following three standards:

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.

(iii) The hospital’s offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the cost-sharing amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under Titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under Title V of the Act, the health care center or facility may reduce or waive the cost-sharing amounts for items or services for which payment may be made in whole or in part by a Federal health care program.

(3) If the cost-sharing amounts are owed to a pharmacy (including, but not limited to, pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian

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organizations) for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:

(i) The waiver or reduction is not offered as part of an advertisement or solicitation; and

(ii) Except for waivers or reductions offered to subsidy-eligible individuals (as defined in section 1860D-14(a)(3)) to which only requirement in paragraph (k)(3)(i) of this section applies:

(A) The pharmacy does not routinely waive or reduce cost-sharing amounts; and

(B) The pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.

(4) If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all the following conditions are met:

(i) The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;

(ii) The ambulance provider or supplier engaged in an emergency response, as defined in 42 CFR 414.605;

(iii) The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and

(iv) The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

(1) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.

(1) As used in section 1128B of the Act, “remuneration” does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee’s obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with CMS or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or

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premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by CMS or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with CMS or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by CMS or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (1) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by CMS or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

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(m) *Price reductions offered to health plans.* (1)

As used in section 1128B of the Act, “remuneration” does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with CMS or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with CMS or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care program, the amount it has paid the contract health care provider under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the

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contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the

responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must

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fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms contract health care provider, enrollee, and health plan have the same meaning as in paragraph (l)(2) of this section.

(n) **Practitioner recruitment.** As used in section 1128B of the Act, “remuneration” does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated

from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

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(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP), all as defined in paragraph (a) of this section.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

(o) ***Obstetrical malpractice insurance subsidies.***
As used in section 1128B of the Act, “remuneration” does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section 1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

(2)(i) The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the

practitioner’s obstetrical patients treated under the coverage of the malpractice insurance will either—

(A) Reside in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Be part of a MUP, as defined in paragraph (a) of this section.

(ii) Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner’s obstetrical patients treated under the prior coverage period (not to exceed one year) must have—

(A) Resided in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Been part of a MUP, as defined in paragraph (a) of this section.

(3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

(4) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

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(6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(7) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance. For purposes of paragraph (o) of this section, **costs of malpractice insurance premiums** means:

(i) For practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance; or

(ii) For practitioners who engage in obstetrical practice on a part-time or sporadic basis, the costs:

(A) Attributable exclusively to the obstetrical portion of the practitioner’s malpractice insurance and

(B) Related exclusively to obstetrical services provided in a primary care HPSA.

(p) **Investments in group practices.** As used in section 1128B of the Act, “remuneration” does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met—

(1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

(2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

(3) In the case of group practices, the practice must:

(i) Meet the definition of “group practice” in section 1877(h)(4) of the Social Security Act and implementing regulations; and

(ii) Be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

(4) Revenues from ancillary services, if any, must be derived from “in-office ancillary services” that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

(q) **Cooperative hospital service organizations.** As used in section 1128B of the Act, “remuneration” does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met—

(1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO, or

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(2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under section 501(e)(2) of the Internal Revenue Code of 1986.

(r) *Ambulatory surgical centers.* As used in section 1128B of the Act, “remuneration” does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor’s investment interest, and all of the applicable standards are met within one of the following four categories—

(1) Surgeon-owned ASCs—If all of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each surgeon investor’s medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon’s performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any surgeon investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(2) Single-Specialty ASCs—If all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services

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to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon’s performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any physician investors must treat patients receiving

medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(3) Multi-Specialty ASCs—If all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following seven standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician’s performance of procedures (as defined in this paragraph).

(iii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor

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uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(4) Hospital/Physician ASCs—If at least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of

business otherwise generated from that investor to the entity.

(ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and

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integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

(5) For purposes of paragraph (r) of this section, **procedures** means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the **Department and group practice** means a group practice that meets all of the standards of paragraph (p) of this section. **Surgical group practice** means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

(s) *Referral arrangements for specialty services.* As used in section 1128B of the Act, “remuneration” does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare, Medicaid or any other Federal health care programs in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

(1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.

(2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.

(3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.

(4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

(t) *Price reductions offered to eligible managed care organizations.*

(1) As used in section 1128(B) of the Act, “remuneration” does not include any payment between:

(i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met—

(A) The eligible managed care organization and the first tier contractor have an agreement that:

(1) Is set out in writing and signed by both parties;

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(2) Specifies the items and services covered by the agreement;

(3) Is for a period of at least one year; and

(4) Specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement, except for:

(i) HMOs and competitive medical plans with cost-based contracts under section 1876 of the Act where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(ii) Federally qualified HMOs without a contract under sections 1854 or 1876 of the Act, where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program; or

(iii) First tier contractors that are Federally qualified health centers that claim supplemental payments from a Federal health care program.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party to the agreement shifts the financial burden of the

agreement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor or between two downstream contractors to provide or arrange for items or services, as long as the following four standards are met —

(A) The parties have an agreement that:

(1) Is set out in writing and signed by both parties;

(2) Specifies the items and services covered by the agreement;

(3) Is for a period of at least one year; and

(4) Specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(D) The agreement between the eligible managed care organization and first tier contractor covering the items or

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services that are covered by the agreement between the parties does not involve:

- (1) A Federally qualified health center receiving supplemental payments;
- (2) A HMO or CMP with a cost-based contract under section 1876 of the Act; or
- (3) A Federally qualified HMO, unless the items or services are covered by a risk based contract under sections 1854 or 1876 of the Act.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) **Downstream contractor** means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.

(ii) **Eligible managed care organization**⁵ means—

(A) A HMO or CMP with a risk or cost based contract in accordance with section 1876 of the Act;

(B) Any Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by CMS under section 1854 of the Act;

(C) Medicaid managed care organizations as defined in section 1903(m)(1)(A) that provide or arrange for items

or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts);

(D) Any other health plans that provide or arrange for items and services for Medicaid enrollees in accordance with a risk-based contract with a State agency subject to the upper payment limits in §447.361 of this title or an equivalent payment cap approved by the Secretary;

(E) Programs For All Inclusive Care For The Elderly (PACE) under sections 1894 and 1934 of the Act, except for for-profit demonstrations under sections 4801(h) and 4802(h) of Pub.L. 105-33; or

(F) A Federally qualified HMO.

(iii) **First tier contractor** means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

(iv) **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. Marketing and other pre-enrollment activities are not “items or services” for purposes of this section.

⁵ The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect

to items or services covered by the contracts specified in those paragraphs.

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(u) Price reductions offered by contractors with substantial financial risk to managed care organizations.

(1) As used in section 1128(B) of the Act, “remuneration” does not include any payment between:

(i) A qualified managed care plan and a first tier contractor for providing or arranging for items or services, where the following five standards are met—

(A) The agreement between the qualified managed care plan and first tier contractor must:

(1) Be in writing and signed by the parties;

(2) Specify the items and services covered by the agreement;

(3) Be for a period of a least one year;

(4) Require participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; and

(5) Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arms-length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and penalties, if any.

(B) If a first tier contractor has an investment interest in a qualified managed care plan, the investment

interest must meet the criteria of paragraph (a)(1) of this section.

(C) The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies:

(1) A periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided;

(2) Percentage of premium;

(3) Inpatient Federal health care program diagnosis-related groups (DRGs) (other than those for psychiatric services);

(4) Bonus and withhold arrangements, provided—

(i) The target payment for first tier contractors that are individuals or non-institutional providers is at least 20 percent greater than the minimum payment, and for first tier contractors that are institutional providers, i.e., hospitals and nursing homes, is at least 10 percent greater than the minimum payment;

(ii) The amount at risk, i.e., the bonus or withhold, is earned by a first tier contractor in direct proportion to the ratio of the contractor’s actual utilization to its target utilization;

(iii) In calculating the percentage in accordance with paragraph (u)(1)(i)(C)(4)(i) of this section, both the target payment amount and the minimum payment amount include any performance bonus, e.g., payments for timely submission of paperwork,

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continuing medical education, meeting attendance, etc., at a level achieved by 75 percent of the first tier contractors who are eligible for such payments;

(iv) Payment amounts, including any bonus or withhold amounts, are reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements; and

(v) Alternatively, for a first tier contractor that is a physician, the qualified managed care plan has placed the physician at risk for referral services in an amount that exceeds the substantial financial risk threshold set forth in 42 CFR 417.479(f) and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g).

(D) Payments for items and services reimbursable by Federal health care program must comply with the following two standards—

(1) The qualified managed care plan (or in the case of a self-funded employer plan that contracts with a qualified managed care plan to provide administrative services, the self-funded employer plan) must submit the claims directly to the Federal health care program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal health care program. (Notwithstanding the foregoing, inpatient hospital services, other than psychiatric services, will be deemed to comply if the hospital is reimbursed by a Federal health care program under a DRG methodology.)

(2) Payments to first tier contractors and any downstream contractors for providing or

arranging for items or services reimbursed by a Federal health care program must be identical to payment arrangements to or between such parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

(E) In establishing the terms of an arrangement—

(1) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(2) Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met—

(A) Both parties are being paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set out in paragraph (u)(1)(i)(C) of this section;

(B) Payment arrangements for items and services reimbursable by a Federal health care program comply with paragraph (u)(1)(i)(D) of this section; and

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(C) In establishing the terms of an arrangement—

(1) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(2) Neither party to the arrangement shifts the financial burden of the arrangement to the extent that increased payments are claimed from a Federal health care program.

(3) For purposes of this paragraph, the following terms are defined as follows:

(i) **Downstream contractor** means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first tier contractor.

(ii) **First tier contractor** means an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services.

(iii) Is obligated to provide for a contractor refers to items or services:

(A) Provided directly by an individual or entity and its employees;

(B) For which an individual or entity is financially responsible, but which are provided by downstream contractors;

(C) For which an individual or entity makes referrals or arrangements; or

(D) For which an individual or entity receives financial incentives based on its own, its provider group's, or its qualified managed care plan's performance (or combination thereof).

(iv) **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. Marketing or other pre-enrollment activities are not "items or services" for purposes of this definition in this paragraph.

(v) **Minimum payment** is the guaranteed amount that a provider is entitled to receive under an agreement with a first tier or downstream contractor or a qualified managed care plan.

(vi) **Qualified managed care plan** means a health plan as defined in paragraph (1)(2) of this section that:

(A) Provides a comprehensive range of health services;

(B) Provides or arranges for—

(1) Reasonable utilization goals to avoid inappropriate utilization;

(2) An operational utilization review program;

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(3) A quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;

(4) Grievance and hearing procedures;

(5) Protection of enrollees from incurring financial liability other than copayments and deductibles; and

(6) Treatment for Federal health care program beneficiaries that is not different than treatment for other enrollees because of their status as Federal health care program beneficiaries; and

(C) Covers a beneficiary population of which either—

(1) No more than 10 percent are Medicare beneficiaries, not including persons for whom a Federal health care program is the secondary payer; or

(2) No more than 50 percent are Medicare beneficiaries (not including persons for whom a Federal health care program is the secondary payer), provided that payment of premiums is on a periodic basis that does not take into account the dates services are rendered, the frequency of services, or the extent or kind of services rendered, and provided further that such periodic payments for the non-Federal health care program beneficiaries do not take into account the number of Federal health care program fee-for-service beneficiaries covered by the agreement or the amount of services generated by such beneficiaries.

(vii) **Target payment** means the fair market value payment established through arms length negotiations that will be earned by an individual or entity that:

(A) Is dependent on the individual or entity’s meeting a utilization target or range of utilization targets that are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on its own, its provider group’s or the qualified managed care plan’s utilization (or a combination thereof); and

(B) Does not include any bonus or fees that the individual or entity may earn from exceeding the utilization target.

(v) **Ambulance replenishing.** (1) As used in section 1128B of the Act, “remuneration” does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies (including linens) used by the ambulance provider (or a first responder) in connection with the transport of a patient by ambulance to the hospital or other receiving facility if all of the standards in paragraph (v)(2) of this section are satisfied and all of the applicable standards in either paragraph (v)(3)(i), (v)(3)(ii) or (v)(3)(iii) of this section are satisfied. However, to qualify under paragraph (v), the ambulance that is replenished must be used to provide emergency ambulance services an average of three times per week, as measured over a reasonable period of time. Drugs and medical supplies (including linens) initially used by a first responder and replenished at the scene of the illness or injury by the ambulance provider that transports the patient to the hospital or other

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receiving facility will be deemed to have been used by the ambulance provider.

(2) To qualify under paragraph (v) of this section, the ambulance replenishing arrangement must satisfy all of the following four conditions—

(i)(A) Under no circumstances may the ambulance provider (or first responder) and the receiving facility both bill for the same replenished drug or supply. Replenished drugs or supplies may only be billed (including claiming bad debt) to a Federal health care program by either the ambulance provider (or first responder) or the receiving facility.

(B) All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.

(C) Compliance with paragraph (v)(2)(i)(B) of this section will be determined separately for the receiving facility and the ambulance provider (and first responder, if any), so long as the receiving facility, ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations under paragraph (v)(2)(i)(B).

(ii)(A) The receiving facility or ambulance provider, or both, must

(1) Maintain records of the replenished drugs and medical supplies and the patient transport to which the replenished drugs and medical supplies related;

(2) Provide a copy of such records to the other party within a reasonable time (unless the other party is separately maintaining records of the replenished drugs and medical supplies); and

(3) Make those records available to the Secretary promptly upon request.

(B) A pre-hospital care report (including, but not limited to, a trip sheet, patient care report or patient encounter report) prepared by the ambulance provider and filed with the receiving facility will meet the requirements of paragraph (v)(2)(ii)(A) of this section, provided that it documents the specific type and amount of medical supplies and drugs used on the patient and subsequently replenished.

(C) For purposes of paragraph (v)(2)(ii) of this section, documentation may be maintained and, if required, filed with the other party in hard copy or electronically. If a replenishing arrangement includes linens, documentation need not be maintained for their exchange. If documentation is not maintained for the exchange of linens, the receiving facility will be presumed to have provided an exchange of comparable clean linens for soiled linens for each ambulance transport of a patient to the receiving facility. Records required under paragraph (v)(2)(ii)(A) of this section must be maintained for 5 years.

(iii) The replenishing arrangement must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program (other than the referral of the particular patient to

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whom the replenished drugs and medical supplies were furnished).

(iv) The receiving facility and the ambulance provider otherwise comply with all Federal, State, and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

(3) To qualify under paragraph (v) of this section, the arrangement must satisfy all of the standards in one of the following three categories:

(i) General replenishing. (A) The receiving facility must replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the categories described in paragraph (v)(3)(i)(A)(1), (2), or (3) of this section. A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is conducted uniformly within each category. For example, a receiving facility may offer to replenish a broader array of drugs or supplies for ambulance providers that do not charge for their services than for ambulance providers that charge for their services. Within each category, the receiving facility may limit its replenishing arrangements to the replenishing of emergency ambulance transports only. A receiving facility may offer replenishing to one or more of the categories—

(1) All ambulance providers that do not bill any patient or insurer (including Federal health care programs) for ambulance services, regardless of the payor or the patient's ability to

pay (i.e., ambulance providers, such as volunteer companies, that provide ambulance services without charge to any person or entity);

(2) All not-for-profit and State or local government ambulance service providers (including, but not limited to, municipal and volunteer ambulance services providers); or

(3) All ambulance service providers.

(B)(1) The replenishing arrangement must be conducted in an open and public manner. A replenishing arrangement will be considered to be conducted in an open and public manner if one of the following two conditions are satisfied:

(i) A written disclosure of the replenishing program is posted conspicuously in the receiving facility's emergency room or other location where the ambulance providers deliver patients and copies are made available upon request to ambulance providers, Government representatives, and members of the public (subject to reasonable photocopying charges). The written disclosure can take any reasonable form and should include the category of ambulance service providers that qualifies for replenishment; the drugs or medical supplies included in the replenishment program; and the procedures for documenting the replenishment. A sample disclosure form is included in appendix A to subpart C of this part for illustrative purposes only. No written contracts between the parties are required for purposes of paragraph (v)(3)(i)(B)(1)(i) of this section; or

(ii) The replenishment arrangement operates in accordance with a plan or protocol of general application promulgated by an Emergency Medical Services (EMS) Council or comparable entity, agency or organization,

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provided a copy of the plan or protocol is available upon request to ambulance providers, Government representatives and members of the public (subject to reasonable photocopying charges). While parties are encouraged to participate in collaborative, comprehensive, community-wide EMS systems to improve the delivery of EMS in their local communities, nothing in this paragraph shall be construed as requiring the involvement of such organizations or the development or implementation of ambulance replenishment plans or protocols by such organizations.

(2) Nothing in this paragraph (v)(3)(i) shall be construed as requiring disclosure of confidential proprietary or financial information related to the replenishing arrangement (including, but not limited to, information about cost, pricing or the volume of replenished drugs or supplies) to ambulance providers or members of the general public.

(ii) Fair market value replenishing.

(A) Except as otherwise provided in paragraph (v)(3)(ii)(B) of this section, the ambulance provider must pay the receiving facility fair market value, based on an arms-length transaction, for replenished medical supplies; and

(B) If payment is not made at the same time as the replenishing of the medical supplies, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.

(iii) Government mandated replenishing. The replenishing arrangement is undertaken in accordance with a State or local statute, ordinance, regulation or binding protocol

that requires hospitals or receiving facilities in the area subject to such requirement to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.

(4) For purposes of paragraph (v) of this section—

(i) A receiving facility is a hospital or other facility that provides emergency medical services.

(ii) An ambulance provider is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.

(iii) A first responder includes, but is not limited to, a fire department, paramedic service or search and rescue squad that responds to an emergency call (through 9-1-1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility.

(iv) An emergency ambulance service is a transport by ambulance initiated as a result of a call through 9-1-1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

(v) Medical supplies includes linens, unless otherwise provided.

(w) **Health centers.** As used in section 1128B of the Act, “remuneration” does not include the transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash

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or in-kind), or combination thereof from an individual or entity to a health center (as defined in this paragraph), as long as the following nine standards are met—

(1)(i) The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that—

(A) Is set out in writing;

(B) Is signed by the parties; and

(C) Covers, and specifies the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the health center.

(ii) The amount of goods, items, services, donations, or loans specified in the agreement in accordance with paragraph (w)(1)(i)(C) of this section may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of Federal health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the health center as required by paragraph (w)(1)(i)(C) of this section if all separate agreements between the individual or entity and the health center incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.

(2) The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to services provided by the health center as part of the scope of the health center's section 330 grant (including, by way of example, billing services, administrative support services, technology support, and enabling services, such as case management, transportation, and translation services, that are within the scope of the grant).

(3) The health center reasonably expects the arrangement to contribute meaningfully to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, and the health center documents the basis for the reasonable expectation prior to entering the arrangement. The documentation must be made available to the Secretary upon request.

(4) At reasonable intervals, but at least annually, the health center must re-evaluate the arrangement to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (w)(3) of this section, and must document the re-evaluation contemporaneously. The documentation must be made available to the Secretary upon request. Arrangements must not be renewed or renegotiated unless the health center reasonably expects the standard set forth in paragraph (w)(3) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements of paragraph (w)(3) of this section.

(5) The individual or entity does not (i) Require the health center (or its affiliated health care professionals) to refer patients to a particular individual or entity, or (ii) restrict the health

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center (or its affiliated health care professionals) from referring patients to any individual or entity.

(6) Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the health center must furnish such goods, items, or services to all patients from the health center who clinically qualify for the goods, items, or services, regardless of the patient’s payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the health center, provided such limits do not take into account a patient’s payor status or ability to pay.

(7) The agreement must not restrict the health center’s ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors. Where a health center has multiple individuals or entities willing to offer comparable remuneration, the health center must employ a reasonable methodology to determine which individuals or entities to select and must document its determination. In making these determinations, health centers should look to the procurement standards for beneficiaries of Federal grants set forth in 45 CFR 75.326 through 75.340.

(8) The health center must provide effective notification to patients of their freedom to choose any willing provider or supplier. In addition, the health center must disclose the existence and nature of an agreement under paragraph (w)(1) of this section to any patient who inquires. The health center must provide such notification or disclosure in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.

(9) The health center may, at its option, elect to require that an individual or entity charge a referred health center patient the same rate it charges other similarly situated patients not referred by the health center or that the individual or entity charge a referred health center patient a reduced rate (where the discount applies to the total charge and not just to the cost-sharing portion owed by an insured patient).

Note to paragraph (w): For purposes of this paragraph, the term “**health center**” means a Federally Qualified Health Center under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Act, and “**medically underserved population**” means a medically underserved population as defined in regulations at 42 CFR 51c.102(e).

(x) *Electronic prescribing items and services.* As used in section 1128B of the Act, “remuneration” does not include nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice to a prescribing health care professional who is a member of the group practice; and

(iii) A PDP sponsor or MA organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

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(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor’s behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient’s right or ability to use the items or services for any patient.

(5) Neither the recipient nor the recipient’s practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a beneficiary for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor’s cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the beneficiary incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the beneficiary possesses or has obtained items or services equivalent to those provided by the donor.

Note to paragraph (x): For purposes of paragraph (x) of this section, group practice shall have the meaning set forth at 42 CFR 411.352; member of the group practice shall mean all persons covered by the definition of “member of the group or member of a group practice” at 42 CFR 411.351, as well as other prescribing health care professionals who are owners or employees of the group practice; prescribing health care professional shall mean a physician or other health care professional licensed to prescribe drugs in the State in which the drugs are dispensed; PDP sponsor or MA organization shall have the meanings set forth at 42 CFR 423.4 and 422.2, respectively; prescription information shall mean information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription; and electronic health record shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

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(y) *Electronic health records items and services.*

As used in section 1128B of the Act, “remuneration” does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, ~~or~~ receive, or protect electronic health records, if all of the ~~following~~ conditions in paragraphs (y)(1) through (13) of this section are met:

(1) The items and services are provided to an individual or entity engaged in the delivery of health care by:—

(i) An individual or entity, other than a laboratory company, that:

(A) Provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or

(B) Is comprised of the types of individuals or entities in paragraph (y)(1)(i)(A) of this section; or

(ii) A health plan.

(2) The software is interoperable at the time it is provided to the recipient. For purposes of this ~~subparagraph~~ paragraph (y)(2) of this section, software is deemed to be interoperable if, on the date it is provided to the recipient, it ~~has been~~ is certified by a certifying body authorized by the National Coordinator for Health Information Technology to ~~an edition of the electronic health record~~ certification criteria identified in the then-applicable version of 45 CFR part 170.

~~(3) The donor (or any person on the donor’s behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services). Reserved.~~

(4) Neither the recipient nor the recipient’s practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(5) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph (y)(5), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the beneficiary (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);

(ii) The determination is based on the size of the recipient’s medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the recipient practices medicine;

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(iv) The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the recipient; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(6) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the beneficiary incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

~~(7) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the beneficiary possesses or has obtained items or services equivalent to those provided by the donor.~~ Reserved.

(8) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

(9) The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations.

(10) [Reserved]

~~(11) Before receipt of the items and services, the~~ The recipient pays 15 percent of the donor's cost for the items and services. The following conditions apply to such contribution:

(i) If the donation is the initial donation of EHR items and services, or the replacement of part or all of an existing system of EHR items and services, the recipient must pay 15 percent of the donor's cost before receiving the items and services. The contribution for updates to previously donated EHR items and services need not be paid in advance of receiving the update; and

(ii) The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.

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(12) The donor does not shift the costs of the items or services to any Federal health care program.

(13) ~~The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2021.~~ Reserved.

~~Note to paragraph (y):~~ (14) For purposes of this paragraph (y), the following definitions apply: ~~of this section,~~

(i) Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

(ii) ~~health~~ Health plan shall have the meaning set forth at § 1001.952(1)(2);

(iii) ~~interoperable~~ Interoperable shall mean able to:

(A) ~~communicate and~~ Securely exchange data ~~accurately, effectively, securely, and consistently with different~~ with and use data from other health information technology ~~systems; and software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered~~

(B) Allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; ~~and~~

(iv) ~~electronic~~ Electronic health record shall mean a repository of consumer health status information in computer processable form

used for clinical diagnosis and treatment for a broad array of clinical conditions.

(z) **Federally Qualified Health Centers and Medicare Advantage Organizations.** As used in section 1128B of the Act, “remuneration” does not include any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage organization pursuant to a written agreement described in section 1853(a)(4) of the Act.

(aa) **Medicare Coverage Gap Discount Program.** As used in section 1128B of the Act, “remuneration” does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program established in section 1860D–14A of the Act, as long as all the following requirements are met:

(1) The discounted drug meets the definition of “applicable drug” set forth in section 1860D–14A(g) of the Act;

(2) The beneficiary receiving the discount meets the definition of “applicable beneficiary” set forth in section 1860D–14A(g) of the Act; and

(3) The manufacturer of the drug participates in, and is in compliance with the requirements of, the Medicare Coverage Gap Discount Program.

(bb) **Local Transportation.** As used in section 1128B of the Act, “remuneration” does not include free or discounted local transportation made available by an eligible entity (as defined in this paragraph (bb)):

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(1) To Federal health care program beneficiaries if all the following conditions are met:

(i) The availability of the free or discounted local transportation services —

(A) Is set forth in a policy, which the eligible entity applies uniformly and consistently; and

(B) Is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

(ii) The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;

(iii) The eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

(iv) The eligible entity makes the free or discounted transportation available only:

(A) To an individual who is:

(1) An established patient (as defined in this paragraph (bb)) of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services; and

(2) An established patient of the provider or supplier to or from which the individual is being transported;

(B) Within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within ~~50-75~~ miles if the patient resides in a rural area, as defined in this paragraph (bb) except that, if the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours and transported to the patient's residence, or another residence of the patient's choice, the mileage limits in this paragraph (bb)(1)(iv)(B) shall not apply; and

(C) For the purpose of obtaining medically necessary items and services.

(v) The eligible entity that makes the transportation available bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals; and

(2) In the form of a “shuttle service” (as defined in this paragraph (bb)) if all of the following conditions are met:

(i) The shuttle service is not air, luxury, or ambulance-level transportation;

(ii) The shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

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(iii) The eligible entity makes the shuttle service available only within the eligible entity’s local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50-75 miles between that ~~that~~ stop and ~~all~~ any providers or suppliers on the route; ~~and~~

(iv) The eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.

~~Note to paragraph (bb)-(3)~~ For purposes of this paragraph (bb), the following definitions apply:

~~(i) an~~ An “eligible entity” is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items.;

(ii) “An established patient” is a person who has selected and initiated contact to schedule an appointment with a provider or supplier ~~to schedule an appointment~~, or who previously has attended an appointment with the provider or supplier.;

(iii) A “shuttle service” is a vehicle that runs on a set route, on a set schedule.;

(iv) A “rural area” is an area that is not an urban area, as defined in ~~this rule paragraph (bb)(3)(v) of this section.~~ and

(v) An “urban area” as is:

~~(a)~~ (A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

~~(b)~~ (B) the following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(cc) Point-of-sale reductions in price for prescription pharmaceutical products. (1) As used in section 1128B of the Act, “remuneration” does not include a reduction in price from a manufacturer to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization, provided the following conditions are met with regard to that reduction in price:

(i) The manufacturer and the plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either, set the reduction in price in advance, in writing, by the time of the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee;

(ii) The reduction in price does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or



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series of point-of-sale chargebacks, or is required by law; and

(iii) The reduction in price must be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary.

(2)(i) For purposes of this paragraph (cc), the terms manufacturer, pharmacy benefit manager or PBM, prescription pharmaceutical product, and rebate have the meanings ascribed to them in paragraph (h) of this section.

(ii) For purposes of this paragraph (cc), a point-of-sale chargeback is a payment by a manufacturer made directly or indirectly (through a PBM or other entity) to a dispensing pharmacy equal to the reduction in price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.

(iii) For purposes of this paragraph (cc), the term Medicaid Managed Care Organization or Medicaid MCO carries the meaning ascribed to it in section 1903(m) of the Social Security Act.

(dd) *PBM service fees.* (1) As used in section 1128B of the Act, “remuneration” does not include any payment by a pharmaceutical manufacturer to a pharmacy benefit manager (PBM) for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans as long as the following conditions are met:

(i) The PBM has a written agreement with the pharmaceutical

manufacturer, signed by the parties, that covers all of the services the PBM provides to the manufacturer in connection with the PBM’s arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.

(ii) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(iii) The compensation paid to the PBM is:

(A) Is consistent with fair market value in an arm’s-length transaction;

(B) Is a fixed payment, not based on a percentage of sales; and

(C) Is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM’s health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

(iv) The PBM discloses in writing to each health plan with which it contracts at least annually the services rendered to each pharmaceutical manufacturer related to the PBM’s arrangements to furnish pharmacy benefit management services to the health plan, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM’s arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services.



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(2) For purposes of safe harbor in this paragraph (dd), the terms manufacturer, pharmacy benefit manager or PBM, and prescription pharmaceutical product have the meanings ascribed to them in paragraph (h) of this section, and health plan has the meaning ascribed to it in paragraph (l) of this section.

(ee) Care coordination arrangements to improve quality, health outcomes, and efficiency. As used in section 1128B of the Act, “remuneration” does not include the exchange of anything of value between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement if all of the standards in paragraphs (ee)(1) through (13) of this section are met:

(1) The remuneration exchanged:

(i) Is in-kind;

(ii) Is used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target patient population; and

(iii) Is not exchanged or used:

(A) More than incidentally for the recipient’s billing or financial management services; or

(B) For the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(2) The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.

(3) The terms of the value-based arrangement are set forth in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement. The writing states at a minimum:

(i) The value-based purpose(s) of the value-based activities provided for in the value-based arrangement;

(ii) The value-based activities to be undertaken by the parties to the value-based arrangement;

(iii) The term of the value-based arrangement;

(iv) The target patient population;

(v) A description of the remuneration;

(vi) Either the offeror’s cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration;

(vii) The percentage and amount contributed by the recipient;

(viii) If applicable, the frequency of the recipient’s contribution payments for ongoing costs; and



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(ix) The outcome or process measure(s) against which the recipient will be measured.

(4) The parties to the value-based arrangement establish one or more legitimate outcome or process measures that:

(i) The parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health sciences support;

(ii) Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the target patient population;

(iii) Are monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continue to advance the coordination and management of care of the target patient population;

(iv) Relate to the remuneration exchanged under the value-based arrangement; and

(v) Are not based solely on patient satisfaction or patient convenience.

(5) The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based

arrangement.

(6) The recipient pays at least 15 percent of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

(7) The value-based arrangement does not:

(i) Limit the VBE participant's ability to make decisions in the best interests of its patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act; or

(iii) Induce parties to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient.

(8) The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned



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on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.

(9) The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses the following and reports the monitoring and assessment of the following to the VBE's accountable body or responsible person, as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year:

(i) The coordination and management of care for the target patient population in the value-based arrangement;

(ii) Any deficiencies in the delivery of quality care under the value-based arrangement; and

(iii) Progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement.

(10) If the VBE's accountable body or responsible person determines, based on the monitoring and assessment conducted pursuant to paragraph (ee)(9) of this section, that the value-based arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population, the parties must within 60 days either:

(i) Terminate the arrangement;
or

(ii) Develop and implement a corrective action plan designed to remedy the deficiencies within 120 days, and if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the value-based arrangement.

(11) The offeror does not and should not know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

(12) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ee).

(13) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) Except to the extent the entity is a limited technology participant, a manufacturer of a device or medical supply;

(vi) Except to the extent the entity or individual is a limited technology participant, an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a



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physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(14) For purposes of this paragraph (ee), the following definitions apply:

(i) *Coordination and management of care (or coordinating and managing care)* means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

(ii) *Digital health technology* means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

(iii) *Limited technology participant* means a VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is:

(A) A manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be

obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year (for purposes of this paragraph, the terms “ownership or investment interest,” “physician,” and “immediate family member” have the same meaning as set forth in 42 CFR 403.902); or

(B) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

(iv) *Manufacturer of a device or medical supply* means an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply in 42 CFR 403.902, but not including entities under common ownership with such entity.

(v) *Target patient population* means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

(A) Are set out in writing in advance of the commencement of the value-based arrangement; and

(B) Further the value-based enterprise’s value-based purpose(s).

(vi) *Value-based activity.*

(A) Means any of the following activities, provided that the activity is



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reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

- (1) The provision of an item or service;
- (2) The taking of an action; or
- (3) The refraining from taking an action;

and

(B) Does not include the making of a referral.

(vii) Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:

(A) The value-based enterprise and one or more of its VBE participants; or

(B) VBE participants in the same value-based enterprise.

(viii) Value-based enterprise or VBE means two or more VBE participants:

(A) Collaborating to achieve at least one value-based purpose;

(B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(D) That have a governing document that describes the value-

based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

(ix) Value-based enterprise participant or VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.

(x) Value-based purpose means:

(A) Coordinating and managing the care of a target patient population;

(B) Improving the quality of care for a target patient population;

(C) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(D) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

(ff) Value-based arrangements with substantial downside financial risk. As used in section 1128B of the Act, “remuneration” does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if all of the following standards in paragraphs (ff)(1) through (8) of this section are met:

(1) The remuneration is not exchanged by:



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(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(2) The VBE (directly or through a VBE participant, other than a payor, acting on the VBE's behalf) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 6 months) substantial downside financial risk from a payor for a period of at least 1 year.

(3) The VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) is at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population.

(4) The remuneration provided by, or shared among, the VBE and VBE participant:

(i) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be a value-based purpose defined in §1001.952(ee)(14)(x)(A), (B), or (C);

(ii) Unless exchanged pursuant to risk methodologies defined in paragraph (ff)(9)(i) or (ii) of this section, is used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume in the next 6 months) substantial downside financial risk;

(iii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(iv) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(5) The value-based arrangement is set forth in writing, is signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement and any material change to the value-based arrangement, and specifies all material terms including:

(i) Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next 6 months for the target patient population;

(ii) A description of the manner in which the VBE participant (unless the



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VBE participant is the payor from which the VBE is assuming risk) has a meaningful share of the VBE’s substantial downside financial risk; and

(iii) The value-based activities, the target patient population, and the type of remuneration exchanged.

(6) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(7) The value-based arrangement does not:

(i) Limit the VBE participant’s ability to make decisions in the best interests of its patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient’s payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law under titles XVIII and XIX of the Act; or

(iii) Induce parties to reduce or limit medically necessary items or services furnished to any patient.

(8) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ff).

(9) For purposes of this paragraph (ff), the following definitions apply:

(i) Substantial downside financial risk means:

(A) Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;

(B) Financial risk equal to at least 20 percent of any loss, where:

(1) Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and

(2) The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or



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(C) The VBE receives from the payor a prospective, per-patient payment that is:

(1) Designed to produce material savings; and

(2) Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

(ii) Meaningful share means the VBE participant:

(A) Assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

(B) Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services.

(iii) Manufacturer of a device or medical supply, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose, and VBE participant shall have the meaning set forth in paragraph (ee) of this section.

(gg) Value-based arrangements with full financial risk. As used in section 1128B of the

Act, “remuneration” does not include the exchange of payments or anything of value between the VBE and a VBE participant pursuant to a value-based arrangement if all of the standards in paragraphs (gg)(1) through (9) of this section are met:

(1) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(2) The VBE (directly or through a VBE participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 1 year) full financial risk from a payor.



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(3) The value-based arrangement is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.

(4) The VBE participant (unless the VBE participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor described in paragraph (2).

(5) The remuneration provided by, or shared among, the VBE and VBE participant:

(i) Is directly connected to one or more of the VBE's value-based purposes;

(ii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(iii) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(6) The value-based arrangement does not induce parties to reduce or limit medically necessary items or services furnished to any patient.

(7) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(8) The VBE provides or arranges for a quality assurance program for services furnished to the target patient population that:

(i) Protects against underutilization; and

(ii) Assesses the quality of care furnished to the target patient population.

(9) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (gg).

(10) For purposes of this paragraph (gg), the following definitions apply:

(i) Full financial risk means the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year.

(ii) Prospective basis means that the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

(iii) Items and services means health care items, devices, supplies, and services.

(iv) Manufacturer of a device or medical supply, target patient population, value-based activity, value-based arrangement, value-based enterprise, value-based purpose, and VBE



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participant shall have the meaning set forth in paragraph (ee) of this section.

(hh) Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency. As used in section 1128B of the Act, “remuneration” does not include a patient engagement tool or support furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party if all of the conditions in paragraphs (hh)(1) through (9) of this section are met:

(1) The VBE participant is not:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply, unless the patient engagement tool or support is digital health technology;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply; or

(viii) A manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year, even if the patient engagement tool or support is digital health technology (for purposes of this paragraph, the terms “ownership or investment interest,” “physician,” and “immediate family member” have the same meaning as set forth in 42 CFR 403.902).

(2) The patient engagement tool or support is furnished directly to the patient (or the patient’s caregiver, family member, or other individual acting on the patient’s behalf) by a VBE participant that is a party to the value-based arrangement or its eligible agent.

(3) The patient engagement tool or support:

(i) Is an in-kind item, good, or service;

(ii) That has a direct connection to the coordination and management of care of the target patient population;

(iii) Does not include any cash or cash equivalent;

(iv) Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;

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(v) Is recommended by the patient's licensed health care professional; and

(vi) Advances one or more of the following goals:

(A) Adherence to a treatment regimen determined by the patient's licensed health care professional.

(B) Adherence to a drug regimen determined by the patient's licensed health care professional.

(C) Adherence to a followup care plan established by the patient's licensed health care professional.

(D) Prevention or management of a disease or condition as directed by the patient's licensed health care professional.

(E) Ensure patient safety.

(4) The patient engagement tool or support is not funded or contributed by:

(i) A VBE participant that is not a party to the applicable value-based arrangement; or

(ii) An entity listed in paragraph (hh)(1) of this section.

(5) The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed \$500. The monetary cap set forth in this paragraph (hh)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPIU) for the 12-month period ending the

preceding September 30. OIG will publish guidance after September 30 of each year reflecting the increase in the CPI-U for the 12-month period ending September 30 and the new monetary cap applicable for the following calendar year.

(6) The VBE participant or any eligible agent does not exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.

(7) For a period of at least 6 years, the VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions of this paragraph (hh).

(8) The availability of a tool or support is not determined in a manner that takes into account the type of insurance coverage of the patient.

(9) For purposes of this paragraph (hh), the following definitions apply:

(i) Eligible agent means any person or entity that is not identified in paragraphs (hh)(1)(i) through (viii) of this section as ineligible to furnish protected tools and supports under this paragraph.

(ii) Coordination and management of care, target patient population, value-based arrangement, VBE, VBE participant, manufacturer of a device or medical supply, and digital health technology shall have the meaning set forth in paragraph (ee) of this section.



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(ii) CMS-sponsored model arrangements and CMS-sponsored model patient incentives.

(1) As used in section 1128B of the Act, “remuneration” does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;

(ii) The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;

(iii) The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-sponsored model;

(iv) The CMS-sponsored model parties in advance of or contemporaneous with the commencement of the CMS-sponsored model arrangement set forth the terms of the CMS-sponsored model arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement;

(v) The parties to the CMS-sponsored model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and

(vi) The CMS-sponsored model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(2) As used in section 1128B of the Act, “remuneration” does not include a CMS-sponsored model patient incentive for which CMS has determined that this safe harbor is available if all of the following conditions are met:

(i) The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model;

(ii) The CMS-sponsored model patient incentive has a direct connection to the patient’s health care unless the participation documentation expressly specifies a different standard;

(iii) The CMS-sponsored model patient incentive is furnished by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant’s direction and control), unless otherwise specified by the participation documentation;

(iv) The CMS-sponsored model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was



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distributed in a manner that meets the conditions of this safe harbor; and

(v) The CMS-sponsored model patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

(3) For purposes of this paragraph (ii), the following definitions apply:

(i) CMS-sponsored model means:

(A) A model being tested under section 1115A(b) of the Act or a model expanded under section 1115A(c) of the Act; or

(B) The Medicare shared savings program under section 1899 of the Act.

(ii) CMS-sponsored model arrangement means a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model that is consistent with, and is not a type of arrangement prohibited by, the participation documentation.

(iii) CMS-sponsored model participant means an individual or entity that is subject to and is operating under participation documentation with CMS to participate in a CMS-sponsored model.

(iv) CMS-sponsored model party means:

(A) A CMS-sponsored model participant; or

(B) Another individual or entity whom the participation documentation specifies may enter into a CMS-sponsored model arrangement.

(v) CMS-sponsored model patient incentive means remuneration not of a type prohibited by the participation documentation that is furnished to a patient under the terms of a CMS-sponsored model.

(vi) Participation documentation means the participation agreement, legal instrument setting forth the terms and conditions of a grant or cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that specifies the terms of a CMS-sponsored model.

(4) For purposes of remuneration that satisfies this paragraph (ii), the safe harbor protects:

(i) For a CMS-sponsored model governed by participation documentation other than the legal instrument setting forth the terms and conditions of a grant or a cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day on which services under the CMS-sponsored model begin and no later than 6 months after the final payment determination made by CMS under the model;

(ii) For a CMS-sponsored model governed by the legal instrument setting forth the terms and conditions of a grant or cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day of the



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period of performance (as defined at 45 CFR 75.2) or such other date specified in the participation documentation and no later than 6 months after closeout occurs pursuant to 45 CFR 75.381; and

(iii) For a CMS-sponsored model patient incentive, an incentive given on or after the first day on which patient care services may be furnished under the CMS-sponsored model as specified by CMS in the participation documentation and no later than the last day on which patient care services may be furnished under the CMS-sponsored model, unless a different timeframe is established in the participation documentation. A patient may retain any incentives furnished in compliance with paragraph (ii)(2) of this section.

(jj) *Cybersecurity technology and related services.* As used in section 1128B of the Act, “remuneration” does not include nonmonetary remuneration (consisting of cybersecurity technology and services) that is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity if all of the conditions in paragraphs (jj)(1) through (4) of this section are met.

(1) The donor does not:

(i) Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or

(ii) Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.

(2) Neither the recipient nor the recipient’s practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(3) A general description of the technology and services being provided and the amount of the recipient’s contribution, if any, are set forth in writing and signed by the parties.

(4) The donor does not shift the costs of the technology or services to any Federal health care program.

(5) For purposes of this paragraph (jj) the following definitions apply:

(i) *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.

(ii) *Technology* means any software or other types of information technology.

(kk) *ACO Beneficiary Incentive Program.* As used in section 1128B of the Act, “remuneration” does not include an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act, as amended by Congress from time to time, if the incentive payment is made in accordance with the requirements found in such subsection.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996; 64 FR 63513, Nov. 19, 1999; 64 FR 63551, Nov. 19, 1999; 64 FR 71317, Dec. 21, 1999; 66 FR 62989, Dec. 4, 2001; 66 FR 63749, Dec. 10, 2001; 67 FR 11933, Mar. 18, 2002; 71 FR 45136,

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Aug. 8, 2006; 72 FR 56644, Oct. 4, 2007; 78 FR 79219, Dec. 27, 2013; 81 FR 3012, Jan. 20, 2016; 81 FR 88407, Dec. 7, 2016; 84 FR 20810, May 13, 2019]

AUTHORITY: 42 U.S.C. 1302; 1320a-7; 1320a-7b; 1395u(j); 1395u(k); 1395w-104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub.L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

END AKS.

CMP

**PART 1003—CIVIL MONEY PENALTIES,
ASSESSMENTS AND EXCLUSIONS
CONTENTS**

Authority: 42 U.S.C. 262a, 1302, 1320-7, 1320a-7a, 1320b-10, 1395u(j), 1395u(k), 1395cc(j), 1395w-141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

Source: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

SUBPART A—GENERAL PROVISIONS

42 C.F.R. § 1003.100 BASIS AND PURPOSE.

(a) **Basis.** This part implements sections 1128(c), 1128A, 1140, 1819(b)(3)(B), 1819(g)(2)(A), 1857(g)(2)(A), 1860D-12(b)(3)(E), 1860D-31(i)(3), 1862(b)(3)(C), 1867(d)(1), 1876(i)(6), 1877(g), 1882(d), 1891(c)(1); 1903(m)(5), 1919(b)(3)(B), 1919(g)(2)(A), 1927(b)(3)(B), 1927(b)(3)(C), and 1929(i)(3) of the Social Security Act; sections 421(c) and 427(b)(2) of Public Law 99-660; and section 201(i) of Public Law 107-188 (42 U.S.C. 1320a-7(c), 1320a-7a, 1320b-10, 1395i-3(b)(3)(B), 1395i-3(g)(2)(A), 1395w-27(g)(2)(A), 1395w-112(b)(3)(E), 1395w-141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm(i)(6), 1395nn(g), 1395ss(d), 1395bbb(c)(1), 1396b(m)(5), 1396r(b)(3)(B), 1396r(g)(2)(A), 1396r-8(b)(3)(B), 1396r-8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a(i)).

(b) **Purpose.** This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments and exclusions against persons who have committed an act or omission that violates one or more provisions of this part and

(2) Sets forth the appeal rights of persons subject to a penalty, assessment, and exclusion.

[81 FR 88354, Dec. 7, 2016]

42 C.F.R. § 1003.110 DEFINITIONS.

For purposes of this part:

Assessment means the amounts described in this part and includes the plural of that term.

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Claim means an application for payment for an item or service under a Federal health care program.

Contracting organization means a public or private entity, including a health maintenance organization, Medicare Advantage organization, Prescription Drug Plan sponsor, or other organization that has contracted with the Department or a State to furnish, or otherwise pay for, items and services to Medicare or Medicaid beneficiaries pursuant to sections 1857, 1860D-12, 1876(b), or 1903(m) of the Act.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization.

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any Federal or State health care program reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.

Material means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's, or other health care practitioner's provision of, or failure to provide, health care services and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Non-separately-billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

Overpayment means any funds that a person receives or retains under Medicare or Medicaid to which the person, after applicable reconciliation, is not entitled under such program.

Participating hospital means either a hospital or a critical access hospital, as defined in section 1861(mm)(1) of the Act, that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in this part and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician or physician group that may directly or indirectly

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have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Preventive care, for purposes of the definition of the term Remuneration as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services, and

(2) Is reimbursable in whole or in part by Medicare or an applicable State health care program.

Reasonable request, with respect to §1003.200(b)(10), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. The request will include: A statement of the authority for the request, the person’s rights in responding to the request, the definition of “reasonable request” and “failure to grant timely access” under part 1003, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

Remuneration, for the purposes of §1003.1000(a) of this part, is consistent with the definition in section 1128A(i)(6) of the Act and includes the waiver of copayment, coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other

than fair market value. The term “remuneration” does not include:

(1) The waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts;

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary;

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented;

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionately large in relationship to the value of the preventive care service (*i.e.*, either the value of the service itself or the future

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health care costs reasonably expected to be avoided as a result of the preventive care).

(5) A reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the Act;

(6) Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

(i) Being unlikely to interfere with, or skew, clinical decision making;

(ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

(iii) Not raising patient safety or quality-of-care concerns;

(7) The offer or transfer of items or services for free or less than fair market value by a person if—

(i) The items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State

health care program (as defined in section 1128(h) of the Act);

(8) The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) The items or services are not offered as part of any advertisement or solicitation;

(ii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(iii) There is a reasonable connection between the items or services and the medical care of the individual; and

(iv) The person provides the items or services after determining in good faith that the individual is in financial need;

(9) Waivers by a Part D Plan sponsor (as that term is defined in 42 CFR 423.4) of any copayment for the first fill of a covered Part D drug (as defined in section 1860D-2(e)) that is a generic drug (as defined in 42 CFR 423.4) or an authorized generic drug (as defined in 21 CFR 314.3) for individuals enrolled in the Part D plan (as that term is defined in 42 CFR 423.4), as long as such waivers are included in the benefit design package submitted to CMS. This exception is applicable to coverage years beginning on or after January 1, 2018.

(10) The provision of telehealth technologies by a provider of services, physician, or a renal dialysis facility (as such terms are defined for purposes of title XVIII of the Act) to

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an individual with end-stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if:

(i) The telehealth technologies are furnished to the individual by the provider of services, physician, or the renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the individual, or has been selected or contacted by the individual to schedule an appointment or provide services;

(ii) The telehealth technologies are not offered as part of any advertisement or solicitation; and

(iii) The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage renal disease.

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible Official means the individual designated pursuant to 42 CFR part 73 to serve as the Responsible Official for the person holding a certificate of registration to possess, use, or transfer select agents or toxins.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department requesting examination or treatment, including any physician who is on-call for the care of such individual and fails or refuses to appear within a

reasonable time at such hospital to provide services relating to the examination, treatment, or transfer of such individual. Responsible physician also includes a physician who is responsible for the examination or treatment of individuals at hospitals with specialized capabilities or facilities, as provided under section 1867(g) of the Act, including any physician who is on-call for the care of such individuals and refuses to accept an appropriate transfer or fails or refuses to appear within a reasonable time to provide services related to the examination or treatment of such individuals.

Select agents and toxins is defined consistent with the definition of “select agent and/or toxin” and “overlap select agent and/or toxin” as set forth in 42 CFR part 73.

Separately billable item or service means an item or service for which an identifiable payment may be made under a Federal health care program, e.g., an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

Should know, or should have known, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant Program means the program authorized under Title XX of the Act.

Telehealth technologies, for purposes of paragraph (10) of the definition of the term “remuneration” as set forth in this section, means hardware, software, and services that support distant or remote communication

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between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management.

Timely basis means, in accordance with §1003.300(a) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 66 FR 39452, July 31, 2001; 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004. Redesignated and amended at 81 FR 88355, Dec. 7, 2016; 81 FR 88409, Dec. 7, 2016]

42 C.F.R. § 1003.120 LIABILITY FOR PENALTIES AND ASSESSMENTS.

(a) In any case in which it is determined that more than one person was responsible for a violation described in this part, each such person may be held liable for the penalty prescribed by this part.

(b) In any case in which it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her

agency. This provision does not limit the underlying liability of the agent.

[81 FR 88356, Dec. 7, 2016]

42 C.F.R. § 1003.130 ASSESSMENTS.

The assessment in this part is in lieu of damages sustained by the Department or a State agency because of the violation.

[81 FR 88356, Dec. 7, 2016]

42 C.F.R. § 1003.140 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND ASSESSMENTS AND THE PERIOD OF EXCLUSION.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment or the period of exclusion in accordance with this part, the OIG will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty, assessment, or exclusion is proposed. It should be considered an aggravating circumstance if the respondent had actual knowledge where a lower level of knowledge was required to establish liability (e.g., for a provision that establishes liability if the respondent “knew or should have known” a claim was false or fraudulent, it will be an aggravating circumstance if the respondent knew the claim was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the OIG through the Self-

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Disclosure Protocol and fully cooperating with the OIG's review and resolution of such disclosure, or in cases of physician self-referral law violations, disclosing the violation to CMS through the Self-Referral Disclosure Protocol;

(3) The history of prior offenses.

Aggravating circumstances include, if at any time prior to the violation, the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) Other wrongful conduct.

Aggravating circumstances include proof that the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) Such other matters as justice may require. Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty, assessment, or period of exclusion to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the OIG considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the OIG, sufficient financial documentation, including, but not limited to, audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the OIG to determine the person's ability to pay the penalty or assessment.

(2) If the person requests a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review is that which the person provided to the OIG during the administrative process, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

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(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors is present.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the OIG to settle any issue or case as provided by §1003.1530 or to compromise any exclusion and any penalty and assessment as provided by §1003.1550.

(4) Penalties, assessments, and exclusions imposed under this part are in

addition to any other penalties, assessments, or other sanctions prescribed by law.

[81 FR 88356, Dec. 7, 2016]

42 C.F.R. § 1003.150 DELEGATION OF AUTHORITY.

The OIG is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments and exclusions against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose and compromise civil monetary penalties, assessments, and exclusion under section 1128A of the Act.

[81 FR 88356, Dec. 7, 2016]

42 C.F.R. § 1003.160 WAIVER OF EXCLUSION.

(a) The OIG will consider a request from the administrator of a Federal health care program for a waiver of an exclusion imposed under this part as set forth in paragraph (b) of this section. The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) If the OIG subsequently obtains information that the basis for a waiver no longer exists, the waiver will cease and the person will be fully excluded from the Federal health care programs for the remainder of the exclusion period, measured from the time the full exclusion would have been imposed if the waiver had not been granted.

(c) The OIG will notify the administrator of the Federal health care program whether his or her request for a waiver has been granted or denied.

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(d) If a waiver is granted, it applies only to the program(s) for which waiver is requested.

(e) The decision to grant, deny, or rescind a waiver is not subject to administrative or judicial review.

[81 FR 88356, Dec. 7, 2016]

SUBPART B—CMPs, ASSESSMENTS, AND EXCLUSIONS FOR FALSE OR FRAUDULENT CLAIMS AND OTHER SIMILAR MISCONDUCT

Source:

81 FR 88357, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.200 BASIS FOR CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS.

(a) The OIG may impose a penalty, assessment, and an exclusion against any person who it determines has knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from

participation in the Federal health care program to which the claim was presented;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified by a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not medically necessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person who it determines—

(1) Has knowingly presented, or caused to be presented, a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

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(iii) An agreement to be a participating physician or supplier under section 1842(h)(1) of the Act; or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act;

(2) Has knowingly given, or caused to be given, to any person, in the case of inpatient hospital services subject to section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital;

(3) Is an individual who is excluded from participating in a Federal health care program under section 1128 or 1128A of the Act, and who—

(i) Knows, or should know, of the action constituting the basis for the exclusion and retains a direct or indirect ownership or control interest of 5 percent or more in an entity that participates in a Federal health care program or

(ii) Is an officer or a managing employee (as defined in section 1126(b) of the Act) of such entity;

(4) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program;

(5) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under a Federal health care program if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act or violates the requirements for such an arrangement;

(6) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(7) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(8) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(9) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(10) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose

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of audits, investigations, evaluations, or other
OIG statutory functions. Such **failure to grant
timely access** means:

(i) Except when the OIG
reasonably believes that the requested material is
about to be altered or destroyed, the failure to
produce or make available for inspection and
copying the requested material upon reasonable
request or to provide a compelling reason why
they cannot be produced, by the deadline
specified in the OIG's written request, and

(ii) When the OIG has reason
to believe that the requested material is about to
be altered or destroyed, the failure to provide
access to the requested material at the time the
request is made.

(c) The OIG may impose a penalty against any
person who it determines, in accordance with
this part, is a physician and who executes a
document falsely by certifying that a Medicare
beneficiary requires home health services when
the physician knows that the beneficiary does not
meet the eligibility requirements in section
1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(d) The OIG may impose a penalty against any
person who it determines knowingly certifies, or
causes another individual to certify, a material
and false statement in a resident assessment
pursuant to sections 1819(b)(3)(B) and
1919(b)(3)(B).

42 C.F.R. § 1003.210 AMOUNT OF PENALTIES AND ASSESSMENTS.

(a) *Penalties.*⁶

⁶ The penalty amounts in this section are updated annually, as
adjusted in accordance with the Federal Civil Monetary
Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140),
as amended by the Federal Civil Penalties Inflation

(1) Except as provided in this section,
the OIG may impose a penalty of not more than
\$10,000 for each individual violation that is
subject to a determination under this subpart.

(2) The OIG may impose a penalty of
not more than \$15,000 for each person with
respect to whom a determination was made that
false or misleading information was given under
§1003.200(b)(2).

(3) The OIG may impose a penalty of
not more than \$10,000 per day for each day that
the prohibited relationship described in
§1003.200(b)(3) occurs.

(4) For each individual violation of
§1003.200(b)(4), the OIG may impose a penalty
of not more than \$10,000 for each separately
billable or non-separately-billable item or service
provided, furnished, ordered, or prescribed by an
excluded individual or entity.

(5) The OIG may impose a penalty of
not more than \$2,000 for each bill or request for
payment for items and services furnished to a
hospital patient in violation of §1003.200(b)(5).

(6) The OIG may impose a penalty of
not more than \$50,000 for each false statement,
omission, or misrepresentation of a material fact
in violation of §1003.200(b)(7).

(7) The OIG may impose a penalty of
not more than \$50,000 for each false record or
statement in violation of §1003.200(b)(9).

Adjustment Act Improvements Act of 2015 (section 701 of
Pub. L. 114-74). Annually adjusted amounts are published at
45 CFR part 102.

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(8) The OIG may impose a penalty of not more than \$10,000 for each item or service related to an overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of §1003.200(b)(8).

(9) The OIG may impose a penalty of not more than \$15,000 for each day of failure to grant timely access in violation of §1003.200(b)(10).

(10) For each false certification in violation of §1003.200(c), the OIG may impose a penalty of not more than the greater of—

(i) \$5,000; or

(ii) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician, as prohibited by section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(11) For each false certification in violation of §1003.200(d), the OIG may impose a penalty of not more than—

(i) \$1,000 with respect to an individual who willfully and knowingly falsely certifies a material and false statement in a resident assessment; and

(ii) \$5,000 with respect to an individual who willfully and knowingly causes another individual to falsely certify a material and false statement in a resident assessment.

(b) **Assessments.** (1) Except for violations of §1003.200(b)(4), (5), and (7), and §1003.200(c) and (d), the OIG may impose an assessment for each individual violation of §1003.200, of not more than 3 times the amount claimed for each item or service.

(2) For violations of §1003.200(b)(4), the OIG may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of §1003.200(b)(7), the OIG may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement, omission, or misrepresentation of material fact.

42 C.F.R. § 1003.220 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND ASSESSMENTS AND THE PERIOD OF EXCLUSION.

In considering the factors listed in §1003.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than \$5,000.

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(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was \$50,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under § 1003.200(b)(3).

SUBPART C—CMPs, ASSESSMENTS, AND EXCLUSIONS FOR ANTI-KICKBACK AND PHYSICIAN SELF-REFERRAL VIOLATIONS

Source: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.300 BASIS FOR CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS.

The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines in accordance with this part—

⁷ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(a) Has not refunded on a timely basis, as defined in §1003.110, amounts collected as a result of billing an individual, third party payer, or other entity for a designated health service furnished pursuant to a prohibited referral as described in 42 CFR 411.353.

(b) Is a physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would be in violation of the prohibitions of 42 CFR 411.353.

(c) Has knowingly presented, or caused to be presented, a claim that is for a payment that such person knows, or should know, may not be made under 42 CFR 411.353;

(d) Has violated section 1128B(b) of the Act by unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by Medicare, Medicaid, or other Federal health care programs.

42 C.F.R. § 1003.310 AMOUNT OF PENALTIES AND ASSESSMENTS.

(a) *Penalties.*⁷

The OIG may impose a penalty of not more than—

(1) \$15,000 for each claim or bill for a designated health service, as defined in §411.351

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of this title, that is subject to a determination under §1003.300(a) or (c);

(2) \$100,000 for each arrangement or scheme that is subject to a determination under §1003.300(b); and

(3) \$50,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under §1003.300(d).

(b) *Assessments*. The OIG may impose an assessment of not more than 3 times—

(1) The amount claimed for each designated health service that is subject to a determination under §1003.300(a), (b), or (c).

(2) The total remuneration offered, paid, solicited, or received that is subject to a determination under §1003.300(d). Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

42 C.F.R. § 1003.320 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND ASSESSMENTS AND THE PERIOD OF EXCLUSION.

In considering the factors listed in §1003.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was \$50,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

SUBPART D—CMPs AND ASSESSMENTS FOR CONTRACTING ORGANIZATION MISCONDUCT

Source: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.400 BASIS FOR CIVIL MONEY PENALTIES AND ASSESSMENTS.

(a) *All contracting organizations*. The OIG may impose a penalty against any contracting organization that—

(1) Fails substantially to provide an enrollee with medically necessary items and services that are required (under the Act, applicable regulations, or contract with the Department or a State) to be provided to such enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(2) Imposes a premium on an enrollee in excess of the amounts permitted under the Act;

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(3) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by the Act;

(4) Misrepresents or falsifies information furnished to a person under sections 1857, 1860D-12, 1876, or 1903(m) of the Act;

(5) Misrepresents or falsifies information furnished to the Secretary or a State, as applicable, under sections 1857, 1860D-12, 1876, or 1903(m) of the Act;

(6) Fails to comply with the requirements of 42 CFR 417.479(d) through (i) for Medicare and 42 CFR 417.479(d) through (g) and (i) for Medicaid regarding certain prohibited incentive payments to physicians; or

(7) Fails to comply with applicable requirements of the Act regarding prompt payment of claims.

(b) **All Medicare contracting organizations.** The OIG may impose a penalty against any contracting organization with a contract under section 1857, 1860D-12, or 1876 of the Act that—

(1) Acts to expel or to refuse to reenroll a beneficiary in violation of the Act; or

(2) Employs or contracts with a person excluded, under section 1128 or 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person.

(c) **Medicare Advantage and Part D contracting organizations.** The OIG may impose a penalty, and for §1003.400(c)(4) or (5), an assessment, against a contracting organization with a contract under section 1857 or 1860D-12 of the Act that:

(1) Enrolls an individual without the individual's (or his or her designee's) prior consent, except as provided under subparagraph (C) or (D) of section 1860D-1(b)(1) of the Act;

(2) Transfers an enrollee from one plan to another without the individual's (or his or her designee's) prior consent;

(3) Transfers an enrollee solely for the purpose of earning a commission;

(4) Fails to comply with marketing restrictions described in subsection (h) or (j) of section 1851 of the Act or applicable implementing regulations or guidance; or

(5) Employs or contracts with any person who engages in the conduct described in paragraphs (a) through (c) of this section.

(d) **Medicare Advantage contracting organizations.** The OIG may impose a penalty against a contracting organization with a contract under section 1857 of the Act that fails to comply with the requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) of the Act.

(e) **Medicaid contracting organizations.** The OIG may impose a penalty against any contracting organization with a contract under section 1903(m) of the Act that acts to discriminate among individuals in violation of the Act, including expulsion or refusal to reenroll an individual or engaging in any practice that would reasonably be expected to have the effect of

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denying or discouraging enrollment by eligible individuals with the contracting organization whose medical condition or history indicates a need for substantial future medical services.

42 C.F.R. § 1003.410 AMOUNT OF PENALTIES AND ASSESSMENTS FOR CONTRACTING ORGANIZATION.

(a) *Penalties.*⁸

(1) The OIG may impose a penalty of up to \$25,000 for each individual violation under §1001.400, except as provided in this section.

(2) The OIG may impose a penalty of up to \$100,000 for each individual violation under §1003.400(a)(3), (a)(5), or (e).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the OIG may impose—

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of §1003.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional \$15,000⁹ penalty for each individual expelled or not enrolled in violation of §1003.400(a)(3) or (e).

(c) *Assessments.* The OIG may impose an assessment against a contracting organization with a contract under section 1857 or 1860D-12 of the Act (Medicare Advantage or Part D) of not more than the amount claimed in violation of

§1003.400(a)(4) or (a)(5) on the basis of the misrepresentation or falsified information involved.

(d) The OIG may impose a penalty or, when applicable, an assessment, against a contracting organization with a contract under section 1857 or 1860D-12 of the Act (Medicare Advantage or Part D) if any of its employees, agents, or contracting providers or suppliers engages in any of the conduct described in §1003.400(a) through (d).

42 C.F.R. § 1003.420 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND ASSESSMENTS.

In considering the factors listed in §1003.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was \$15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit

⁸ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

⁹ This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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medically necessary services provided with respect to a specific enrollee in the organization.

SUBPART E—CMPS AND EXCLUSIONS FOR EMTALA VIOLATIONS

Source: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.500 BASIS FOR CIVIL MONEY PENALTIES AND EXCLUSIONS.

(a) The OIG may impose a penalty against any participating hospital with an emergency department or specialized capabilities or facilities for each negligent violation of section 1867 of the Act or §489.24 (other than §489.24(j)) of this title.

(b) The OIG may impose a penalty against any responsible physician for each—

(1) Negligent violation of section 1867 of the Act;

(2) Certification signed under section 1867(c)(1)(A) of the Act if the physician knew, or should have known, that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(3) Misrepresentation made concerning an individual’s condition or other information, including a hospital’s obligations under section 1867 of the Act.

(c) The OIG may, in lieu of or in addition to any penalty available under this subpart, exclude any responsible physician who commits a gross and flagrant, or repeated, violation of this subpart

from participation in Federal health care programs.

(d) For purposes of this subpart, a “gross and flagrant violation” is a violation that presents an imminent danger to the health, safety, or well-being of the individual who seeks examination and treatment or places that individual unnecessarily in a high-risk situation.

42 C.F.R. § 1003.510 AMOUNT OF PENALTIES.

The OIG may impose¹⁰—

(a) Against each participating hospital, a penalty of not more than \$50,000 for each individual violation, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed \$25,000 for each violation, and

(b) Against each responsible physician, a penalty of not more than \$50,000 for each individual violation.

42 C.F.R. § 1003.520 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND THE PERIOD OF EXCLUSION.

In considering the factors listed in §1003.140,

(a) It should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation. For purposes of this subpart, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of section 1867 of the Act and must include

¹⁰ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

(b) Aggravating circumstances include:

(1) Requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition;

(2) Patient harm, or risk of patient harm, resulted from the incident; or

(3) The individual presented to the hospital with a request for examination or treatment of a medical condition that was an emergency medical condition, as defined by §489.24(b) of this title.

SUBPART F—CMPs FOR SECTION 1140 VIOLATIONS

Source: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.600 BASIS FOR CIVIL MONEY PENALTIES.

(a) The OIG may impose a penalty against any person who it determines in accordance with this part has used the words, letters, symbols, or emblems as defined in paragraph (b) of this section in such a manner that such person knew, or should have known, would convey, or in a manner that reasonably could be interpreted or construed as conveying, the false impression that an advertisement, a solicitation, or other item was authorized, approved, or endorsed by the Department or CMS or that such person or

organization has some connection with or authorization from the Department or CMS.

(b) Civil money penalties may be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department, or its programs, for misuse of—

(1) The words “Department of Health and Human Services,” “Health and Human Services,” “Centers for Medicare & Medicaid Services,” “Medicare,” or “Medicaid” or any other combination or variations of such words;

(2) The letters “DHHS,” “HHS,” or “CMS,” or any other combination or variation of such letters; or

(3) A symbol or an emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under Title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems.

(c) Civil money penalties will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that uses any symbol or emblem or any words or letters that specifically identify that agency or instrumentality of the State or political subdivision.

42 C.F.R. § 1003.610 AMOUNT OF PENALTIES.

BLUE UNDERLINE = INSERTION; ~~RED STRIKETHROUGH~~ = DELETION

(a) The OIG may impose a penalty of not more than¹¹—

(1) \$5,000 for each individual violation resulting from the misuse of Departmental, CMS, or Medicare or Medicaid program words, letters, symbols, or emblems as described in §1003.600(a) relating to printed media;

(2) \$5,000 for each individual violation in the case of such misuse related to an electronic communication, Web page, or telemarketing solicitation;

(3) \$25,000 for each individual violation in the case of such misuse related to a broadcast or telecast.

(b) For purposes of this paragraph, a **violation** is defined as—

(1) In the case of a direct mailing solicitation or advertisement, each separate piece of mail that contains one or more words, letters, symbols, or emblems related to a determination under §1003.600(a);

(2) In the case of a printed solicitation or advertisement, each reproduction, reprinting, or distribution of such item related to a determination under §1003.600(a);

(3) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under §1003.600(a);

(4) In the case of an electronic communication, each dissemination, viewing, or accessing of the electronic communication that contains one or more words, letters, symbols, or

emblems related to a determination under §1003.600(a);

(5) In the case of a **Web page accessed by a computer or other electronic** means, each instance in which the Web page was viewed or accessed and that Web page contains one or more words, letters, symbols, or emblems related to a determination under §1003.600(a); and

(6) In the case of a telemarketing solicitation, each individual unsolicited telephone call regarding an item or service under Medicare or Medicaid related to a determination under §1003.600(a).

42 C.F.R. §1003.620 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

(a) In considering the factors listed in §1003.140, the following circumstances are to be considered—

(1) The nature and objective of the advertisement, solicitation, or other communication and the degree to which it had the capacity to deceive members of the public;

(2) The frequency and scope of the violation and whether a specific segment of the population was targeted; and

(3) The prior history of the individual, organization, or entity in its willingness or refusal to comply with a formal or informal request to correct violations.

(b) The use of a disclaimer of affiliation with the United States Government, the Department, or its programs will not be considered as a

¹¹ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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mitigating factor in determining the amount of penalty in accordance with §1003.600(a).

SUBPART G [RESERVED]

SUBPART H—CMPs FOR ADVERSE ACTION REPORTING AND DISCLOSURE VIOLATIONS

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.800 BASIS FOR CIVIL MONEY PENALTIES.

The OIG may impose a penalty against any person (including an insurance company) who it determines—

(a) Fails to report information concerning—

(1) A payment made under an insurance policy, self-insurance, or otherwise for the benefit of a physician, dentist, or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist, or other practitioner in accordance with section 421 of Public Law 99-660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60 or

(2) An adverse action required to be reported under section 1128E, as established by section 221 of Public Law 104-191.

(b) Improperly discloses, uses, or permits access to information reported in accordance with Part B of Title IV of Public Law 99-660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance

with Part B of Title IV in response to a subpoena or a discovery request is considered an improper disclosure in violation of section 427 of Public Law 99-660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered an improper disclosure in violation of section 427 of Public Law 99-660.)

42 C.F.R. § 1003.810 AMOUNT OF PENALTIES.

The OIG may impose a penalty of not more than¹²—

(a) \$11,000 for each payment for which there was a failure to report required information in accordance with §1003.800(a)(1) or for each improper disclosure, use, or access to information in accordance with a determination under §1003.800(b); and

(b) \$25,000 against a health plan for each failure to report information on an adverse action required to be reported in accordance with section 1128E of the Act and §1003.800(a)(2).

42 C.F.R. § 1003.820 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

In determining the amount of any penalty in accordance with this subpart, the OIG will consider the factors listed in §1003.140.

SUBPART I—CMPs FOR SELECT AGENT PROGRAM VIOLATIONS

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

¹² The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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42 C.F.R. § 1003.900 BASIS FOR CIVIL MONEY PENALTIES.

The OIG may impose a penalty against any person who it determines in accordance with this part is involved in the possession or use in the United States, receipt from outside the United States or transfer within the United States, of select agents and toxins in violation of sections 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73.

42 C.F.R. § 1003.910 AMOUNT OF PENALTIES.

For each individual violation of section 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73, the OIG may impose a penalty of not more than \$250,000 in the case of an individual, and not more than \$500,000 in the case of any other person.¹⁵

42 C.F.R. § 1003.920 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

In considering the factors listed in §1003.140, aggravating circumstances include:

- (a) The Responsible Official participated in or knew, or should have known, of the violation;
- (b) The violation was a contributing factor to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person's physical location as identified on the person's certificate of registration; or

(c) The person previously received an observation, finding, or other statement of deficiency from the Department or the Department of Agriculture for the same or substantially similar conduct.

SUBPART J—CMPs, ASSESSMENTS, AND EXCLUSIONS FOR BENEFICIARY INDUCEMENT VIOLATIONS

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.1000 BASIS FOR CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS.

(a) The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines offers or transfers remuneration (as defined in §1003.110) to any individual eligible for benefits under Medicare or a State health care program that such person knows, or should know, is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier, any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(b) The OIG may impose a penalty against any person who it determines offered any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act.

¹⁵ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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42 C.F.R. § 1003.1010 AMOUNT OF PENALTIES AND ASSESSMENTS.

The OIG may impose a penalty of not more than¹⁴—

(a) \$10,000 for each item or service for which payment may be made, in whole or in part, under Medicare or a State health care program, ordered by or received from a particular provider, practitioner, or supplier for a beneficiary who was offered or received remuneration in violation of §1003.1000(a) that was likely to influence the beneficiary to order or receive the item or service from the provider, practitioner, or supplier, and an assessment of not more than 3 times the amount claimed for each such item or service and

(b) \$5,000 for each individual violation of §1003.1000(b).

42 C.F.R. § 1003.1020 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES AND ASSESSMENTS AND THE PERIOD OF EXCLUSION.

In determining the amount of any penalty or assessment or the period of exclusion under this subpart, the OIG will consider the factors listed in § 1003.140, as well as the amount of remuneration or the amount or nature of any other incentive.

SUBPART K—CMPs FOR THE SALE OF MEDICARE SUPPLEMENTAL POLICIES

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.1100 BASIS FOR CIVIL MONEY PENALTIES.

The OIG may impose a penalty against any person who—

(a) Knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to—

(1) The compliance of any policy with the standards and requirements for Medicare supplemental policies set forth in section 1882(c) of the Act or in promulgating regulations, or

(2) The use of the emblem designed by the Secretary under section 1882(a) of the Act for use as an indication that a policy has received the Secretary's certification;

(b) Falsely assumes or pretends to be acting, or misrepresents in any way that he or she is acting, under the authority of or in association with Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value;

(c) Knowingly, directly, or through his or her agent, mails or causes to be mailed any matter for the advertising, solicitation, or offer for sale of a Medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance;

(d) Issues or sells to any individual entitled to benefits under Part A or enrolled under Part B of Medicare—

¹⁴ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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(1) A health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid,

(2) A health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law,

(3) In the case of an individual not electing a Part C plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another Medicare supplemental policy, or

(4) In the case of an individual electing a Part C plan, a Medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Part C plan or under another Medicare supplemental policy;

(e) Issues or sells a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III)) to any individual entitled to benefits under Medicare Part A or enrolled under Medicare Part B who is applying for a health insurance policy and fails to furnish the appropriate disclosure statement described in section 1882(d)(3)(A)(vii); or

(f) Issues or sells a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Medicare Part B without obtaining the written statement or the written

acknowledgment described in section 1882(d)(3)(B) of the Act.

42 C.F.R. § 1003.1110 AMOUNT OF PENALTIES.

The OIG may impose a penalty of not more than¹⁵—

(a) \$5,000 for each individual violation of §1003.1100(a), (b), or (c).

(b) \$25,000 for each individual violation of §1003.1100(d), (e), or (f) by a seller who is also the issuer of the policy; and

(c) \$15,000 for each individual violation of §1003.1100(d), (e), or (f) by a seller who is not the issuer of the policy.

42 C.F.R. § 1003.1120 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in §1003.140.

SUBPART L—CMPs FOR DRUG PRICE REPORTING

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.1200 BASIS FOR CIVIL MONEY PENALTIES.

The OIG may impose a penalty against—

(a) Any wholesaler, manufacturer, or direct seller of a covered outpatient drug that—

¹⁵ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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(1) Refuses a request for information by,
or

(2) Knowingly provides false information to, the Secretary about charges or prices in connection with a survey being conducted pursuant to section 1927(b)(3)(B) of the Act; and

(b) Any manufacturer with an agreement under section 1927 of the Act that—

(1) Fails to provide any information required by section 1927(b)(3)(A) of the Act by the deadlines specified therein, or

(2) Knowingly provides any item information required by section 1927(b)(3)(A) or (B) of the Act that is false.

42 C.F.R. § 1003.1210 AMOUNT OF PENALTIES.

The OIG may impose a penalty of not more than¹⁶—

(a) \$100,000 for each individual violation of §1003.1200(a) or §1003.1200(b)(2); and

(b) \$10,000 for each day that such information has not been provided in violation of §1003.1200(b)(1).

42 C.F.R. § 1003.1220 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

¹⁶ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

SUBPART M—CMPs FOR NOTIFYING A SKILLED NURSING FACILITY, NURSING FACILITY, HOME HEALTH AGENCY, OR COMMUNITY CARE SETTING OF A SURVEY

Source: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.1300 BASIS FOR CIVIL MONEY PENALTIES.

The OIG may impose a penalty against any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, a community care setting, of the time or date on which a survey pursuant to sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), or 1929(i) of the Act is scheduled to be conducted.

42 C.F.R. § 1003.1310 AMOUNT OF PENALTIES.

The OIG may impose a penalty of not more than \$2,000 for each individual violation of § 1003.1300.¹⁷

42 C.F.R. § 1003.1320 DETERMINATIONS REGARDING THE AMOUNT OF PENALTIES.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

SUBPART N [RESERVED]

SUBPART O—PROCEDURES FOR THE IMPOSITION OF CMPs, ASSESSMENTS, AND EXCLUSIONS

¹⁷ This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

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Source: 81 FR 88364, Dec. 7, 2016, unless otherwise noted.

42 C.F.R. § 1003.1500 NOTICE OF PROPOSED DETERMINATION.

(a) If the OIG proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in all Federal health care programs, as applicable, in accordance with this part, the OIG must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice of the OIG’s intent to impose a penalty, an assessment, and an exclusion, as applicable. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment, and exclusion;

(2) A description of the violation for which the penalty, assessment, and exclusion are proposed (except in cases in which the OIG is relying upon statistical sampling in accordance with §1003.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the OIG is relying and will briefly describe the statistical sampling technique used by the OIG);

(3) The reason why such violation subjects the respondent to a penalty, an assessment, and an exclusion,

(4) The amount of the proposed penalty and assessment, and the length of the period of proposed exclusion (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty

and assessment and the length of the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent’s right to a hearing and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the respondent’s provider agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the OIG has proposed the imposition of a penalty, an assessment, or an exclusion may appeal such proposed penalty, assessment, or exclusion to the Departmental Appeals Board in accordance with 42 CFR 1005.2. The provisions of 42 CFR part 1005 govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

42 C.F.R. § 1003.1510 FAILURE TO REQUEST A HEARING.

If the respondent does not request a hearing within 60 days after the notice prescribed by §1003.1500(a) is received, as determined by 42 CFR 1005.2(c), by the respondent, the OIG may impose the proposed penalty, assessment, and

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exclusion, or any less severe penalty, assessment, or exclusion. The OIG shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty, assessment, and exclusion that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment, or an exclusion with respect to which he or she has not made a timely request for a hearing under 42 CFR 1005.2.

42 C.F.R. § 1003.1520 COLLATERAL ESTOPPEL.

(a) Where a final determination pertaining to the respondent's liability for acts that violate this part has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action.

42 C.F.R. § 1003.1530 SETTLEMENT.

The OIG has exclusive authority to settle any issues or case without consent of the ALJ.

42 C.F.R. § 1003.1540 JUDICIAL REVIEW.

(a) Section 1128A(e) of the Act authorizes judicial review of a penalty, an assessment, or an exclusion that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to 42 CFR 1005.21, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Act, concerning any penalty, assessment, or exclusion imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with 42 CFR 1005.21(j).

42 C.F.R. § 1003.1550 COLLECTION OF PENALTIES AND ASSESSMENTS.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health Services Block Grant Program, in which the collection will be the responsibility of the Public Health Service (PHS); in the case of the Social Services Block Grant program, in which the collection will be the responsibility of the Administration for Children and Families; and in the case of violations of subpart I, collection will be the responsibility of the Program Support Center (PSC).

(b) A penalty or an assessment imposed under this part may be compromised by the OIG and may be recovered in a civil action brought in the United States district court for the district where

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the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

42 C.F.R. § 1003.1560 NOTICE TO OTHER AGENCIES.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate State licensing authority, the State Office of Aging, the long-term-care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

42 C.F.R. § 1003.1570 LIMITATIONS.

No action under this part will be entertained unless commenced, in accordance with §1003.1500(a), within 6 years from the date on which the violation occurred.

42 C.F.R. § 1003.1580 STATISTICAL SAMPLING.

(a) In meeting the burden of proof in 42 CFR 1005.15, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment, as described in this part.

(b) Once the OIG has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

42 C.F.R. § 1003.1590 EFFECT OF EXCLUSION.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

42 C.F.R. § 1003.1600 REINSTATEMENT.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in

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accordance with the provisions of 42 CFR
1001.3001 through 1001.3004.

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