

Redline Comparing Existing AKS Safe Harbor Regulations (as of November 23, 2020) to Final AKS Safe Harbor “Regulatory Sprint” Regulations (to be effective January 19, 2021)¹

Provided by Dorsey & Whitney LLP

Title 42: Public Health
PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS
Subpart C—Permissive Exclusions

§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

¹ This redline includes the final rules to revise the AKS safe harbor regulations as part of the HHS “Regulatory Sprint to Coordinated Care,” based on the public inspection copy of these final rules that was released on November 20, 2020 (available at <https://public-inspection.federalregister.gov/2020-26072.pdf>). This redline does *not* include separate final rules to revise the AKS safe harbor regulations that were also released in public inspection form on November 20, 2020 (at <https://public-inspection.federalregister.gov/2020-25841.pdf>)—specifically: (1) revisions to the safe harbor for discounts at §1001.952(h); and (2) new safe harbors for (a) point-of-sale reductions in price for prescription pharmaceutical products (to be added at §1001.952(cc)); and (b) PBM service fees (to be added at §1001.952(dd)).

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.

(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—

(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.

(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 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—:

~~(4)~~i) The agency agreement is set out in writing and signed by the parties.

~~(2)~~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.~~

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

~~(5)~~iv) 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.

~~(6)~~v) 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.

~~(7)~~vi) 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.

(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) ~~of this section, an:~~

(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

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

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

(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—

(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~~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 through~~ ~~(g)(4)~~(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.

(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 item~~, ~~which was~~ items and services) 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)~~(g)(1) and ~~(a)~~(g)(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), 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

~~For purposes of paragraph (g) of this section, the term warranty means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6)(iii), 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.

(h) *Discounts.*² 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

² As noted above, this redline does not include separate final rules to revise the AKS safe harbor regulations that were also released in public inspection form on November 20, 2020 (at <https://public-inspection.federalregister.gov/2020-25841.pdf>), which include revisions to the safe harbor for discounts at §1001.952(h).

(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 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 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;

(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 paragraph (h)(5) of this section.

(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, 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 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.

(l) *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 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 (l) 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.

(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 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 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.

(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.

(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

(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 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 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 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;

(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 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*¹ means—

¹The 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.

(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.

(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, 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

(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.

(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 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 (l)(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;

(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 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 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, 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 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 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.

(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.

(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 ~~provides~~;

(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;

(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 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 ~~pays~~ must pay 15 percent of the donor's cost ~~for~~ 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.

(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) ~~of this section, health, the following definitions apply:~~

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

(ii) Health plan shall have the meaning set forth at § 1001.952(l)(2); ~~interoperable.~~

(iii) Interoperable shall mean able to ~~communicate and;~~

(A) Securely exchange data ~~accurately, effectively, securely, and consistently with different~~ with and use data from other health information technology ~~systems, 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; and electronic; and~~

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

(iv) 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)):

(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;

(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), ~~an~~ the following definitions apply:

(i) 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 paragraph (bb)(3)(v) of this rule; ~~and~~ section.

(v) An urban area ~~as is:~~

(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)~~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)-(dd) [Reserved]³

(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;

³ As noted above, this redline does not include separate final rules to revise the AKS safe harbor regulations that were also released in public inspection form on November 20, 2020 (at <https://public-inspection.federalregister.gov/2020-25841.pdf>), which include new safe harbors for (1) point-of-sale reductions in price for prescription pharmaceutical products (to be added at §1001.952(cc)); and (2) PBM service fees (to be added at §1001.952(dd)).

(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

(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 valuebased 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 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 valuebased 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 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 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:

(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 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

(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.

(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 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;

(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.

(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 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 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 (j)(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.