SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

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SOURCE: 57 FR 3330, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and,

where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 64 FR 39426, July 22, 1999]

§ 1001.2 Definitions.

For purposes of this part:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

HHS means Department of Health and Human Services.

Immediate family member means a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10-percent ownership interest in the entity at issue if he or she has a 20-percent ownership interest in a corporation that wholly owns a subsidiary that is a 50-percent owner of the entity in issue.)

Managing employee means an individual (including a general manager, business manager, administrator, or director) who exercises operational or managerial control over the entity or part thereof or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

Member of household means, with respect to a person, any individual with whom the person is sharing a common abode as part of a single-family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

Ownership interest means an interest in:

(1) The capital, the stock, or the profits of the entity, or

(2) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

Ownership or control interest means, with respect to an entity, a person who

(1) Has a direct or an indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(2) Is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, if such interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(3) Is an officer or a director of the entity;

(4) Is a partner in the entity if the entity is organized as a partnership;

(5) Is an agent of the entity; or

(6) Is a managing employee of the entity.

Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or

emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided.

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage area for that medical specialty, as listed in 42 part 5, appendices B–F;

(2) Is a sole community hospital, as defined in § 412.92 of this title; or

(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and § 1002.305 of this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 82 FR 4111, Jan. 12, 2017]

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996, relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

(2) Holds, or has held, a direct or an indirect ownership or control interest

in an entity that furnished or furnishes items or services or is, or has ever been, an officer, director, agent, or managing employee of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998, as amended at 67 FR 11932, Mar. 18, 2002; 82 FR 4112, Jan. 12, 2017]

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with §1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, caused, or were intended to cause, a financial loss to a government agency or program or to one or more other entities of $50,000 or more. (The entire amount of financial loss to such government agencies or programs or to other entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts;

(5) The sentence imposed by the court included incarceration;

(6) The convicted individual or entity has a prior criminal, civil or administrative sanction record;

(7) The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances;

(8) The individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) In the case of an exclusion under §1001.101(a), whether the individual or entity was convicted of three or fewer misdemeanor offenses and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State, or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than $5,000;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

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

(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

(d) In the case of an exclusion under this subpart, based on a conviction occurring on or after August 5, 1997, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one previous occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the

Act. (The aggravating and mitigating factors in paragraphs (b) and (c) of this section can be used to impose a period of time in excess of the 10-year mandatory exclusion); or

(2) Permanent if the individual has been convicted on two or more previous occasions of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 63 FR 57918, Oct. 29, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002; 82 FR 4112, Jan. 12, 2017]

Subpart C—Permissive Exclusions

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(ii) With respect to any act or omission in a health care program, other than Medicare and a State health care program, operated by, or financed in whole or in part by, any Federal, State or local government agency; or

(2) Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated by or financed in whole or in part by any Federal, State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, caused or reasonably could have been expected to cause, a financial loss of $50,000 or more to a government agency or program or to one or more other entities or had a significant financial impact on program beneficiaries or other individuals. (The entire amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of three or fewer offenses, and the entire amount of financial loss (both actual loss and reasonably expected loss) to a government agency or program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $5,000;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional, or physical condition, before or during the commission of the offense, that reduced the individual's culpability; or

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

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002; 67 FR 21579, May 1, 2002; 82 FR 4112, Jan. 12, 2017]

§ 1001.301 Conviction relating to obstruction of an investigation or audit.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit related to—

(1) Any offense described in § 1001.101 or § 1001.201; or

(2) The use of funds received, directly or indirectly, from any Federal health care program.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of three years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference or obstruction caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion;

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

(viii) The acts resulting in the conviction, or similar acts, caused, or reasonably could have been expected to cause, a financial loss of $50,000 or more to a government agency or program or to one or more other entities or had a significant financial impact on program beneficiaries or other individuals. (The entire amount of financial loss or intended loss identified in the investigation or audit will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made).

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional, or physical condition, before or during the commission of the offense, that reduced the individual's culpability; or

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

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992; 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 82 FR 4112, Jan. 12, 2017]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

(2) Holds, or held, a direct or indirect ownership or control interest in an entity that furnished or furnishes items or services or is or has ever been an officer, director, agent, or managing employee of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and to be a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;

(iii) The sentence imposed by the court included incarceration;

(iv) Whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing;

(v) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

(3) Only the following factor may be considered to be mitigating and to be a basis for shortening the period of exclusion: The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare, Medicaid, and any other Federal health care program;

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(iii) The imposition of a civil money penalty against others.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 82 FR 4113, Jan. 12, 2017]

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) Except as provided in paragraph (b)(2) of this section, an exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended, or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iii) The acts, or similar acts, had or could have had a significant adverse impact on the financial integrity of the programs; or

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

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with a State licensing authority resulted in—

(i) The sanctioning of other individuals or entities, or

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with §1001.3001 if:

(i) The individual or entity obtains the license in the State where the license was originally revoked, suspended, surrendered, or otherwise lost or

(ii) The individual meets the conditions for early reinstatement set forth in paragraph (c) of this section.

(c) *Consideration of early reinstatement.* (1) If an individual or entity that is excluded in accordance with this section fully and accurately discloses the circumstances surrounding the action that formed the basis for the exclusion to a licensing authority of a different State or to a different licensing authority in the same State and that licensing authority grants the individual or entity a new health care license or has decided to take no adverse action as to a currently held health care license, the OIG will consider a request for early reinstatement. The OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(1) will be granted:

(i) The circumstances that formed the basis for the exclusion;

(ii) Whether the second licensing authority is in a state that is not the individual's primary place of practice;

(iii) Evidence that the second licensing authority was aware of the circumstances surrounding the action that formed the basis for the exclusion;

(iv) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(v) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vii) Any additional or pending license actions in any State;

(viii) Any ongoing investigations involving the individual; and

(ix) All the factors set forth in §1001.3002(b).

(2) If an exclusion has been imposed under this section and the individual does not have a valid health care license of any kind in any State, that individual may request the OIG to consider whether he or she may be eligible

for early reinstatement. The OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(2) will be granted:

(i) The length of time the individual has been excluded. The OIG will apply a presumption against early reinstatement under paragraph (c)(2) of this section if the person has been excluded for less than 3 years; however, if the revocation or suspension on which the exclusion is based was for a set period longer than 3 years, the presumption against early reinstatement will be coterminous with the period set by the licensing board;

(ii) The circumstances that formed the basis for the exclusion;

(iii) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(iv) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(v) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) Any additional or pending license actions in any State;

(vii) Any ongoing investigations involving the individual; and

(viii) All the factors set forth in §1001.3002(b).

(3) Notwithstanding paragraphs (c)(1) and (2) of this section, if an individual's license revocation or suspension was for reasons related to patient abuse or neglect, the OIG will not consider an application for early reinstatement.

(4) Except for §1001.3002(a)(1)(i), all the provisions of subpart F (§§1001.3001 through 1001.3005) apply to early reinstatements under this section.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4113, Jan. 12, 2017]

§1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term ''or otherwise sanctioned'' in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended from a Federal or State health care program.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under Medicare, Medicaid and all other Federal health care programs had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

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

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with Federal or State officials resulted in—

(i) The sanctioning of other individuals or entities, or

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses.

(4) If the individual or entity is eligible to apply for reinstatement in accordance with §1001.3001 and the sole reason why the State or Federal health care program denied reinstatement to that program is the existing exclusion imposed by the OIG as a result of the original State or Federal health care program action, the OIG will consider a request for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4114, Jan. 12, 2017]

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iv) The violation resulted in financial loss to Medicare, Medicaid, or any other Federal health care program of $15,000 or more; or

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

(3) Only the following factor may be considered mitigating and a basis for reducing the period of exclusion: Whether there were few violations and they occurred over a short period of time.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4114, Jan. 12, 2017]

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) *Circumstances for exclusion.* The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) CMS's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service that had or could have had a serious adverse effect;

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

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

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4114, Jan. 12, 2017]

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

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

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

(5) Other matters as justice may require.

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

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

§ 1001.951 Fraud and kickbacks and other prohibited activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Sanctioning of other individuals or entities, or

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

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

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

§ 1001.952 Exceptions.

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

(a) *Investment interests.* As used in section 1128B of the Act, ''remuneration'' does not include any payment

that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

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

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

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

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

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

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

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

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

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

(v) 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.

(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):

(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 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 items and services, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) through (6) of this section:

(1) The buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) 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 standards:

(i) The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free 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 (g)(1) and (2) of this section.

(ii) When the amount of 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 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 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

(iii) 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 paragraph (g)), on terms equal to the agreement that it replaces.

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

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

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

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

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

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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

[1] The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect to items or services covered by the contracts specified in those paragraphs.

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 no 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 nonemergency 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, receive, or protect electronic health records, if all of the conditions in paragraphs (y)(1) through (13) of this section are met:

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

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

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

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

(ii) A health plan.

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

(3) [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) [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) The recipient pays 15 percent of the donor's cost for the items and services. The following conditions apply to such contribution:

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

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

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

(13) [Reserved]

(14) For purposes of this paragraph (y), 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).

(iii) *Interoperable* shall mean able to:

(A) Securely exchange data with and use data from other health information technology; 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 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 75 miles between that stop and any providers or suppliers on the route;

(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.

(3) For purposes of this paragraph (bb), 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, 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 section.

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

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

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

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

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

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

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

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

(i) The PBM has a written agreement with the pharmaceutical manufacturer, signed by the parties, that covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.

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

(iii) The compensation paid to the PBM is:

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

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

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

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

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

(ee) *Care coordination arrangements to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, ''remuneration'' does not include the exchange of anything of value between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement if all of the

standards in paragraphs (ee)(1) through (13) of this section are met:

(1) The remuneration exchanged:

(i) Is in-kind;

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

(iii) Is not exchanged or used:

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

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

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

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

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

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

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

(iv) The target patient population;

(v) A description of the remuneration;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) The value-based arrangement does not:

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

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

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

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

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

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

(8) The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.

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

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

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

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

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

(i) Terminate the arrangement; or

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

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

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

(13) The remuneration is not exchanged by:

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

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

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

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

(vi) Except to the extent the entity or individual is a limited technology participant, an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a 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 (CPI–U) 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 (jj)(1) through (4) of this section are met.

(1) The donor does not:

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

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

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

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

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

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

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

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

(kk) *ACO Beneficiary Incentive Program.* As used in section 1128B of the Act, ''remuneration'' does not include an incentive payment made by an ACO

to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Act, as amended by Congress from time to time, if the incentive payment is made in accordance with the requirements found in such subsection.

[57 FR 3330, Jan. 29, 1992]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1001.952, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstance for exclusion.* The OIG may exclude an entity:

(1) If a person with a relationship with such entity—

(i) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b)(1), (2), or (3) of the Act;

(ii) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(iii) Has been excluded from participation in Medicare or any State health care program, and

(2) Such a person has a direct or indirect ownership or control interest in the entity, or formerly held an ownership or control interest in the entity but no longer holds an ownership or control interest because of a transfer of the interest to an immediate family member or a member of the person's household in anticipation of or following a conviction, imposition of a civil money penalty or assessment under section 1128A of the Act, or imposition of an exclusion.

(b) *Length of exclusion.* (1) Except as provided in §1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in §1001.3001(a)(2).

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999; 82 FR 4114, Jan. 12, 2017]

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

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

(4) Any other facts that bear on the nature or seriousness of the conduct; and

(5) The extent to which the entity knew that the disclosures made were not full or accurate.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 82 FR 4115, Jan. 12, 2017]

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes, orders, refers for furnishing, or certifies the need for items or services for which payment may be made under Medicare or any of the State health care programs and that—

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue; and

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

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 82 FR 4115, Jan. 12, 2017]

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for individuals with intellectual disabilities), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for reviewing records, documents, and other material or data in any medium (including electronically stored information and any tangible thing) necessary to the OIG's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Reasonable request means a written request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized entity, during hours that the facility, agency or institution is open for business.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the

penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means—

(i) The failure to produce or make available for inspection and copying the requested material upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request, except when the OIG or State Medicaid Fraud Control Unit (MFCU) reasonably believes that the requested material is about to be altered or destroyed, or

(ii) When the OIG or MFCU has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

Reasonable request means a written request, signed by a designated representative of the OIG or MFCU and made by a properly identified agent of the OIG or an MFCU during reasonable business hours, where there is information to suggest that the person has violated statutory or regulatory requirements under Titles V, XI, XVIII, XIX, or XX of the Act. The request will include a statement of the authority for the request, the person's rights in responding to the request, the definition of ''reasonable request'' and ''failure to grant immediate access'' under part 1001, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

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

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993; 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999; 82 FR 4115, Jan. 12, 2017]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that CMS determines has failed substantially to comply with a corrective action plan required by CMS under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

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

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the administrator of the health education loan, scholarship, or loan repayment program determines is in default on repayments of scholarship obligations or loans, or the obligations of any loan repayment program, in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that the administrator of the health education loan, scholarship, or loan repayment program has taken all reasonable administrative steps to secure repayment of the loans or obligations. When an individual has been offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare, Medicaid or other Federal health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until the administrator of the health education loan, scholarship, or loan repayment program notifies the OIG that the default has been cured or that there is no longer an outstanding debt. Upon such notice, the OIG will inform the individual of his or her right to apply for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999; 67 FR 11935, Mar. 18, 2002; 82 FR 4115, Jan. 12, 2017]

§ 1001.1551 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term ''sanctioned entity'' means an entity that—

(1) Has been convicted of any offense described in §§ 1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare, Medicaid and all other Federal health care programs.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in § 1001.3001.

[63 FR 46689, Sept. 2, 1998. Redesignated and amended at 82 FR 4115, Jan. 12, 2017]

§ 1001.1552 Making false statements or misrepresentation of material facts.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has knowingly made or caused to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal

health care program, including Medicare Advantage organizations under Part C of Medicare, prescription drug plan sponsors under Part D of Medicare, Medicaid managed care organizations, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.

(b) *Definition of ''Material''.* For purposes of this section, the term ''material'' means having a natural tendency to influence or be capable of influencing the decision to approve or deny the request to participate or enroll as a provider of services or supplier under a Federal health care program.

(c) *Sources.* The OIG's determination under paragraph (a) of this section will be made on the basis of information from the following sources:

(1) CMS;

(2) Medicaid State agencies;

(3) Fiscal agents or contractors or private insurance companies;

(4) Law enforcement agencies;

(5) State or local licensing or certification authorities;

(6) State or local professional societies; or

(7) Any other sources deemed appropriate by the OIG.

(d) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors:

(1) The nature and circumstances surrounding the false statement;

(2) Whether and to what extent payments were requested or received from the Federal health care program under the application, agreement, bid, or contract on which the false statement, omission, or misrepresentation was made; and

(3) Whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing.

[82 FR 4115, Jan. 12, 2017]

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and''

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges; and

(iv) Whether the physician has a documented history of criminal, civil, or administrative wrongdoing (the lack of any prior record is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 82 FR 4116, Jan. 12, 2017]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) *Circumstance for exclusion.* The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled

under Part B of the Medicare program (or his or her representative) for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier; and

(v) Whether the physician has a documented history of criminal, civil, or administrative wrongdoing (the lack of any prior record is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 82 FR 4116, Jan. 12, 2017]

APPENDIX A TO SUBPART C OF PART 1001

The following is a sample written disclosure for purposes of satisfying the requirements of §1001.952(v)(3)(i)(B)(*1*)(*i*) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in §1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated:____

/s/____

Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from the administrator of a Federal health care program (as defined in section 1128B(f) of the Act) that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) With respect to exclusions under § 1001.101(a), (c), or (d), a request from a Federal health care program for a waiver of the exclusion will be considered only if the Federal health care program administrator determines that—

(1) The individual or entity is the sole community physician or the sole source of essential specialized services in a community; and

(2) The exclusion would impose a hardship on beneficiaries (as defined in section 1128A(i)(5) of the Act) of that program.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

[57 FR 3330, Jan. 29, 1992, as amended at 82 FR 4116, Jan. 12, 2017]

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid, and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, including Medicare Advantage and Prescription Drug Plans, Medicaid, or any other Federal health care program for any item or service furnished, on or after the effective date specified in the notice—

(i) By an excluded individual or entity; or

(ii) At the medical direction or on the prescription of a physician or an authorized individual who is excluded when the person furnishing such item or service knew, or had reason to know, of the exclusion.

(2) This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(3) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(4) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made, for items or services furnished, ordered, or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B

of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995; 63 FR 46690, Sept. 2, 1998; 64 FR 39427, July 22, 1999; 82 FR 4116, Jan. 12, 2017]

Subpart E—Notice and Appeals

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG intends to exclude an individual or entity under the provisions of §1001.701, §1001.801, or §1001.1552, in conjunction with the submission of documentary evidence and

written argument, an individual or entity may request an opportunity to present oral argument to an OIG official.

(c) *Exception.* If the OIG intends to exclude an individual or entity under the provisions of §1001.901, §1001.951, §1001.1301, §1001.1401, §1001.1601, or §1001.1701, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

[63 FR 46690, Sept. 2, 1998, as amended at 63 FR 57918, Oct. 29, 1998; 82 FR 4116, Jan. 12, 2017]

§1001.2002 Notice of exclusion.

(a) Except as provided in §1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with §1001.1301.

(e) No later than 15 days prior to the final exhibit exchanges required under §1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §1001.901, §1001.951, §1001.1601, or §1001.1701, it will send a written notice of proposal to exclude to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in §1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b) If the individual or entity makes a timely written request for a hearing and the OIG has determined that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect as of the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior

to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 65 FR 24414, Apr. 26, 2000; 82 FR 4116, Jan. 12, 2017]

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual is known to be serving as an employee, administrator, operator, or in which the individual is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect CMS's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Quality Improvement Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act;

(8) The National Practitioner Data Bank.

(9) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability by Federal, State or local court, a determination by another Government agency, or any other prior determination where the facts were adjudicated

and a final decision was made, the basis for the underlying conviction, civil judgment or determination is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

[57 FR 3330, Jan. 29, 1992, as amended at 67 FR 11935, Mar. 18, 2002]

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraph (a)(2) of this section or in § 1001.501(b)(2), § 1001.501(c), or § 1001.601(b)(4), an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Obtaining a program provider number or equivalent does not reinstate eligibility.

(2) An entity excluded under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(b) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(c) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 82 FR 4117, Jan. 12, 2017]

§ 1001.3002 Basis for reinstatement.

(a) The OIG will authorize reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(3) There is no additional basis under sections 1128(a) or (b) or 1128A of the Act for continuation of the exclusion.

(b) In making the reinstatement determination described in paragraph (a) of this section, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, and all other Federal health care programs have been paid or satisfactory arrangements have been made to fulfill obligations;

(4) Whether CMS has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations;

(5) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered, or prescribed, including health care administrative services. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated; and

(c) If the OIG determines that the criteria in paragraphs (a)(2) and (3) of this section have been met, an entity excluded in accordance with §1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion, or civil money penalty was the basis for the entity's exclusion—

(1) Has properly reduced his or her ownership or control interest in the entity below 5 percent;

(2) Is no longer an officer, director, agent or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or §1001.3005.

(d) Reinstatement will not be effective until the OIG grants the request and provides notice under §1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in §1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 64 FR 39427, July 22, 1999; 82 FR 4117, Jan. 12, 2017]

§1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify CMS of the date of the individual's or entity's reinstatement;

(3) Notify appropriate Federal and State agencies that administer health care programs that the individual or entity has been reinstated into all Federal health care programs; and

(4) To the extent applicable, give notice to others that were originally notified of the exclusion.

(b) A determination by the OIG to reinstate an individual or entity has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities.

[64 FR 39428, July 22, 1999]

§1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until at least one year after the date of denial, or approving the request consistent with the procedures set forth in §1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§1001.3005 Withdrawal of exclusion for reversed or vacated decisions.

(a) An exclusion will be withdrawn and an individual or entity will be reinstated into Medicare, Medicaid, and other Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal;

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal; or

(3) An OIG exclusion action that is reversed or vacated at any stage of an individual's or entity's administrative appeal process.

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, CMS and other Federal health care programs will make payment for services covered under such program that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with §1001.3003(a).

(d) An action taken by the OIG under this section will not require any other Federal health care program to reinstate the individual or entity if such program has imposed an exclusion under its own authority.

(e) If an action which results in the retroactive reinstatement of an individual or entity is subsequently overturned, the OIG may reimpose the exclusion for the initial period of time, less the period of time that was served prior to the reinstatement of the individual or entity.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39428, July 22, 1999; 67 FR 11935, Mar. 18, 2002; 82 FR 4117, Jan. 12, 2017]

PART 1002—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

Sec.

Subpart B—State Exclusion of Certain Managed Care Entities

Subpart C—Procedures for State-Initiated Exclusions

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

AUTHORITY: 42 U.S.C. 1302, 1320a–3, 1320a–5, 1320a–7, 1396(a)(4)(A), 1396a(p), 1396a(a)(39), 1396a(a)(41), and 1396b(i)(2).

SOURCE: 57 FR 3343, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1002.1 Basis and scope.

(a) *Statutory basis.* This part implements sections 1902(a)(4), 1902(a)(39), 1902(a)(41), 1902(p), 1903(i)(2), 1124, 1126, and 1128 of the Act.

(1) Under authority of section 1902(a)(4) of the Act, this part sets forth methods of administration and procedures the State agency must follow to exclude a provider from participation in the State Medicaid program. State-initiated exclusion from Medicaid may lead to OIG exclusion from all Federal health care programs.

(2) Under authority of sections 1124 and 1126 of the Act, this part requires the Medicaid agency to obtain and disclose to the OIG certain provider ownership and control information, along with actions taken on a provider's application to participate in the program.

(3) Under authority of sections 1902(a)(41) and 1128 of the Act, this part requires the State agency to notify the OIG of sanctions and other actions the State takes to limit a provider's participation in Medicaid.

(4) Section 1902(p) of the Act permits the State to exclude an individual or entity from Medicaid for any reason the Secretary can exclude and requires the State to exclude certain managed care entities that could be excluded by the OIG.

(5) Sections 1902(a)(39) and 1903(i)(2) of the Act prohibit State payments to providers and deny Federal financial participation (FFP) in State expenditures for items or services furnished by an individual or entity that has been excluded by the OIG from participation in Federal health care programs.

(b) *Scope.* This part specifies certain bases upon which the State may or, in some cases, must exclude an individual or entity from participation in the Medicaid program and the administrative procedures the State must follow to do so. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. In addition,