**(6) Covered recipient**

**(A) In general**

Except as provided in subparagraph (B), the term ''covered recipient'' means the following:

(i) A physician.

(ii) A teaching hospital.

**(B) Exclusion**

Such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

**(7) Employee**

The term ''employee'' has the meaning given such term in section 1395nn(h)(2) of this title.

**(8) Knowingly**

The term ''knowingly'' has the meaning given such term in section 3729(b) of title 31.

**(9) Manufacturer of a covered drug, device, biological, or medical supply**

The term ''manufacturer of a covered drug, device, biological, or medical supply'' means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

**(10) Payment or other transfer of value**

**(A) In general**

The term ''payment or other transfer of value'' means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

**(B) Exclusions**

An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) Product samples that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use.

(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1395nn(c) of this title).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

**(11) Physician**

The term ''physician'' has the meaning given that term in section 1395x(r) of this title.

(Aug. 14, 1935, ch. 531, title XI, § 1128G, as added Pub. L. 111–148, title VI, § 6002, Mar. 23, 2010, 124 Stat. 689.)

### § 1320a–7i. Reporting of information relating to drug samples

**(a) In general**

Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized distributor of record of an applicable drug shall submit to the Secretary (in a form and manner specified by the Secretary) the following information with respect to the preceding year:

(1) In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier under subsection (d)(2) of section 353 of title 21, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individ-

ual who makes or signs for the request on behalf of the practitioner; and

(B) any other category of information determined appropriate by the Secretary.

(2) In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier under subsection (d)(3) of such section 353 of title 21, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

(B) any other category of information determined appropriate by the Secretary.

**(b) Definitions**

In this section:

**(1) Applicable drug**

The term ''applicable drug'' means a drug—

(A) which is subject to subsection (b) of such section 353 of title 21; and

(B) for which payment is available under subchapter XVIII or a State plan under subchapter XIX or XXI (or a waiver of such a plan).

**(2) Authorized distributor of record**

The term ''authorized distributor of record'' has the meaning given that term in subsection (e)(3)(A) of such section.

**(3) Manufacturer**

The term ''manufacturer'' has the meaning given that term for purposes of subsection (d) of such section.

(Aug. 14, 1935, ch. 531, title XI, § 1128H, as added Pub. L. 111–148, title VI, § 6004, Mar. 23, 2010, 124 Stat. 697.)

### § 1320a–7j. Accountability requirements for facilities

**(a) Definition of facility**

In this section, the term ''facility'' means—

(1) a skilled nursing facility (as defined in section 1395i–3(a) of this title); or

(2) a nursing facility (as defined in section 1396r(a) of this title).

**(b) Effective compliance and ethics programs**

**(1) Requirement**

On or after the date that is 36 months after March 23, 2010, a facility shall, with respect to the entity that operates the facility (in this subparagraph[1] referred to as the ''operating organization'' or ''organization''), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this chapter and in promoting quality of care consistent with regulations developed under paragraph (2).

**(2) Development of regulations**

**(A) In general**

Not later than the date that is 2 years after March 23, 2010, the Secretary, working jointly with the Inspector General of the Department of Health and Human Services, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

**(B) Design of regulations**

Such regulations with respect to specific elements or formality of a program shall, in the case of an organization that operates 5 or more facilities, vary with the size of the organization, such that larger organizations should have a more formal program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements may specifically apply to the corporate level management of multi unit nursing home chains.

**(C) Evaluation**

Not later than 3 years after the date of the promulgation of regulations under this paragraph, the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subsection. Such evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of patient quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

**(3) Requirements for compliance and ethics programs**

In this subsection, the term ''compliance and ethics program'' means, with respect to a facility, a program of the operating organization that—

(A) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this chapter and in promoting quality of care; and

(B) includes at least the required components specified in paragraph (4).

**(4) Required components of program**

The required components of a compliance and ethics program of an operating organization are the following:

(A) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this chapter.

(B) Specific individuals within high-level personnel of the organization must have

[1] So in original. Probably should be ''subsection''.