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; amended Pub. L. 115–271, title VI, § 6111(a)(1), (b), Oct. 24, 2018, 132 Stat. 4006, 4007.)

APPLICABILITY OF AMENDMENT

Amendment of section by section 6111(a)(1) of Pub. L. 115–271 applicable with respect to information required to be submitted under this section on or after Jan. 1, 2022. See 2018 Amendment notes below.

AMENDMENTS

2018—Subsec. (c)(1)(C)(viii). Pub. L. 115–271, § 6111(b), substituted ''in the case of information made available under this subparagraph prior to January 1, 2022, does not contain'' for ''does not contain''.

Subsec. (e)(6)(A)(iii) to (v). Pub. L. 115–271, § 6111(a)(1)(A), added cls. (iii) to (v).

Subsec. (e)(6)(B). Pub. L. 115–271, § 6111(a)(1)(B), inserted '', physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, or certified nurse-midwife'' after ''physician''.

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–271, title VI, § 6111(a)(2), Oct. 24, 2018, 132 Stat. 4006, provided that: ''The amendments made by this subsection [amending this section] shall apply with respect to information required to be submitted under section 1128G of the Social Security Act (42 U.S.C. 1320a–7h) on or after January 1, 2022.''

ADMINISTRATION

Pub. L. 115–271, title VI, § 6111(c), Oct. 24, 2018, 132 Stat. 4007, provided that: ''Chapter 35 of title 44, United States Code, shall not apply to this section [amending this section and enacting provisions set out as notes under this section] or the amendments made by this section.''

§ 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 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.

(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.

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

(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 been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

(C) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this chapter.

(D) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

(E) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this chapter by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

(F) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

(G) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this chapter.

(H) The organization must periodically undertake reassessment of its compliance pro-