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.

(3) Requirements for compliance and ethics programs

In this subsection, the term ''compliance and ethics program'' means, with respect to a

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