''(5) TRANSITION PERIOD DEFINED.—For purposes of this subsection, the term 'transition period' means the period that begins on the date of enactment of this Act [Mar. 23, 2010] and ends on the later of—

''(A) the date that is 1 year after such date of enactment; or

''(B) the effective date of the regulations promulgated under paragraph (2).

''(6) EFFECTIVE DATE.—The amendments made by subsections (a), (b), and (c) [amending this section and sections 1320a–7c and 1396r–2 of this title] shall take effect on the first day after the final day of the transition period.''

§ 1320a–7f. Coordination of medicare and medicaid surety bond provisions

In the case of a home health agency that is subject to a surety bond requirement under subchapter XVIII and subchapter XIX, the surety bond provided to satisfy the requirement under one such subchapter shall satisfy the requirement under the other such subchapter so long as the bond applies to guarantee return of overpayments under both such subchapters.

(Aug. 14, 1935, ch. 531, title XI, § 1128F, as added Pub. L. 106–113, div. B, § 1000(a)(6) [title III, § 304(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–361.)

§ 1320a–7g. Funds to reduce medicaid fraud and abuse

(1) In general

For purposes of reducing fraud and abuse in the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]—

(A) there is appropriated to the Office of the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $25,000,000, for fiscal year 2009; and

(B) there is authorized to be appropriated to such Office $25,000,000 for fiscal year 2010 and each subsequent fiscal year.

Amounts appropriated under this section shall remain available for expenditure until expended and shall be in addition to any other amounts appropriated or made available to such Office for such purposes with respect to the Medicaid program.

(2) Annual report

Not later than September 30 of 2009 and of each subsequent year, the Inspector General of the Department of Health and Human Services shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Finance and Appropriations of the Senate a report on the activities (and the results of such activities) funded under paragraph (1) to reduce waste, fraud, and abuse in the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] during the previous 12 month period, including the amount of funds appropriated under such paragraph for each such activity and an estimate of the savings to the Medicaid program resulting from each such activity.

(Pub. L. 110–252, title VII, § 7001(b), June 30, 2008, 122 Stat. 2389.)

REFERENCES IN TEXT

The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§ 1396 et seq.) of this chapter. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

This section, referred to in par. (1), means section 7001 of Pub. L. 110–252, which enacted this section and section 1396w of this title, amended sections 1396a and 1396b of this title, and repealed provisions set out as a note under section 1396a of this title.

CODIFICATION

Section was enacted as part of the Supplemental Appropriations Act, 2008, and not as part of the Social Security Act which comprises this chapter.

§ 1320a–7h. Transparency reports and reporting of physician ownership or investment interests

(a) Transparency reports

(1) Payments or other transfers of value

(A) In general

On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(i) The name of the covered recipient.

(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(iii) The amount of the payment or other transfer of value.

(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Secretary).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;

(IX) research;

(X) charitable contribution;

(XI) royalty or license;

(XII) current or prospective ownership or investment interest;

(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

(XIV) grant; or

(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) Special rule for certain payments or other transfers of value

In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) Physician ownership

In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1395nn(c) of this title) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1395nn(a) of this title)) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, ''physician'' shall be substituted for ''covered recipient'' each place it appears.

(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(b) Penalties for noncompliance

(1) Failure to report

(A) In general

Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.

(B) Limitation

The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

(2) Knowing failure to report

(A) In general

Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.

(B) Limitation

The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

(3) Use of funds

Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) Procedures for submission of information and public availability

(1) In general

(A) Establishment

Not later than October 1, 2011, the Secretary shall establish procedures—

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) Definition of terms

The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) Public availability

Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

(i) is searchable and is in a format that is clear and understandable;

(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industry-physician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) in the case of information made available under this subparagraph prior to January 1, 2022, does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) Clarification of time period for review and corrections

In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) Delayed publication for payments made pursuant to product research or development agreements and clinical investigations

(i) In general

In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) Confidentiality of information prior to publication

Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5 or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) Consultation

In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) Annual reports and relation to State laws

(1) Annual report to Congress

Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) Annual reports to States

Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) Relation to State laws

(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) Consultation

The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) Definitions

In this section:

(1) Applicable group purchasing organization

The term ''applicable group purchasing organization'' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) Applicable manufacturer

The term ''applicable manufacturer'' means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) Clinical investigation

The term ''clinical investigation'' means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) Covered device

The term ''covered device'' means any device for which payment is available under subchapter XVIII or a State plan under subchapter XIX or XXI (or a waiver of such a plan).

(5) Covered drug, device, biological, or medical supply

The term ''covered drug, device, biological, or medical supply'' means any drug, biological product, device, or medical supply for which payment is available under subchapter XVIII or a State plan under subchapter XIX or XXI (or a waiver of such a plan).

(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.

(iii) A physician assistant, nurse practitioner, or clinical nurse specialist (as such terms are defined in section 1395x(aa)(5) of this title).

(iv) A certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title).

(v) A certified nurse-midwife (as defined in section 1395x(gg)(2) of this title).

(B) Exclusion

Such term does not include a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anes-

thetist, or certified nurse-midwife 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; 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.

(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''.