(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 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

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

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 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 program to identify changes necessary to reflect changes within the organization and its facilities.

(c) Quality assurance and performance improvement program

(1) In general

Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this subparagraph referred to as the ''QAPI program'') for facilities, including multi unit chains of facilities. Under the QAPI program, the Secretary shall establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under paragraph (2), a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under sections 1395i–3(b)(1)(B) and 1396r(b)(1)(B) of this title, as applicable.

(2) Regulations

The Secretary shall promulgate regulations to carry out this subsection.

(f)[2] Standardized complaint form

(1) Development by the Secretary

The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a facility.

[2] So in original. No subsecs. (d) and (e) have been enacted.

(2) Complaint forms and resolution processes

(A) Complaint forms

The State must make the standardized complaint form developed under paragraph (1) available upon request to—

(i) a resident of a facility; and

(ii) any person acting on the resident's behalf.

(B) Complaint resolution process

The State must establish a complaint resolution process in order to ensure that the legal representative of a resident of a facility or other responsible party is not denied access to such resident or otherwise retaliated against if they have complained about the quality of care provided by the facility or other issues relating to the facility. Such complaint resolution process shall include—

(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint; and

(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation.

(3) Rule of construction

Nothing in this subsection shall be construed as preventing a resident of a facility (or a person acting on the resident's behalf) from submitting a complaint in a manner or format other than by using the standardized complaint form developed under paragraph (1) (including submitting a complaint orally).

(g) Submission of staffing information based on payroll data in a uniform format

Beginning not later than 2 years after March 23, 2010, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

(1) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

(2) include resident census data and information on resident case mix;

(3) include a regular reporting schedule; and

(4) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in paragraph (1) per resident per day.

Nothing in this subsection shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subsection with respect to agency and contract staff shall be kept separate from information on employee staffing.

(h) Notification of facility closure

(1) In general

Any individual who is the administrator of a facility must—

(A) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

(i) subject to clause (ii), not later than the date that is 60 days prior to the date of such closure; and

(ii) in the case of a facility where the Secretary terminates the facility's participation under this subchapter, not later than the date that the Secretary determines appropriate;

(B) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

(C) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

(2) Relocation

(A) In general

The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

(B) Continuation of payments until residents relocated

The Secretary may, as the Secretary determines appropriate, continue to make payments under this subchapter with respect to residents of a facility that has submitted a notification under paragraph (1) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.

(3) Sanctions

Any individual who is the administrator of a facility that fails to comply with the requirements of paragraph (1)—

(A) shall be subject to a civil monetary penalty of up to $100,000;

(B) may be subject to exclusion from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title); and

(C) shall be subject to any other penalties that may be prescribed by law.

(4) Procedure

The provisions of section 1320a–7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty or exclusion under paragraph (3) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(Aug. 14, 1935, ch. 531, title XI, § 1128I, as added and amended Pub. L. 111–148, title VI, §§ 6102, 6105(a), 6106, 6113(a), Mar. 23, 2010, 124 Stat. 702, 711, 712, 718.)

AMENDMENTS

2010—Subsec. (f). Pub. L. 111–148, § 6105(a), added subsec. (f).

Subsec. (g). Pub. L. 111–148, § 6106, added subsec. (g).

Subsec. (h). Pub. L. 111–148, § 6113(a), added subsec. (h).

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title VI, § 6105(b), Mar. 23, 2010, 124 Stat. 712, provided that: ''The amendment made by this section [amending this section] shall take effect 1 year after the date of the enactment of this Act [Mar. 23, 2010].''

Pub. L. 111–148, title VI, § 6113(c), Mar. 23, 2010, 124 Stat. 720, provided that: ''The amendments made by this section [amending this section and section 1395i–3 of this title] shall take effect 1 year after the date of the enactment of this Act [Mar. 23, 2010].''

NATIONAL INDEPENDENT MONITOR DEMONSTRATION PROJECT

Pub. L. 111–148, title VI, § 6112, Mar. 23, 2010, 124 Stat. 716, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—The Secretary [of Health and Human Services], in consultation with the Inspector General of the Department of Health and Human Services, shall conduct a demonstration project to develop, test, and implement an independent monitor program to oversee interstate and large intrastate chains of skilled nursing facilities and nursing facilities.

''(2) SELECTION.—The Secretary shall select chains of skilled nursing facilities and nursing facilities described in paragraph (1) to participate in the demonstration project under this section from among those chains that submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

''(3) DURATION.—The Secretary shall conduct the demonstration project under this section for a 2-year period.

''(4) IMPLEMENTATION.—The Secretary shall implement the demonstration project under this section not later than 1 year after the date of the enactment of this Act [Mar. 23, 2010].

''(b) REQUIREMENTS.—The Secretary shall evaluate chains selected to participate in the demonstration project under this section based on criteria selected by the Secretary, including where evidence suggests that a number of the facilities of the chain are experiencing serious safety and quality of care problems. Such criteria may include the evaluation of a chain that includes a number of facilities participating in the 'Special Focus Facility' program (or a successor program) or multiple facilities with a record of repeated serious safety and quality of care deficiencies.

''(c) RESPONSIBILITIES.—An independent monitor that enters into a contract with the Secretary to participate in the conduct of the demonstration project under this section shall—

''(1) conduct periodic reviews and prepare root-cause quality and deficiency analyses of a chain to assess if facilities of the chain are in compliance with State and Federal laws and regulations applicable to the facilities;

''(2) conduct sustained oversight of the efforts of the chain, whether publicly or privately held, to achieve compliance by facilities of the chain with State and Federal laws and regulations applicable to the facilities;

''(3) analyze the management structure, distribution of expenditures, and nurse staffing levels of facilities of the chain in relation to resident census, staff turnover rates, and tenure;

''(4) report findings and recommendations with respect to such reviews, analyses, and oversight to the chain and facilities of the chain, to the Secretary, and to relevant States; and

''(5) publish the results of such reviews, analyses, and oversight.

''(d) IMPLEMENTATION OF RECOMMENDATIONS.—

''(1) RECEIPT OF FINDING BY CHAIN.—Not later than 10 days after receipt of a finding of an independent monitor under subsection (c)(4), a chain participating in the demonstration project shall submit to the independent monitor a report—

''(A) outlining corrective actions the chain will take to implement the recommendations in such report; or

''(B) indicating that the chain will not implement such recommendations, and why it will not do so.

''(2) RECEIPT OF REPORT BY INDEPENDENT MONITOR.—Not later than 10 days after receipt of a report submitted by a chain under paragraph (1), an independent monitor shall finalize its recommendations and submit a report to the chain and facilities of the chain, the Secretary, and the State or States, as appropriate, containing such final recommendations.

''(e) COST OF APPOINTMENT.—A chain shall be responsible for a portion of the costs associated with the appointment of independent monitors under the demonstration project under this section. The chain shall pay such portion to the Secretary (in an amount and in accordance with procedures established by the Secretary).

''(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) as may be necessary for the purpose of carrying out the demonstration project under this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

''(h) DEFINITIONS.—In this section:

''(1) ADDITIONAL DISCLOSABLE PARTY.—The term 'additional disclosable party' has the meaning given such term in section 1124(c)(5)(A) of the Social Security Act [42 U.S.C. 1320a–3(c)(5)(A)], as added by section 4201(a) [probably should be ''6101(a)'']].

''(2) FACILITY.—The term 'facility' means a skilled nursing facility or a nursing facility.

''(3) NURSING FACILITY.—The term 'nursing facility' has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

''(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation.

''(5) SKILLED NURSING FACILITY.—The term 'skilled nursing facility' has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a) [1395i–3(a)]).

''(i) EVALUATION AND REPORT.—

''(1) EVALUATION.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall evaluate the demonstration project conducted under this section.

''(2) REPORT.—Not later than 180 days after the completion of the demonstration project under this section, the Secretary shall submit to Congress a re-

port containing the results of the evaluation conducted under paragraph (1), together with recommendations—

''(A) as to whether the independent monitor program should be established on a permanent basis;

''(B) if the Secretary recommends that such program be so established, on appropriate procedures and mechanisms for such establishment; and

''(C) for such legislation and administrative action as the Secretary determines appropriate.''

§ 1320a–7k. Medicare and Medicaid program integrity provisions

(a) Data matching

(1) Integrated data repository

(A) Inclusion of certain data

(i) In general

The Integrated Data Repository of the Centers for Medicare & Medicaid Services shall include, at a minimum, claims and payment data from the following:

(I) The programs under subchapters XVIII and XIX (including parts A, B, C, and D of subchapter XVIII).

(II) The program under subchapter XXI.

(III) Health-related programs administered by the Secretary of Veterans Affairs.

(IV) Health-related programs administered by the Secretary of Defense.

(V) The program of old-age, survivors, and disability insurance benefits established under subchapter II.

(VI) The Indian Health Service and the Contract Health Service program.

(ii) Priority for inclusion of certain data

Inclusion of the data described in subclause (I) of such clause[1] in the Integrated Data Repository shall be a priority. Data described in subclauses (II) through (VI) of such clause[1] shall be included in the Integrated Data Repository as appropriate.

(B) Data sharing and matching

(i) In general

The Secretary shall enter into agreements with the individuals described in clause (ii) under which such individuals share and match data in the system of records of the respective agencies of such individuals with data in the system of records of the Department of Health and Human Services for the purpose of identifying potential fraud, waste, and abuse under the programs under subchapters XVIII and XIX.

(ii) Individuals described

The following individuals are described in this clause:

(I) The Commissioner of Social Security.

(II) The Secretary of Veterans Affairs.

(III) The Secretary of Defense.

(IV) The Director of the Indian Health Service.

(iii) Definition of system of records

For purposes of this paragraph, the term ''system of records'' has the meaning given such term in section 552a(a)(5) of title 5.

[1] So in original. Probably should be ''clause (i)''.

(2) Access to claims and payment databases

For purposes of conducting law enforcement and oversight activities and to the extent consistent with applicable information, privacy, security, and disclosure laws, including the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 552a of title 5, and subject to any information systems security requirements under such laws or otherwise required by the Secretary, the Inspector General of the Department of Health and Human Services and the Attorney General shall have access to claims and payment data of the Department of Health and Human Services and its contractors related to subchapters XVIII, XIX, and XXI.

(b) OIG authority to obtain information

(1) In general

Notwithstanding and in addition to any other provision of law, the Inspector General of the Department of Health and Human Services may, for purposes of protecting the integrity of the programs under subchapters XVIII and XIX, obtain information from any individual (including a beneficiary provided all applicable privacy protections are followed) or entity that—

(A) is a provider of medical or other items or services, supplier, grant recipient, contractor, or subcontractor; or

(B) directly or indirectly provides, orders, manufactures, distributes, arranges for, prescribes, supplies, or receives medical or other items or services payable by any Federal health care program (as defined in section 1320a–7b(f) of this title) regardless of how the item or service is paid for, or to whom such payment is made.

(2) Inclusion of certain information

Information which the Inspector General may obtain under paragraph (1) includes any supporting documentation necessary to validate claims for payment or payments under subchapter XVIII or XIX, including a prescribing physician's medical records for an individual who is prescribed an item or service which is covered under part B of subchapter XVIII, a covered part D drug (as defined in section 1395w–102(e) of this title) for which payment is made under an MA–PD plan under part C of such subchapter, or a prescription drug plan under part D of such subchapter, and any records necessary for evaluation of the economy, efficiency, and effectiveness of the programs under subchapters XVIII and XIX.

(c) Administrative remedy for knowing participation by beneficiary in health care fraud scheme

(1) In general

In addition to any other applicable remedies, if an applicable individual has knowingly participated in a Federal health care fraud offense or a conspiracy to commit a Federal health care fraud offense, the Secretary shall impose an appropriate administrative penalty commensurate with the offense or conspiracy.