

(1) a PDP sponsor of a prescription drug plan or an MA organization offering an MA-PD plan under part D of subchapter XVIII; or

(2) a qualified health benefits plan offered through an exchange established by a State under section 18031 of this title,

shall provide the information described in subsection (b) to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify.

(b) Information described

The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:

(1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.

(2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(c) Confidentiality

Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines to be necessary to carry out this section or part D of subchapter XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(4) To States to carry out section 18031 of this title.

(d) Penalties

The provisions of subsection (b)(3)(C) of section 1396r-8 of this title shall apply to a health benefits plan or PBM that fails to provide information required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.

(Aug. 14, 1935, ch. 531, title XI, §1150A, as added Pub. L. 111-148, title VI, §6005, Mar. 23, 2010, 124 Stat. 698.)

PRIOR PROVISIONS

A prior section 1320b-23 of this title, act Aug. 14, 1935, ch. 531, title XI, §1150A, as added Pub. L. 106-553, §1(a)(2) [title VI, §635(c)(1)], Dec. 21, 2000, 114 Stat. 2762, 2762A-115, which related to prohibition of certain misuses of social security numbers, was repealed by Pub. L. 106-554, §1(a)(4) [div. A, §213(a)(6), (b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-180, effective as if included in Pub. L. 106-553 on Dec. 21, 2000.

§ 1320b-24. Consultation with Tribal Technical Advisory Group

The Secretary of Health and Human Services shall maintain within the Centers for Medicaid & Medicare Services¹ (CMS) a Tribal Technical Advisory Group (TTAG), which was first established in accordance with requirements of the charter dated September 30, 2003, and the Secretary of Health and Human Services shall include in such Group a representative of a national urban Indian health organization and a representative of the Indian Health Service. The inclusion of a representative of a national urban Indian health organization in such Group shall not affect the nonapplication of the Federal Advisory Committee Act (5 U.S.C. App.) to such Group.

(Pub. L. 111-5, div. B, title V, §5006(e)(1), Feb. 17, 2009, 123 Stat. 510.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in text, is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

Section was enacted as part of the American Recovery and Reinvestment Act of 2009, and not as part of the Social Security Act which comprises this chapter.

§ 1320b-25. Reporting to law enforcement of crimes occurring in federally funded long-term care facilities

(a) Determination and notification

(1) Determination

The owner or operator of each long-term care facility that receives Federal funds under this chapter shall annually determine whether the facility received at least \$10,000 in such Federal funds during the preceding year.

(2) Notification

If the owner or operator determines under paragraph (1) that the facility received at

¹ So in original. Probably should be "Centers for Medicare & Medicaid Services".

least \$10,000 in such Federal funds during the preceding year, such owner or operator shall annually notify each covered individual (as defined in paragraph (3)) of that individual's obligation to comply with the reporting requirements described in subsection (b).

(3) Covered individual defined

In this section, the term "covered individual" means each individual who is an owner, operator, employee, manager, agent, or contractor of a long-term care facility that is the subject of a determination described in paragraph (1).

(b) Reporting requirements

(1) In general

Each covered individual shall report to the Secretary and 1 or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime (as defined by the law of the applicable political subdivision) against any individual who is a resident of, or is receiving care from, the facility.

(2) Timing

If the events that cause the suspicion—

(A) result in serious bodily injury, the individual shall report the suspicion immediately, but not later than 2 hours after forming the suspicion; and

(B) do not result in serious bodily injury, the individual shall report the suspicion not later than 24 hours after forming the suspicion.

(c) Penalties

(1) In general

If a covered individual violates subsection (b)—

(A) the covered individual shall be subject to a civil money penalty of not more than \$200,000; and

(B) the Secretary may make a determination in the same proceeding to exclude the covered individual from participation in any Federal health care program (as defined in section 1320a-7b(f) of this title).

(2) Increased harm

If a covered individual violates subsection (b) and the violation exacerbates the harm to the victim of the crime or results in harm to another individual—

(A) the covered individual shall be subject to a civil money penalty of not more than \$300,000; and

(B) the Secretary may make a determination in the same proceeding to exclude the covered individual from participation in any Federal health care program (as defined in section 1320a-7b(f) of this title).

(3) Excluded individual

During any period for which a covered individual is classified as an excluded individual under paragraph (1)(B) or (2)(B), a long-term care facility that employs such individual shall be ineligible to receive Federal funds under this chapter.

(4) Extenuating circumstances

(A) In general

The Secretary may take into account the financial burden on providers with underserved populations in determining any penalty to be imposed under this subsection.

(B) Underserved population defined

In this paragraph, the term "underserved population" means the population of an area designated by the Secretary as an area with a shortage of elder justice programs or a population group designated by the Secretary as having a shortage of such programs. Such areas or groups designated by the Secretary may include—

(i) areas or groups that are geographically isolated (such as isolated in a rural area);

(ii) racial and ethnic minority populations; and

(iii) populations underserved because of special needs (such as language barriers, disabilities, alien status, or age).

(d) Additional penalties for retaliation

(1) In general

A long-term care facility may not—

(A) discharge, demote, suspend, threaten, harass, or deny a promotion or other employment-related benefit to an employee, or in any other manner discriminate against an employee in the terms and conditions of employment because of lawful acts done by the employee; or

(B) file a complaint or a report against a nurse or other employee with the appropriate State professional disciplinary agency because of lawful acts done by the nurse or employee,

for making a report, causing a report to be made, or for taking steps in furtherance of making a report pursuant to subsection (b)(1).

(2) Penalties for retaliation

If a long-term care facility violates subparagraph (A) or (B) of paragraph (1) the facility shall be subject to a civil money penalty of not more than \$200,000 or the Secretary may classify the entity as an excluded entity for a period of 2 years pursuant to section 1320a-7(b) of this title, or both.

(3) Requirement to post notice

Each long-term care facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of employees under this section. Such sign shall include a statement that an employee may file a complaint with the Secretary against a long-term care facility that violates the provisions of this subsection and information with respect to the manner of filing such a complaint.

(e) 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 this section in the same manner as such provisions

apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(f) Definitions

In this section, the terms “elder justice”, “long-term care facility”, and “law enforcement” have the meanings given those terms in section 1397j of this title.

(Aug. 14, 1935, ch. 531, title XI, §1150B, as added Pub. L. 111-148, title VI, §6703(b)(3), Mar. 23, 2010, 124 Stat. 800.)

PART B—PEER REVIEW OF UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

§ 1320c. Purpose

The purpose of this part is to establish the contracting process which the Secretary must follow pursuant to the requirements of section 1395y(g) of this title, including the definition of the quality improvement organizations with which the Secretary shall contract, the functions such quality improvement organizations are to perform, the confidentiality of medical records, and related administrative matters to facilitate the carrying out of the purposes of this part.

(Aug. 14, 1935, ch. 531, title XI, §1151, as added Pub. L. 97-248, title I, §143, Sept. 3, 1982, 96 Stat. 382; amended Pub. L. 112-40, title II, §261(a)(2)(C), Oct. 21, 2011, 125 Stat. 423.)

PRIOR PROVISIONS

A prior section 1320c, act Aug. 14, 1935, ch. 531, title XI, §1151, as added Oct. 30, 1972, Pub. L. 92-603, title II, §249F(b), 86 Stat. 1429; amended Aug. 13, 1981, Pub. L. 97-35, title XXI, §2113(a), 95 Stat. 794, set out the Congressional declaration of purpose of former part B, in the general revision of this part by Pub. L. 97-248.

AMENDMENTS

2011—Pub. L. 112-40 substituted “the quality improvement organizations” for “the utilization and quality control peer review organizations” and “such quality improvement organizations” for “such peer review organizations”.

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 112-40, title II, §261(e), Oct. 21, 2011, 125 Stat. 426, provided that: “The amendments made by this section [amending this section and sections 1320c-1 to 1320c-5, 1320c-7, 1320c-9, 1320c-10, 1395g, 1395k, 1395u, 1395x, 1395y, 1395cc, 1395dd, 1395ff, 1395mm, 1395pp, and 1395ww of this title] shall apply to contracts entered into or renewed on or after January 1, 2012.”

EFFECTIVE DATE

Section 149 of Pub. L. 97-248, as amended by Pub. L. 98-369, div. B, title III, §2354(c)(3)(C), July 18, 1984, 98 Stat. 1102, provided that: “The amendments made by this subtitle [subtitle C (§§141-150) of title I of Pub. L. 97-248, enacting this part, amending sections 1395b-1, 1395g, 1395k, 1395l, 1395x, 1395y, 1395cc, 1395pp, 1396a, and 1396b of this title, and enacting provisions set out as notes under sections 1305 and 1320c of this title] shall, subject to section 150 [section 150 of Pub. L. 97-248, set out as a note below], be effective with respect to contracts entered into or renewed on or after the date of the enactment of this Act [Sept. 3, 1982].”

IOM STUDY OF QIOS

Pub. L. 108-173, title I, §109(d), Dec. 8, 2003, 117 Stat. 2173, provided that:

“(1) IN GENERAL.—The Secretary [of Health and Human Services] shall request the Institute of Medi-

cine of the National Academy of Sciences to conduct an evaluation of the program under part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.]. The study shall include a review of the following:

“(A) An overview of the program under such part.

“(B) The duties of organizations with contracts with the Secretary under such part.

“(C) The extent to which quality improvement organizations improve the quality of care for medicare beneficiaries.

“(D) The extent to which other entities could perform such quality improvement functions as well as, or better than, quality improvement organizations.

“(E) The effectiveness of reviews and other actions conducted by such organizations in carrying out those duties.

“(F) The source and amount of funding for such organizations.

“(G) The conduct of oversight of such organizations.

“(2) REPORT TO CONGRESS.—Not later than June 1, 2006, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

“(3) INCREASED COMPETITION.—If the Secretary finds based on the study conducted under paragraph (1) that other entities could improve quality in the medicare program as well as, or better than, the current quality improvement organizations, then the Secretary shall provide for such increased competition through the addition of new types of entities which may perform quality improvement functions.”

COORDINATION OF PROS AND CARRIERS

Pub. L. 101-508, title IV, §4205(c), Nov. 5, 1990, 104 Stat. 1388-113, provided that:

“(1) DEVELOPMENT AND IMPLEMENTATION OF PLAN.—The Secretary of Health and Human Services shall develop and implement a plan to coordinate the physician review activities of peer review organizations and carriers. Such plan shall include—

“(A) the development of common utilization and medical review criteria;

“(B) criteria for the targeting of reviews by peer review organizations and carriers; and

“(C) improved methods for exchange of information among peer review organizations and carriers.

“(2) REPORT.—Not later than January 1, 1992, the Secretary shall submit to Congress a report on the development of the plan described under paragraph (1) and shall include in the report such recommendations for changes in legislation as may be appropriate.”

EVALUATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Pub. L. 97-448, title III, §309(d), Jan. 12, 1983, 96 Stat. 2410, provided that: “In order to avoid unfairly discriminating against professional standards review organizations whose performance was evaluated during the first and second calendar quarters of 1982, the Secretary of Health and Human Services shall disregard the results of such evaluations and shall carry out such new evaluations of such organizations as may be necessary to select utilization and quality control peer review organizations in accordance with subtitle C of title I of the Tax Equity and Fiscal Responsibility Act of 1982 [sections 141-150 of Pub. L. 97-248] and part B of title XI of the Social Security Act [42 U.S.C. 1320c et seq.] as amended by such subtitle.”

MAINTENANCE OF CURRENT PROFESSIONAL STANDARDS REVIEW ORGANIZATION AGREEMENTS

Pub. L. 97-248, title I, §150, Sept. 3, 1982, 96 Stat. 395, as amended by Pub. L. 97-448, title III, §309(a)(9), Jan. 12, 1983, 96 Stat. 2408, provided that:

“(a) The Secretary of Health and Human Services shall not terminate or fail to renew any agreement in effect with a professional standards review organization under part B of title XI of the Social Security Act