

nology in accordance with paragraph (4); and

(iii) such other information as the Secretary may require.

(3) Sharing

(A) In general

The Secretary shall ensure that appropriate enrollment HIT adopted under grants under this subsection is made available to other qualified State, qualified political subdivisions of a State, or other appropriate qualified entities (as described in subparagraph (B)) at no cost.

(B) Qualified entities

The Secretary shall determine what entities are qualified to receive enrollment HIT under subparagraph (A), taking into consideration the recommendations of the HIT Advisory Committee.

(July 1, 1944, ch. 373, title XXX, §3021, as added Pub. L. 111-148, title I, §1561, Mar. 23, 2010, 124 Stat. 262; amended Pub. L. 114-255, div. A, title IV, §4003(e)(2)(A)(ii), Dec. 13, 2016, 130 Stat. 1174.)

Editorial Notes

REFERENCES IN TEXT

March 23, 2010, referred to in subsec. (a)(1), was in the original “the date of enactment of this title”, which was translated as meaning the date of enactment of Pub. L. 111-148, which enacted this part, to reflect the probable intent of Congress.

AMENDMENTS

2016—Subsecs. (a)(1), (c), (d)(3)(B). Pub. L. 114-255 substituted “HIT Advisory Committee” for “HIT Policy Committee and the HIT Standards Committee”.

§ 300jj-52. Information blocking

(a) Definition

(1) In general

In this section, the term “information blocking” means a practice that—

(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(2) Practices described

The information blocking practices described in paragraph (1) may include—

(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treat-

ment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

(C) implementing health information technology in ways that are likely to—

(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

(3) Rulemaking

The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

(4) No enforcement before exception identified

The term “information blocking” does not include any practice or conduct occurring prior to the date that is 30 days after December 13, 2016.

(5) Consultation

The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

(6) Application

The term “information blocking”, with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

(7) Clarification

In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this subchapter.

(b) Inspector General authority

(1) In general

The inspector general of the Department of Health and Human Services (referred to in this section as the “Inspector General”) may investigate any claim that—

(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

(i) submitted a false attestation under section 300jj-11(c)(5)(D)(vii) of this title; or

(ii) engaged in information blocking;

(B) a health care provider engaged in information blocking; or

(C) a health information exchange or network engaged in information blocking.

(2) Penalties

(A) Developers, networks, and exchanges

Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed \$1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

(B) Providers

Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rule-making.

(C) Procedure

The provisions of section 1320a-7a of this title (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1320a-7a(a) of this title.

(D) Recovered penalty funds

The amounts recovered under this paragraph shall be allocated as follows:

(i) Annual operating expenses

Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

(ii) Application to other programs

The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in such proportion as the Secretary determines appropriate.

(E) Authorization of appropriations

There is authorized to be appropriated to the Office of the Inspector General to carry out this section \$10,000,000, to remain available until expended.

(3) Resolution of claims

(A) In general

The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

(B) Limitation on liability

If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

(4) Application of authorities under inspector general act of 1978

In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(c) Identifying barriers to exchange of certified health information technology

(1) Trusted exchange defined

In this section, the term “trusted exchange” with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

(2) Guidance

The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

(3) Referral

The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

(d) Additional provisions

(1) Information sharing provisions

The National Coordinator may serve as a technical consultant to the Inspector General

and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

(2) Protection from disclosure of information

Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

(B) shall be exempt from mandatory disclosure under section 552 of title 5, as provided by subsection (b)(3) of such section; and

(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

(3) Standardized process

(A) In general

The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

(iii) any other act described in subsection (a).

(B) Collection of information

The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

(4) Nonduplication of penalty structures

In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before December 13, 2016.

(July 1, 1944, ch. 373, title XXX, §3022, as added Pub. L. 114-255, div. A, title IV, §4004, Dec. 13, 2016, 130 Stat. 1176; amended Pub. L. 116-321, §2(a), Jan. 5, 2021, 134 Stat. 5073.)

Editorial Notes

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(3)(A), is section 264(c) of Pub. L. 104-191, which is set out as a note under section 1320d-2 of this title.

Section 6 of the Inspector General Act of 1978, referred to in subsec. (b)(4), is section 6 of Pub. L. 95-452, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2021—Subsec. (b)(4). Pub. L. 116-321 added par. (4).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2021 AMENDMENT

Pub. L. 116-321, §2(b), Jan. 5, 2021, 134 Stat. 5073, provided that: “The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114-255).”

SUBCHAPTER XXIX—DATA COLLECTION,
ANALYSIS, AND QUALITY

§ 300kk. Data collection, analysis, and quality

(a) Data collection

(1) In general

The Secretary shall ensure that, by not later than 2 years after March 23, 2010, any federally conducted or supported health care or public health program, activity or survey (including Current Population Surveys and American Community Surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census) collects and reports, to the extent practicable—

(A) data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants;

(B) data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;

(C) sufficient data to generate statistically reliable estimates by racial, ethnic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and

(D) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

(2) Collection standards

In collecting data described in paragraph (1), the Secretary or designee shall—

(A) use Office of Management and Budget standards, at a minimum, for race and ethnicity measures;

(B) develop standards for the measurement of sex, primary language, and disability status;

(C) develop standards for the collection of data described in paragraph (1) that, at a minimum—

(i) collects self-reported data by the applicant, recipient, or participant; and

(ii) collects data from a parent or legal guardian if the applicant, recipient, or participant is a minor or legally incapacitated;