Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) for a single act or omission.

(4) Equitable relief

(A) In general

Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) of this section and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) Against State employees

An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) of this section unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

(g) Rule of construction

Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d–5 of this title (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) Clarification

Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) Clarification of application of HIPAA confidentiality regulations to patient safety organizations

For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) Reports on strategies to improve patient safety

(1) Draft report

Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) Final report

Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

(July 1, 1944, ch. 373, title IX, § 922, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 427.)

REFERENCES IN TEXT

Section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (f)(3), is section 264(c)(1) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

PRIOR PROVISIONS

A prior section 922 of act July 1, 1944, was renumbered section 942 and is classified to section 299c–1 of this title.

Another prior section 922 of act July 1, 1944, was classified to section 299c–1 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 299b–23. Network of patient safety databases

(a) In general

The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) Data standards

The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of this section of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such

work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.].

(c) Use of information

Information reported to and among the network of patient safety databases under subsection (a) of this section shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 299b–2(b)(2) of this title.

(July 1, 1944, ch. 373, title IX, § 923, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 431.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Part C of title XI of the Act is classified generally to part C (§ 1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 923 of act July 1, 1944, was renumbered section 943 and is classified to section 299c–2 of this title.

Another prior section 923 of act July 1, 1944, was classified to section 299c–2 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 299b–24. Patient safety organization certification and listing

(a) Certification

(1) Initial certification

An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity—

(A) has policies and procedures in place to perform each of the patient safety activities described in section 299b–21(5) of this title; and

(B) upon being listed under subsection (d) of this section, will comply with the criteria described in subsection (b) of this section.

(2) Subsequent certifications

An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) of this section a subsequent certification to the Secretary that the entity—

(A) is performing each of the patient safety activities described in section 299b–21(5) of this title; and

(B) is complying with the criteria described in subsection (b) of this section.

(b) Criteria

(1) In general

The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d) of this section, has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 300gg–91(b)(2) of this title).

(E) The entity shall fully disclose—

(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(2) Additional criteria for component organizations

If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

(c) Review of certification

(1) In general

(A) Initial certification

Upon the submission by an entity of an initial certification under subsection (a)(1) of this section, the Secretary shall determine if the certification meets the requirements of subparagraphs (A) and (B) of such subsection.

(B) Subsequent certification

Upon the submission by an entity of a subsequent certification under subsection (a)(2) of this section, the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

(2) Notice of acceptance or non-acceptance

If the Secretary determines that—