

(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 non-identifiable 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),