work of patient safety databases maintained under subsection (a) 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) 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), will comply with the criteria described in subsection (b).

**(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) 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).

**(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), 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), 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), 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—

(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefor.

**(3) Disclosures regarding relationship to providers**

The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

**(d) Listing**

The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

**(e) Revocation of acceptance of certification**

**(1) In general**

If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

**(2) Supplying confirmation of notification to providers**

Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation.

**(3) Publication of decision**

If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall—

(A) remove the organization from the listing maintained under subsection (d); and

(B) publish notice of the revocation in the Federal Register.

**(f) Status of data after removal from listing**

**(1) New data**

With respect to the privilege and confidentiality protections described in section 299b–22 of this title, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

**(2) Protection to continue to apply**

If the privilege and confidentiality protections described in section 299b–22 of this title applied to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

**(g) Disposition of work product and data**

If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall—

(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

(2) return such work product or data to the entity that submitted the work product or data; or

(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

(July 1, 1944, ch. 373, title IX, § 924, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 431.)

PRIOR PROVISIONS

A prior section 924 of act July 1, 1944, was renumbered section 944 and is classified to section 299c–3 of this title.

Another prior section 924 of act July 1, 1944, was classified to section 299c–3 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

### § 299b–24a. Activities regarding women's health

**(a) Establishment**

There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the ''Office''). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

**(b) Purpose**

The official designated under subsection (a) shall—

(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Agency;