(Pub. L. 108–173, title X, § 1013, Dec. 8, 2003, 117 Stat. 2438.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1)(A), (2)(C)(i), (3)(A)(iii), (C)(i), (4)(A), (6)(A), (C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 et seq.), XIX (§ 1396 et seq.), and XXI (§ 1397aa et seq.), respectively, of chapter 7 of this title. Parts C and D of title XVIII of the Act are classified generally to parts C (§ 1395w–21 et seq.) and D (§ 1395w–101 et seq.), respectively, of subchapter XVIII of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(3)(C)(ii)(I), (4)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Public Health Service Act, referred to in subsec. (a)(3)(C)(ii)(I), (4)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to this chapter. Title IX of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and not as part of the Public Health Service Act which comprises this chapter.

DEFINITION OF ''SECRETARY''

''Secretary'' as meaning the Secretary of Health and Human Services, see section 1(c)(2) of Pub. L. 108–173, set out as a note under section 1301 of this title.

§ 299b–8. Omitted

CODIFICATION

Section, Pub. L. 111–5, div. A, title VIII, § 804, Feb. 17, 2009, 123 Stat. 187, established the Federal Coordinating Council for Comparative Effectiveness Research.

TERMINATION OF FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH

Pub. L. 111–148, title VI, § 6302, Mar. 23, 2010, 124 Stat. 747, provided that the Federal Coordinating Council for Comparative Effectiveness Research established under this section terminated on Mar. 23, 2010.

PART C—PATIENT SAFETY IMPROVEMENT

§ 299b–21. Definitions

In this part:

(1) HIPAA confidentiality regulations

The term ''HIPAA confidentiality regulations'' means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

(2) Identifiable patient safety work product

The term ''identifiable patient safety work product'' means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 299b–22(e) of this title.

(3) Nonidentifiable patient safety work product

The term ''nonidentifiable patient safety work product'' means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

(4) Patient safety organization

The term ''patient safety organization'' means a private or public entity or component thereof that is listed by the Secretary pursuant to section 299b–24(d) of this title.

(5) Patient safety activities

The term ''patient safety activities'' means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) Patient safety evaluation system

The term ''patient safety evaluation system'' means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) Patient safety work product

(A) In general

Except as provided in subparagraph (B), the term ''patient safety work product'' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) Clarification

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) Provider

The term ''provider'' means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

(July 1, 1944, ch. 373, title IX, § 921, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 424.)

REFERENCES IN TEXT

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

PRIOR PROVISIONS

A prior section 921 of act July 1, 1944, was renumbered section 941 and is classified to section 299c of this title.

Another prior section 921 of act July 1, 1944, was classified to section 299c of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 299b–22. Privilege and confidentiality protections

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) subject to disclosure pursuant to section 552 of title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Confidentiality of patient safety work product

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

(c) Exceptions

Except as provided in subsection (g)(3) of this section—

(1) Exceptions from privilege and confidentiality

Subsections (a) and (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A) of this section.

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) Exceptions from confidentiality

Subsection (b) of this section shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) Exception from privilege

Subsection (a) of this section shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) Continued protection of information after disclosure

(1) In general

Patient safety work product that is disclosed under subsection (c) of this section shall continue to be privileged and confidential as provided for in subsections (a) and (b) of this section, and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) Exception

Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) of this section shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) of this section (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) of this section shall no longer apply to such work product.

(3) Construction

Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) of this section with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c) of this section.

(4) Limitations on actions

(A) Patient safety organizations

(i) In general

A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) Nonapplication

The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1) of this section.

(B) Providers

An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) Reporter protection

(1) In general

A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) Adverse employment action

For purposes of this subsection, an ''adverse employment action'' includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) Enforcement

(1) Civil monetary penalty

Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) of this section shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) Procedure

The provisions of section 1320a–7a of this title, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a of this title.

(3) Relation to HIPAA

Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health 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 data-

bases 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—

(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) of this section 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) of this section 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) of this section that has not been revoked under subsection (e) of this section 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) of this section, 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) of this section; 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) of this section 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) of this section.

(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) of this section, with respect to the patient safety work product or data described in subsection (f)(1) of this section 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;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of this title).

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title IX, § 925, as added Pub. L. 111–148, title III, § 3509(e)(2), Mar. 23, 2010, 124 Stat. 534.)

PRIOR PROVISIONS

A prior section 925 of act July 1, 1944, was renumbered section 926 and is classified to section 299b–25 of this title.

Another prior section 925 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

Another prior section 925 of act July 1, 1944, was classified to section 299c–4 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 299b–25. Technical assistance

The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

(July 1, 1944, ch. 373, title IX, § 926, formerly § 925, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 434; renumbered § 926, Pub. L. 111–148, title III, § 3509(e)(1), Mar. 23, 2010, 124 Stat. 534.)

PRIOR PROVISIONS

A prior section 926 of act July 1, 1944, was renumbered section 927 and is classified to section 299b–26 of this title.

Another prior section 926 of act July 1, 1944, was renumbered section 946 and is classified to section 299c–5 of this title.

Another prior section 926 of act July 1, 1944, was classified to section 299c–5 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§ 299b–26. Severability

If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.

(July 1, 1944, ch. 373, title IX, § 927, formerly § 926, as added Pub. L. 109–41, § 2(a)(5), July 29, 2005, 119 Stat. 434; renumbered § 927, Pub. L. 111–148, title III, § 3509(e)(1), Mar. 23, 2010, 124 Stat. 534.)

PRIOR PROVISIONS

A prior section 927 of act July 1, 1944, was renumbered section 947, and is classified to section 299c–6 of this title.

Another prior section 927 of act July 1, 1944, was classified to section 299c–6 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

PART D—HEALTH CARE QUALITY IMPROVEMENT

PRIOR PROVISIONS

A prior part D, consisting of sections 299c to 299c–7, was redesignated part E of this subchapter.

SUBPART 1—QUALITY MEASURE DEVELOPMENT

§ 299b–31. Quality measure development

(a) Quality measure

In this subpart, the term ''quality measure'' means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

(b) Identification of quality measures

(1) Identification

The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality and the Administrator of the Centers for Medicare & Medicaid Services, shall identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion, consistent with the national strategy under section 280j of this title, to the extent available, for use in Federal health programs. In identifying such gaps and existing quality measures that need improvement, the Secretary shall take into consideration—

(A) the gaps identified by the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] and other stakeholders;

(B) quality measures identified by the pediatric quality measures program under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a]; and

(C) quality measures identified through the Medicaid Quality Measurement Program under section 1139B of the Social Security Act [42 U.S.C. 1320b–9b].

(2) Publication

The Secretary shall make available to the public on an Internet website a report on any gaps identified under paragraph (1) and the process used to make such identification.