

(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to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) of this section that has not been revoked under subsection (e) of this section or voluntarily relinquished.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 ac-

tions 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, non-governmental 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.