

AMENDMENTS

2014—Subsec. (a)(3). Pub. L. 113-240, §5(1)(B)(i), substituted “information” for “data”.

Subsec. (a)(4), (5). Pub. L. 113-240, §5(1)(A), (B)(ii), (C), added pars. (4) and (5).

Subsec. (b)(4)(D). Pub. L. 113-240, §5(2), substituted “Newborn Screening Saves Lives Reauthorization Act of 2014” for “Newborn Screening Saves Lives Act of 2008”.

Subsec. (c). Pub. L. 113-240, §5(3), substituted “carrying out activities” for “developing the clearinghouse” and “activities minimize duplication and supplement, not supplant” for “clearinghouse minimizes duplication and supplements, not supplants”.

Subsec. (d). Pub. L. 113-240, §5(4), struck out subsec. (d). Text read as follows: “There are authorized to be appropriated to carry out this section, \$2,500,000 for fiscal year 2009, \$2,531,250 for fiscal year 2010, \$2,562,500 for fiscal year 2011, \$2,593,750 for fiscal year 2012, and \$2,625,000 for fiscal year 2013.”

2008—Subsec. (b)(4)(D). Pub. L. 110-237, §1(a)(4)(A), substituted “2008” for “2007”.

Subsec. (d). Pub. L. 110-237, §1(a)(4)(B), substituted “2009, \$2,531,250 for fiscal year 2010, \$2,562,500 for fiscal year 2011, \$2,593,750 for fiscal year 2012, and \$2,625,000 for fiscal year 2013.” for “2008, \$2,531,250 for fiscal year 2009, \$2,562,500 for fiscal year 2010, \$2,593,750 for fiscal year 2011, and \$2,625,000 for fiscal year 2012.”

§ 300b-12. Laboratory quality and surveillance**(a) In general**

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 300b-10 of this title, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, timeliness for processing such tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

(b) Surveillance activities

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 300b-10 of this title, may provide, as appropriate, for the coordination of surveillance activities, including—

(1) through standardized data collection and reporting, as well as the use of electronic health records; and

(2) by promoting data sharing regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs.

(July 1, 1944, ch. 373, title XI, §1113, as added Pub. L. 110-204, §6, Apr. 24, 2008, 122 Stat. 710; amended Pub. L. 110-237, §1(a)(5), May 27, 2008, 122 Stat. 1557; Pub. L. 113-240, §6, Dec. 18, 2014, 128 Stat. 2854.)

AMENDMENTS

2014—Pub. L. 113-240, §6(1), inserted “and surveillance” after “quality” in section catchline.

Subsec. (a). Pub. L. 113-240, §6(2)(A), substituted “and taking into consideration the expertise of the Advisory Committee” for “and in consultation with the Advisory Committee” in introductory provisions.

Subsec. (a)(1). Pub. L. 113-240, §6(2)(B), inserted “timeliness for processing such tests,” after “newborn-screening tests.”

Subsec. (b). Pub. L. 113-240, §6(3), added subsec. (b) and struck out former subsec. (b). Prior to amendment, text read as follows: “For the purpose of carrying out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 2009, \$5,062,500 for fiscal year 2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fiscal year 2012, and \$5,250,000 for fiscal year 2013.”

2008—Subsec. (b). Pub. L. 110-237 substituted “2009, \$5,062,500 for fiscal year 2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fiscal year 2012, and \$5,250,000 for fiscal year 2013.” for “2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.”

§ 300b-13. Interagency Coordinating Committee on Newborn and Child Screening**(a) Purpose**

It is the purpose of this section to—

(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 247b-4 of this title, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children under section 300b-10 of this title, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

(b) Establishment

The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the “Interagency Coordinating Committee”) to carry out the purpose of this section.

(c) Composition

The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, or their designees.

(d) Activities

The Interagency Coordinating Committee shall—

(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

(2) carry out other activities determined appropriate by the Secretary.

(July 1, 1944, ch. 373, title XI, §1114, as added Pub. L. 110-204, §6, Apr. 24, 2008, 122 Stat. 710;