

(July 1, 1944, ch. 373, title III, §319I, as added Pub. L. 107-188, title I, §107, June 12, 2002, 116 Stat. 608; amended Pub. L. 109-417, title III, §303(b), Dec. 19, 2006, 120 Stat. 2857; Pub. L. 113-5, title II, §203(b)(1), Mar. 13, 2013, 127 Stat. 175.)

AMENDMENTS

2013—Subsec. (k). Pub. L. 113-5 substituted “\$5,000,000 for each of fiscal years 2014 through 2018” for “\$2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011”.

2006—Subsecs. (a), (b). Pub. L. 109-417, §303(b)(2), added subsecs. (a) and (b) and struck out former subsecs. (a) and (b) which related to establishment of a verification system and provisions regarding its promptness and efficiency.

Subsec. (c). Pub. L. 109-417, §303(b)(3), substituted “network” for “system”.

Subsecs. (d) to (k). Pub. L. 109-417, §303(b)(1), (4), (5), added subsecs. (d) to (i), redesignated former subsecs. (e) and (f) as (j) and (k), respectively, substituted “2011” for “2006” in subsec. (k), and struck out heading and text of former subsec. (d). Text read as follows: “The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.”

§ 247d-7c. Supplies and services in lieu of award funds

(a) In general

Upon the request of a recipient of an award under any of sections 247d through 247d-7b of this title or section 247d-7d of this title, the Secretary may, subject to subsection (b) of this section, provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(b) Corresponding reduction in payments

With respect to a request described in subsection (a) of this section, the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title III, §319J, as added Pub. L. 107-188, title I, §110, June 12, 2002, 116 Stat. 611.)

§ 247d-7d. Security for countermeasure development and production

(a) In general

The Secretary, in consultation with the Attorney General and the Secretary of Defense, may provide technical or other assistance to provide security to persons or facilities that conduct development, production, distribution, or storage of priority countermeasures (as defined in section 247d-6(h)(4) of this title).

(b) Guidelines

The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) of this section to secure their facilities against potential terrorist attack.

(July 1, 1944, ch. 373, title III, §319K, as added Pub. L. 107-188, title I, §124, June 12, 2002, 116 Stat. 614.)

§ 247d-7e. Biomedical Advanced Research and Development Authority

(a) Definitions

In this section:

(1) BARDA

The term “BARDA” means the Biomedical Advanced Research and Development Authority.

(2) Fund

The term “Fund” means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) Other transactions

The term “other transactions” means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10.

(4) Qualified countermeasure

The term “qualified countermeasure” has the meaning given such term in section 247d-6a of this title.

(5) Qualified pandemic or epidemic product

The term “qualified pandemic or epidemic product” has the meaning given the term in section 247d-6d of this title.

(6) Advanced research and development

(A) In general

The term “advanced research and development” means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title.

(B) Activities included

The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to im-