

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 improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

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

(8) Research tool

The term “research tool” means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) Program manager

The term “program manager” means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) Person

The term “person” includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.